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Proposed 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	Allowance for centralized warehouser or wholesale distributor to verify Schedule VI drugs for automated dispensing devices in hospitals
Date this document prepared	June 6, 2022

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.

In response to a petition for rulemaking, the Board is amending 18VAC110-20-460 and 490 to allow a pharmacist at a central distribution company to verify Schedule VI drugs to be placed in an automated dispensing device prior to delivery to the receiving hospital and pharmacy technicians at the hospital to load the drugs directly into the automated dispensing device without further verification by a pharmacist at the hospital.

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.

ADD = automated dispensing devices

Mandate and Impetus

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, or board decision). 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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."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 impetus for the change is response to a petition for rulemaking by updating of regulations to facilitate new technologies in the practice of pharmacy. Since the technologies have already been approved for pilot programs in several hospital systems and have shown to be safe and effective, the Board decided to incorporate the allowances into regulation.

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 of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o 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."

Regulations governing the distribution and dispensing of drugs are promulgated under the authority of Virginia Code § 54.1-3307.

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 purpose of this regulatory action is to update regulations for utilization of newer technologies in the practice of pharmacy in a hospital system and to facilitate time for pharmacists to be more involved in direct patient care. A pilot for remote verification involving more than a dozen facilities have been approved by the Board and have been shown to protect the health and safety of the drug supply and patients in hospitals.

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.

Section 460 currently requires that a pharmacist check all Schedule II-VI drugs delivered to a hospital unit as floor stock before the drugs leave the pharmacy and to initial or sign (manually or electronically) the record of distribution verifying the accuracy of the distribution. Section 490(C) currently requires that a pharmacist loading the ADD at the hospital pharmacy initial the delivery record prior to the drugs leaving the pharmacy to become floor stock.

Amendments to Sections 460 and 490 allow a pharmacist at a warehouser or wholesale distributor to verify Schedule VI drugs to be placed in specific ADDs prior to delivery of the drugs to a hospital. The amendments removes the requirement of the hospital pharmacist to verify Schedule VI drugs in these circumstances and removes the requirement that the hospital pharmacist initial the delivery record. A pharmacist or pharmacy technician may load the Schedule VI drugs specified in the delivery order. The amendments require the warehouser or wholesale distributor to maintain a record of distributed Schedule VI drugs and the hospital to maintain records regarding the barcode scanning rate, the bedside scanning rate, and any errors in drug product received from the warehouser or wholesale distributor.

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 will be use of newer technologies in the practice of pharmacy in a hospital system and more availability of hospital pharmacists to be involved in direct patient care. There should be no disadvantages to the public. A pilot program in more than a dozen facilities have utilized this technology, which has been shown to protect the health and safety of the public.
2) There are no primary advantages or disadvantages to the agency or the Commonwealth.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth. The Board is authorized under § 54.1-2400 "[t]o 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 . . . 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 promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

Requirements More Restrictive than Federal

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 requirements more restrictive than federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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, 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. 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	There are no projected costs, savings, fees or revenues to the agency resulting from the regulatory change.
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 regulation will have no impact that will benefit or harm the agencies.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None.
Benefits the regulatory change is designed to produce.	None.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the	The entities likely to be impacted are hospitals, including hospital pharmacies, and warehousers

regulatory change. If no other entities will be affected, include a specific statement to that effect.	or wholesale distributors of Schedule VI drugs. The individuals likely to be impacted are licensed pharmacists, patients in hospitals, and other healthcare personnel working in hospitals. Pharmacists will be able to devote more time to clinical services to ensure optimal drug therapy because hospital pharmacists will not be required to verify all Schedule VI drugs from a warehouser or wholesale distributor prior to delivering floor stock.
Agency's best estimate of the number of such entities that will be affected. 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 approximately 100 hospitals in Virginia. All would be able to take advantage of this new allowance if the hospital uses ADDs for floor stock. A large hospital could have as many as 75-100 ADDs.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. 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.	DHP has no cost estimate for implementation of this. Technology currently exists to perform these tasks, and hospital pharmacists' time will be freed up by these amendments, so it is possible this will result in a cost savings for hospitals in particular, although the savings may be minimal.
Benefits the regulatory change is designed to produce.	The amendment is designed to allow hospital pharmacists more time to spend on counseling patients and prescribers or those administering drugs while protecting patient safety.

