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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Delivery of Schedule VI devices
Date this document prepared	5/18/20

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*.

Brief Summary

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. Final 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

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

N/A

Statement of Final Agency Action

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 May 18, 2020, the Board of Pharmacy amended 18VAC110-20, Regulations Governing the Practice of Pharmacy.

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

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.*

There are no changes to the previously reported information.

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 and 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 (§ 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, thirdparty
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, thirdparty
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

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

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

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

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than

applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected- None

Public Comment

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

There was a public comment period from 10/14/19 to 12/13/19, and a public hearing was conducted on 12/9/19. No comment was received.

Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

There are no changes.

Detail of All Changes Proposed in this Regulatory Action

*List all changes proposed in this action and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Final regulations are identical to proposed regulations and to the emergency regulations currently in effect.

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.*