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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)	18VAC110-50-10 et seq.
Regulation title(s)	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Action title	Compliance with Chapter 221 of the 2016 General Assembly
Date this document prepared	9/22/16

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

In compliance with Chapter 221 of the 2016 Acts of the Assembly, the proposed regulations eliminates definitions that are no longer applicable or now set forth in the Code; provides for permits for third-party logistics providers and for registration of nonresident manufacturers with fees and schedules for renewal of such permits or registrations; includes third-party logistics providers in all sections currently applicable to wholesale distributors; includes nonresident manufacturers in requirements for manufacturers; and eliminates Part IV on pedigree requirements and replaces those regulations with reference to the federal requirements for an

electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

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.

DSCSA = Drug Supply Chain Security Act

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.

The Board of Pharmacy adopted amendments to 18VAC110-50-10 et seq., Regulations Governing Wholesale Distributors, Manufacturers and Warehousers on September 7, 2016.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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 (§ 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 statutory authority for the Board to promulgate regulations to regulate manufacturing and distributing 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.

B. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

The statutory authority for promulgation of regulations for third-party logistics providers and nonresident manufacturers is found in Chapter 221 of the 2016 Acts of the Assembly:

http://lis.virginia.gov/cgi-bin/legp604.exe?161+ful+CHAP0221

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe 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 Drug Quality and Security Act (DQSA) was signed into law by President Obama on November 27, 2013. Title II of DQSA, Drug Supply Chain Security Act (DSCSA), outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The law intends to enhance the U.S. Food and Drug Administration's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. At the state level, §54.1-3307 assigns certain powers and duties to the Board of Pharmacy which includes regulating "the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices." It goes on to state, "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." Because the DSCSA preempts states from: 1) imposing pedigree (track and trace) requirements which do not comply with federal track and trace requirements for drug distribution; and 2) issuing a wholesale distributor license or nonresident wholesale distributor registration to third-party logistics providers and non-resident manufacturers. Therefore, it was necessary to amend certain state laws and regulations to provide the Board with legal ability to fulfill its duties in regulating the manufacturing, compounding, and distribution of drugs while not violating federal law.

Previously, the law authorized the board to license third-party logistics providers (entities that provide or coordinate warehousing, or other logistics services of a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a drug or device, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product) as wholesale distributors and nonresident wholesale distributors. The DSCSA preempts states from issuing out-of-state manufacturers and in-state and out-of-state third-party logistics providers a wholesale distributor license. Since state law does not authorize an entity to ship controlled substances within or into the Commonwealth without holding a license with the Board, it is necessary to create new licensing categories for these entities in order to ensure the continued ability of third-party logistics providers and non-resident manufacturers to provide services in Virginia and for the Board to continue regulatory oversight of such entities in order to protect the integrity of the drug supply and the health and safety of citizens of the Commonwealth.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

The Board has adopted regulations that conform to the statutory provisions of the Code as amended by the General Assembly. There is no fiscal impact on entities that were previously permitted as wholesale distributors since the fees are identical. Therefore, there should be no opposition to the fast-track process.

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.

The proposed regulations eliminates definitions that are no longer applicable or now set forth in the Code; provides for permits for third-party logistics providers and for registration of nonresident manufacturers with fees and schedules for renewal of such permits or registrations; includes third-party logistics providers in all sections currently applicable to wholesale distributors; includes nonresident manufacturers in requirements for manufacturers; and eliminates Part IV on pedigree requirements and replaces those regulations with reference to the federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

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 to the public is continuation of services currently provided by non-resident manufacturers and third-party logistics providers. There are no disadvantages to the public or the businesses which have previously held permits as wholesale distributors.
2) There are no advantages or disadvantages to the agency; and
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...*"
Additionally, the Code of Virginia requires:
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…
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.

As stated in the "Purpose" section of this document, the DSCSA preempts states from: 1) imposing pedigree (track and trace) requirements which do not comply with federal track and

trace requirements for drug distribution; and 2) issuing a wholesale distributor license or nonresident wholesale distributor registration to third-party logistics providers and non-resident manufacturers. Therefore, it was necessary to amend certain state laws and regulations to provide the Board with legal ability to fulfill its duties in regulating the manufacturing, compounding, and distribution of drugs while not violating federal law.

