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Proposed 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	Delivery of Schedule VI devices
Date this document prepared	3/26/19

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.

The Board is promulgating regulations in accordance with provisions of § 54.1-3415.1 of the Code of Virginia as amended by Chapter 241 of the 2018 Acts of the Assembly. Proposed regulations replace emergency regulations currently in effect. A new section, 18VAC110-50-55, sets out the requirements for delivery of Schedule VI devices directly to an ultimate user or consumer on behalf of a medical equipment supplier upon a valid order from a prescriber or upon request from the medical director of home health agency, nursing home, assisted living facility or hospice.

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

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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The mandate is found in the second enactment of Chapter 241 of the 2018 Acts of the Assembly states: *That the Board of Pharmacy (the Board) shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. Such regulations shall include provisions governing agreements between a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider and a medical equipment supplier, home health agency, hospice, pharmacy, nursing home, or assisted living facility for delivery of Schedule VI prescription devices directly to an ultimate user or consumer and such other provisions as the Board may deem appropriate.*

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:
...
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 authority for delivery of medical devices is found in Chapters 241 and 242 of the 2018 Acts of the Assembly:

§ 54.1-3415.1. Delivery of medical devices on behalf of a medical equipment supplier.

A. A permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider, or registered nonresident manufacturer or nonresident wholesale distributor may deliver Schedule VI prescription devices directly to an ultimate user or consumer on behalf of a medical equipment supplier provided that (i) such delivery occurs at the direction of a medical equipment supplier that has received a valid order from a prescriber authorizing the dispensing of such prescription device to the ultimate user or consumer and (ii) the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider has entered into an agreement with the medical equipment supplier for such delivery.

B. A permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider, or registered nonresident manufacturer or nonresident wholesale distributor may deliver Schedule VI prescription devices directly to an ultimate user's or consumer's residence to be administered by persons authorized to administer such devices, provided that (i) such delivery is made on behalf of a medical director of a home health agency, nursing home, assisted living facility, or hospice who has requested the distribution of the Schedule VI prescription device and directs the delivery of such device to the ultimate user's or consumer's residence and (ii) the medical director on whose behalf such Schedule VI prescription device is being delivered has entered into an agreement with the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider for such delivery.

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.

The primary purpose of the proposed amendments to regulations is to implement legislative action that allows a permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider, or registered nonresident manufacturer or nonresident wholesale distributor may deliver Schedule VI prescription devices directly to an ultimate user's or consumer's residence in accordance with an agreement signed with a medical equipment supplier or a medical director.

The goal of the legislation and subsequent regulation is to facilitate provision of Schedule VI devices more economically and efficiently by allowing delivery to the ultimate user or consumer without a party in the middle of the transaction having to physically possess and store the devices. The medical equipment supplier may have a valid order from a prescriber, which is conveyed to a wholesale distributor or other entity with whom there is an agreement. Before passage of this legislation, the distributor or other entity did not have legal authority to deliver directly to the consumer. Likewise, the director of a home health agency may now request that oxygen be delivered directly to a consumer's residence, rather that the agency possessing and storing the oxygen with a subsequent delivery to the consumer/patient.

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.

Board requirements for delivery of Schedule VI devices are intended to implement the provisions of § 54.1-3415.1, which requires an agreement between the delivering party and a medical equipment supplier or a medical director. The agreement can cover multiple entities under shared ownership, so it does not become burdensome but does ensure existence of an order or request from a prescriber for the safety and integrity of prescription devices and the protection of the patient or ultimate user.

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 advantage to the public is direct delivery of Schedule VI devices from an entity without delays and costs associated with interim deliveries. There are no disadvantages.

2) There are no advantages or disadvantages to this agency or the Commonwealth.

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.) that 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.) This proposal is consistent with the agency's statutory responsibility to protect public health and safety and to protect the integrity and safety of prescription drugs in the Commonwealth.

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 - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

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	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.
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 for other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	There are no benefits.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no costs or savings for localities.
Benefits the regulatory change is designed to produce.	There are no benefits.

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.	The entities likely to be affected would be a permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider, or registered nonresident manufacturer or nonresident wholesale distributor that wish to deliver to a consumer on behalf of a medical equipment supplier or of a medical director
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 that may engage in such a business arrangement. The current count is: Manufacturer (28), wholesale distributor (81), warehouser (98), nonresident warehouser (n/a), third-party logistics provider (5), or nonresident third-party logistics provider (n/a), or registered nonresident manufacturer (134) or nonresident wholesale distributor (673), medical equipment supplier (237)
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 not be additional costs; the proposed regulation should result in cost-savings.
Benefits the regulatory change is designed to produce.	The regulation will benefit the patient by assuring that by facilitating delivery of a Schedule VI prescription device. It will benefit the entities involved in the delivery by allowing direct delivery. Medical equipment suppliers will be able to have an agreement for direct delivery to the ultimate consumer without having to take delivery and store the device. Medical directors of facilities, such as home health or nursing homes, will be able to have an agreement for direct delivery to patients.

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 proposed regulatory action is required in order to implement provisions of Chapters 241 and 242 of the 2018 Acts of the Assembly. There are no alternative methods to achieve the essential purpose of the action.

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.

The Board has a statutory mandate to promulgate regulations and has done so consistent with the provisions of *§ 54.1-3415.1*.

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

A Notice of Intended Regulatory Action was published on December 24, 2018 with comment requested until February 6, 2019. No comment was received.

Public Participation

Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.

In addition to any other comments, the Board of Pharmacy is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960

Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website

Detail of Changes

Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.

The proposed regulations are identical to emergency regulations effective from 12/13/18 to 6/12/20.

Current section number	New section number	Proposed change, intent, and likely impact of proposed requirements
N/A	55	*The Board has added Section 55 to implement provisions of the law passed in 2018 for the delivery of Schedule VI devices. Subsection A follows the allowance in subsection A of the Code section for delivery pursuant to an agreement between the delivering entity and a medical equipment supplier. The agreement may be valid for all delivering entities under shared ownership and medical equipment suppliers under shared ownership. The medical equipment supplier must represent the existence of a valid order for prescription devices to be delivered directly to the patient or ultimate consumer.* *Subsection B contains similar language from subsection B of the Code section, as it pertains to an agreement between a delivering entity and a medical director of a home health agency, nursing home, assisted living, or hospice.* *Subsection C is applicable to both types of agreements and specifies that the agreement must be retained in a written or electronic format and retained for a period of two years after its termination or conclusion.* *Subsection D specifies that the agreement cannot contain any patient-specific information that would be a violation of HIPAA.*