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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	Allowance for centralized warehouser or wholesale distributor to verify Schedule VI drugs for automated dispensing devices in hospitals
Date this document prepared	June 25, 2024 Amended July 25, 2024

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), 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

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 June 25, 2024, the Board of Pharmacy voted to amend 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 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 is 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

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's 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.

Commenter	Comment	Agency response
Courtney Fuller	Requested the following language changes: • In 490 D 3, allow electronic signature as well as initials of the pharmacist to be used • In 490 D 6, clarify that the barcode linking is to the automated dispensing device drug database • In 490 D 8, suggested a minimum bedside barcode scanning rate threshold such as 90%	Electronic signatures are already permitted in any place initials of a pharmacist are required under regulations. Therefore, the Board did not feel it necessary to explicitly state this only in 490 D 3. The Board has amended D 6 to include linking to an "associated drug database." The Board did not want to set a minimum bedside barcode scanning rate threshold in regulation.
Natalie Nguyen (Virginia Society of Health	Requested that the Board amend the proposed regulation to remove the requirement in 490 D 5 to scan each unit dose, because to do so is not	The Board has amended the draft regulations to require scanning "in accordance with the hospital's policies and procedures."

Systems Pharmacists), Gill Abernathy (pharmacist) Courtney Fuller (pharmacist)	feasible at the time of restocking within ADDs. Requested a change to scan one unit dose from a group of doses and visually inspect the remaining doses.	

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.*

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
20-490		D 5: Pharmacist or pharmacy technician required to load drugs into the specific automated dispensing device after scanning each unit.	No new requirement created. “After scanning each unit” amended to “after scanning in accordance with the hospital policies and procedures.”	Board amended language for clarity. “Scanning each unit” may have caused some inefficiencies in loading ADDs. This change was also in response to public comment.
20-490		D 6: Provides requirements related to barcode linking of drugs to drug files.	No new requirement created. “Or associated drug database” added to the end of the provision.	Board amended language following public comment period. Public comment stated some central warehousers or wholesale distributors do not link to ADDs, but to drug databases.

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.*

Current chapter-	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements

section number		
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.