Therefore, the proposed amendments are a foreseeable result of the statute requiring the Board to protect the safety and efficacy of prescription drugs in the Commonwealth. Any restraint on competition that results from this regulation is in accord with the General Assembly's policy as articulated in § 54.1-100 and is necessary for the preservation of the health, safety, and welfare of the public and will further the public's need for assurances of prescription drug safety.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

The proposed amendments comply with federal requirements as set forth in the Drug Supply Chain Security Act of 2013.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

There is no regulatory flexibility consistent with health and safety of prescription drugs.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated 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**	a) 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; b) 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. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Nonresident manufacturers and third-party logistics providers which were previously licensed as wholesale distributors.
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.	There are currently 759 nonresident wholesale distributors and 120 resident wholesale distributors. Some of the entities in those categories will have to change to a new category of licensure as third-party logistics providers or nonresident manufacturers.
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 including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) 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.**	There are no additional costs.
Beneficial impact the regulation is designed to produce.	Compliance with federal law in the DSCSA

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.

There are no viable alternatives; amendments to regulations are necessary for consistency with state and federal law.

Public participation notice

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.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

In several sections of regulations, the words "license, permit or registration" have been added to clarify the intent is inclusion of all other types of authorizations issued by the Board. In previous years, the term "license" was interpreted to be inclusive or a registration, certificate, or permit, but boards have been advised to make their laws and regulations more explicit. Some requirements in this chapter only apply to a license or permit or only apply to a registration, so all three terms are not necessary in all incidences.

Additionally, "wholesale distributors" were interpreted to be inclusive of "nonresident wholesale distributors." The regulation is amended to be clear. Nonresident wholesale distributors are held to the applicable current regulations, so there is no impact on those entities.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10	Sets out definitions for words and terms used in the chapter	The term "manufacturer's exclusive distributor" is used in Part IV which is being repealed, so it is deleted. The term "third-party logistics provider is deleted because it conflicts with the definition added to § 54.1-3401 in the legislation.
20	Sets out the fees charged to applicants and regulated entities	Fees are added for the new categories of third-party logistics provider and nonresident manufacturer. *Those entities were previously licensed as wholesale distributors; the new fees are identical to current fees so there will be no fiscal impact.*
30 – 150	Requirements for wholesale distributors in all sections	Since third-party logistics providers were previously licensed as wholesale distributors, all regulations are amended to include those entities in every applicable section. *The amendments are necessary since third-party logistics providers are now a license type separate from wholesale distributors. There is no impact on third-party logistics providers; they are just registered in a new category.*
130	Sets out requirements for recordkeeping	Subsection A is amended to allow wholesale distributors and third-party logistics providers to maintain records off-site provided they can be readily retrievable and available with 48 hours of a request by an authorized agent of the Board. *Such an allowance already exist for pharmacies, so it is reasonable to allow entities involved in the distribution process to also maintain records off-site.* Subsection A 1 is amended to specify compliance with federal law for tracking and tracing prescription drugs as they are distributed. *The federal requirement for an electronic, interoperable system to identify, trace and verify the distribution of prescription drugs replaces Virginia rules for a pedigree system (Part IV of this chapter).*
140	Sets out requirements for due diligence by wholesale distributors	Subsection A 1 is amended to allow a third-party logistics provider to document licensure by the U. S. Food and Drug Administration in lieu of active licensure held in another state.
150	Sets out the requirement for manufacturers to follow regulations in Good Manufacturing Practice for Finished Pharmaceuticals	Subsection B is amended to include the category of "*nonresident* manufacturers." While nonresident manufacturers were licensed in Virginia as wholesale distributors, all manufacturers had to be licensed by the U. S. Food and Drug Administration and were already required to comply with Good Manufacturing Practice. Therefore, there is no effect in the requirements – simply a change to a new category of licensure.
Part IV 160 - 190	Sets out pedigree requirements for wholesale distribution of prescription drugs	All of Part IV is repealed. *Virginia regulations are superseded by federal rules for track and trace in the DSCSA.*