Alternatives to Regulation

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 of Pharmacy received a petition for rulemaking in May 2021 and published a request for comment until July 7, 2021. There were 40 comments posted on the Town Hall; all were in favor of the petitioner's request as being a safer and more cost-effective delivery method. The proposal would constitute a less burdensome and intrusive alternative to the current regulation.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

Because Sections 460 and 490 currently require hospital pharmacists to verify all Schedule VI drugs placed in ADDs to be used as floor stock in hospitals, there are no methods aside from regulatory amendment that can allow this practice. This amendment, however, constitutes a less burdensome and intrusive alternative to the current regulations.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

The proposed action is not being used to announce a periodic review or a small business impact review.

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 were no comments received by the agency on Town Hall or directly regarding the NOIRA. A public hearing was not held for the NOIRA stage. The agency received 40 public comments on the petition for rulemaking which initiated this action. All comments were in favor of the petitioner's request as being a safer and more cost-effective delivery method of Schedule VI drugs.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail or email to Erin Barrett at erin.barrett@dhp.virginia.gov or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (804) 915-0382. 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 (https://townhall.virginia.gov) and on the Commonwealth Calendar website (https://commonwealthcalendar.virginia.gov/). Both oral and written comments may be submitted at that time.

Detail of Changes

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. 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. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20-460	Hospital pharmacist required to check all Schedule II-VI drugs delivered to a hospital unite as floor-stock before the drugs leave the pharmacy; pharmacist must initial or sign the record of distribution verifying the accuracy of distribution.	Language added: “Except as provided in 18VAC110-20-490(D) . . .” This carve out will allow those pharmacists at hospitals receiving deliveries of Schedule VI drugs for use in a specified ADD from warehousers or wholesale distributors who meet the requirements of 490(D) to spend more time performing other tasks in the hospital pharmacy.

20-490	No allowance for verification of Schedule VI drugs by warehouser or wholesale distributor.	Subsection D is added to allow warehousers or wholesale distributors to distribute Schedule VI drugs to hospitals to be placed in specific ADDs under the following conditions: (1) A pharmacist licensed in Virginia and working at or for a warehouser or wholesale distributor verifies the accuracy of Schedule VI drugs to be placed in specific ADDs for hospital floor stock prior to delivery to the hospital pharmacy. (2) The warehouser or wholesale distributor maintains records of all Schedule VI drugs distributed to a hospital for placement in a specific ADD. The regulation specifies what must be included in the record. (3) The warehouser or wholesale distributor provides an invoice to each hospital pharmacy demonstrating which drugs were delivered to be placed in a specific ADD. (4) A pharmacist or pharmacy technician at the hospital pharmacy must load the drugs into the specific ADD; the hospital will keep a record of which individuals loaded each ADD. (5) A pharmacist licensed in Virginia and working at or for a warehouser or wholesale distributor must perform barcode linking of any drug to the related drug files in the hospital information system and automated dispensing device. (6) Hospitals receiving drugs from a warehouser or wholesale distributor must maintain at least a 90% barcode scanning rate for restocking ADDs. If a 90% rate is not achieved, additional steps are required until a 90% scanning rate for a subsequent quarter is achieved and documented. (7) Hospital pharmacies receiving this service from a warehouser or wholesale distributor must maintain quarterly reports with specific information included, such as any errors in drug products received. The purpose of these changes is to provide a safer, more cost-effective delivery method for Schedule VI drugs to be used as floor-stock in hospitals while reducing current regulatory burdens. These changes allow the verification process to occur outside of a hospital pharmacy but under the control of a Virginia-licensed pharmacist at a third-party provider of Schedule VI drugs for use in ADDs.
