Virginia

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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Modifications to requirements for hospital automated dispensing devices
Date this document prepared	September 11, 2013

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The Board of Pharmacy received three petitions for rulemaking from hospital pharmacists requesting an amendment to the requirement for a monthly audit of automated dispensing devices (ADD) in section 490 in Chapter 20, which provides requirements for automated devices for dispensing and administration of drugs. The petitioners requested less burdensome requirements for verification of storage, location, expiration dates, drug security and validity of access codes. Rather than simply addressing the monthly audit provision, the Board determined that a review of the entire section was appropriate to allow more flexibility in the use of ADD's.

Statement of final agency action

Please 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 or board taking the action, and (3) the title of the regulation.

On September 10, 2013, the Board of Pharmacy adopted final amendments to 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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:

§ 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 statutory authority for the Board of Pharmacy to regulate the practice of pharmacy including regulations pertaining to the safety and integrity of drugs is found in § 54.1-3307 of the Code of Virginia.

§ 54.1-3307. Specific powers and duties of Board.

The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices which do not conform to the requirements of law. In so regulating the Board shall consider any of the following criteria as they are applicable:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

As one of the petitioners stated, automation has been designed and updated to improve drug storage, security and safety, while streamlining work processes and increasing efficiencies. Advancements in technology can accommodate verification requirements that currently require manual processes. The Board has adopted changes to the process and/or parameters to decrease the amount of time required to comply with monthly audits. Certain software that analyses automated dispensing machine transactions could substitute for some of the manual reconciliation process. Hospitals report that the software reports can more quickly and efficiently identify possible diversions from the machines. Taking advantage of technology to replace some of the manual processes appears to be advisable for public health and safety because it could allow pharmacists to spend more time focused on patient care and still continue to protect against diversion and drug security.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The petitioners requested modifications to section 490 to change the requirement that automated dispensing devices must be manually inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates the security of drugs and validity of access codes. The proposed regulations reorganize requirements for use of ADD's in hospitals to clarify the process and also provide exceptions from certain audits for devices with technology that has the capability for monitoring, detection, reconciliation and analysis.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

1) The proposed changes are a significant advantage to pharmacists and the hospitals in which they work. If they are able to substitute electronic monitoring and reporting for manual procedures, the hours spent in compliance with current regulations can be redirected to tasks associated with patient care. The Board does not perceive any disadvantages or risks associated with substitution of manual audits and inspections with reconciliation software that can detect possible diversion.
2) There are no advantages or disadvantages to the agency; pharmacy inspections will continue to include records required for automated dispensing devices.
3) There are no other pertinent matters of interest.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

There were no changes made to the text of the proposed regulation.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
John Lubkowski	Thanked the Board for revision to requirements for automated dispensing; will save many hours of labor currently required to perform administrative audits. Suggested	The Board considered the suggestion for a change in subsection C but did not amend the regulation because: 1) it is a current requirement; and 2) it is necessary for the PIC to be aware of discrepancies in the count of

	allowing discrepancy reports required in subsection C to be reported to a designee of the pharmacist-in-charge (PIC).	drug and responsible for reconciliation or reporting of a loss.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
490	Subsection A establishes that a hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460.	The section has been reorganized to make it easier for pharmacists to follow the steps that must be taken in the use of ADD's for dispensing and administration of controlled substances.
	Subsection B sets out the requirements for a policy and procedure manual and for identification of users by access codes.	#1 of this subsection is identical to #8 in the current section 490. #2 of this subsection is identical to #7 in the current section 490, but authorizes the use of biometric identification or other coded identification that can eliminate sharing or theft of access codes.
	Subsection C describes the record for distribution of drugs from the pharmacy to be placed in the ADD.	The regulation is identical to #1 and #2 in the current section 490.
	Subsection D describes the record for distribution of drugs from the ADD	#1 of this subsection is identical to #3 of current section 490. The requirement for chronological filing if taken from current #9. #2 is identical to #5 in the current section 490.
	Subsection E sets out the requirement for discrepancy reports.	This subsection is identical to #4 b of current section 490.
	Subsection F sets out the requirements for reviews and audits.	In the current regulation, the terms audit and review are used interchangeably. In fact, they are different processes, so the proposed regulations make a distinction about when an audit is necessary and appropriate. Current regulations (#4 e) require a monthly *audit* for compliance with procedures for security and use of the ADD. Proposed

		regulations (F 1) specify a *review* of compliance, including procedures for termination of access codes when applicable. In #2 of subsection F, the requirement for a monthly audit of distribution from the ADD is identical to #4 in current regulation with the following exceptions: • The requirement for a discrepancy report is now in subsection E. • A pharmacy that has a method for perpetually monitoring drugs dispensed from the pharmacy and loaded into the ADD <u>can limit</u> the audit to discrepancies or exceptions as identified by the monitoring method. In #3 of subsection F, the requirement for a monthly audit of administration from the ADD is set forth. The current requirement for a monthly audit of administration records is amended by: 1) deleting the phrase "a sample" since the requirement is a review of "<u>all</u> Schedule II-V drugs administered for a time period of not less than 24 consecutive hours" (the term "sample" was confusing and not consistent with the regulation); 2) deletion of a requirement to check medical records as not necessary or practical; 3) an exemption from the audit requirements if reconciliation software can provide a monthly statistical analysis based on peer-to-peer comparisons for use and monitoring of overrides and unresolved discrepancies; and 4) a requirement for a focused audit of suspicious activity as identified by the report produced by the ADD software.
	Subsection G sets out requirements for monthly inspections of the devices	The requirement is identical to current #6 but the proposed regulations provide an exception from the need for a physical inspection if the device has the capability to perform certain functions electronically and automatically. For example, the ADD must monitor temperature ranges, use a machine readable product identifier, electronic tracking of expiration dates and electronic detection of opening and the identification of the person accessing the device. Since the vast majority of modern ADD's have such capability, the exception to a physical

		inspection is a significant savings in time and effort on the part of the pharmacists in a hospital.
	Subsection H sets out the requirements for maintenance of records associated with ADD's and their audits and reviews.	The amended regulations are virtually identical to current regulations except the requirement for signatures is changed to initials for ease of compliance.