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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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 Warehousemen
Action title	Delivery of Schedule VI devices
Date this document prepared	6/21/18

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to eighteen months), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation. 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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The Board is promulgating emergency 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. 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

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

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, warehouse, nonresident warehouse, 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.*

Therefore, the emergency action is authorized under Code of Virginia § 2.2-4011.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) the promulgating entity, i.e., agency, board, or person.

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, warehouse, nonresident warehouse, 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, warehouse, nonresident warehouse, 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, warehouse, nonresident warehouse, 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, warehouse, nonresident warehouse, third-party logistics provider, or nonresident third-party logistics provider for such delivery.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The primary purpose of the proposed amendments to regulations is to implement legislative action that allows a permitted manufacturer, wholesale distributor, warehouse, nonresident warehouse, 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 than the agency possessing and storing the oxygen with a subsequent delivery to the consumer/patient.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

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.

Substance

Please describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the healthy, safety, or welfare of Virginians.

Current section number	New section number	Proposed change, intent, and likely impact of proposed requirements
N/A	55	<p><i>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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p>

	<i>Subsection D specifies that the agreement cannot contain any patient-specific information that would be a violation of HIPAA.</i>
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Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

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.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments. Please also indicate whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>) or by mail to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; by email to elaine.yeatts@dhp.virginia.gov; by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://www.virginia.gov/connect/commonwealth-calendar>). Both oral and written comments may be submitted at that time.

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.