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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	Incorporation of allowances from pilot programs
Date this document prepared	1/16/21

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 has incorporated into regulations certain allowances for use of technology that have been approved for implementation and safely used by innovative pilot programs in several hospital systems which create efficiencies in storing, dispensing, and distributing drug inventory. In lieu of requiring individual hospitals to apply for an innovative pilot program, amendments are proposed for section 425 on robotic pharmacy systems to allow any interested hospital to use technology commonly referred to as medication carousels to store and guide the selection of drugs to be dispensed or removed from the pharmacy. A pharmacist will not be required to manually check the accuracy of a drug removed from the carousel by a pharmacy technician when the technology is used, in compliance with the regulation, to verify accuracy. Because medication carousels rely on the use of barcode scanning to verify drug accuracy, certain safeguards are adopted to include a verification check by a pharmacist for the accuracy of the barcode assignment to an individual drug.

A new section (505) is added to incorporate another technology already approved for innovative pilot programs – the use of radio-frequency identification to verify the accuracy of drugs placed into a kit for licensed emergency medical services personnel or other kits used as floor stock throughout a hospital. The regulations specify the responsibilities of a pharmacist and the duties of a pharmacy technician in the use of RFID technology.

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.

RFID = radio-frequency identification

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 updating of regulations to facilitate new technologies in the practice of pharmacy. Since the technologies have already been approved for innovative pilot programs in several hospital systems and have shown to be safe and effective, the Board's decision was to incorporate the allowances into regulation so other hospitals can utilize the technology without having to apply for a pilot program.

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 (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which

shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. 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.).

The specific authority for the Board to regulate the dispensing of prescription drugs is found in:

§ 54.1-3307. Specific powers and duties of Board.
A. 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 that do not conform to the requirements of law.
The Board's regulations shall include criteria for:
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.
B. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

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 regulation will allow an interested hospital to utilize these newer and proven technologies that facilitate efficiencies in the management and dispensing of drugs without the cost and burden of applying for an innovative pilot program, allow these proven technologies to be used to verify drug accuracy which decreases risk of human error associated with manual pharmacist verifications, and allow pharmacists more time to focus on patient-centered clinical activities.

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 for facilitating time for pharmacists to be more involved in direct patient care. Technologies such as medication carousels and RFID components of a robotic pharmacy system have already been approved for use as innovative pilot programs 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.

Amendments are proposed for section 425 on robotic pharmacy systems to allow for medication carousels used in a hospital to store and guide the selection of drugs to be dispensed or removed from the pharmacy. A pharmacist will not be required to manually check the accuracy of a drug removed from the carousel by a pharmacy technician when the technology is used, in compliance with the regulation, to verify accuracy. Because medication carousels rely on the use of barcode scanning to verify drug accuracy, certain safeguards are adopted to include a verification check by a pharmacist for the accuracy of the barcode assignment to an individual drug.

A new section (505) is added to incorporate another technology already approved for innovative pilot programs – the use of radio-frequency identification to verify the accuracy of drugs placed into a kit for licensed emergency medical services personnel or other kits used as floor stock throughout a hospital. The regulations specify the responsibilities of a pharmacist and the duties of a pharmacy technician in the use of RFID technology.

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 and the hospital systems is the use of new technology that accurately and efficiently prepares medications for dispensing from a pharmacy to patients on

the floor or to persons receiving emergency services by EMS agencies. There are no disadvantages; there are ample safeguards to ensure the accuracy and integrity of the drugs dispensed through use of medication carousels or RFID technology.

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

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 applicable 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	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities.
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 for other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	There are no benefits.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no costs or savings for localities.
Benefits the regulatory change is designed to produce.	There are no benefits.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	There are currently 26 approved active pilot programs. Of those, 3 use RFID technology and 9 use carousels.
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.	Of the approved pilots, incorporation of these allowances in the proposed regulations will eliminate the need for almost half of the existing pilots. The pilot programs are primarily in large hospital systems and would not be considered small businesses.
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.	There would be a cost savings to the affected individuals as a result of the regulatory change. Hospital systems with currently-approved pilot programs are required to pay a renewal fee of $260 per approval period for the pilot (approval periods are generally every two years) and the cost of any required unannounced inspections. Hospital systems that want to utilize the revised allowances would not have to apply for approval of a pilot, nor pay an application fee of $325.

Benefits the regulatory change is designed to produce.	There is a cost savings by incorporating allowances in regulation, and new regulations will encourage the utilization of newer technologies to improve the efficiency of pharmacy operations.

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 alternative to promulgation of this regulatory change is continuation of approval of innovative technologies on a case-by-case basis. Once the safety and effectiveness of a technology has been established through pilot programs, inclusion of such allowances in regulation is the less intrusive and less costly alternative.

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.

As previously stated, regulatory flexibility is achieved through the pilot program process, which requires an application, an inspection, and an informal conference. The pilot can establish the feasibility, effectiveness, and safety of alternative methods in a pharmacy system. This action is necessary to incorporate those alternative methods or technologies into regulations.

Periodic Review and Small Business Impact Review Report of Findings

This action is not being used to conduct a periodic review of regulation.

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.

Commenter	Comment	Agency response
Clinton Atwater Carillon Clinic	Subsection C puts into place the necessary safeguards for dispensing through bar code technology. It does not specify that the distribution of medications may be to another location within the hospital system. The commenter noted that this regulation is long overdue and is pleased that Virginia is recognizing the value of automation and technology.	In response, the Board amended #3 of subsection C of section 425 to include distribution to another entity legally authorized to possess the drug.
Virginia Society of Health-System Pharmacists	Supports the action and requests the following: 1) To revisit the language for medication carousels as written requiring the scanning of each unit dose / intact blister / unopened manufacturer drug product because the validation of the barcode based on type of product packaging is currently not a customizable option within medication carousel technology. The system requires the scanning of a barcode of the product in order to proceed, regardless of it is a single unit or still attached to a whole box or blister. Although the scanning of each unit is an option that can be implemented in the medication carousel technology, this counteracts the intent of this pharmacy automation technology to improve efficiency in addition to the added safety level of barcode validation. VSHP recommends adding language requiring the visual inspection by the pharmacy technician for all unit doses filled for a patient-specific dose or automated dispensing cabinet. 2) Regarding RFID, asked for clarification of expectations if errors are identified during the 5% check, e.g., does the pharmacist then expand to 10% check for validation?	Language in section 425 in subdivision (C)(2)(b) and (C)(3)(b) of the NOIRA originally allowed for the pharmacy technician to scan "each drug unit, each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug." While this appeared to create efficiencies, comment to the Board indicates that the medication carousel technology cannot validate barcodes based on type of product packaging. Additionally, staff reported that the previously approved innovative pilot programs required the scanning of "each drug unit". The Board appeared to prefer to rely on the proven technology to verify accuracy, instead of authorizing a hybrid approach allowing a pharmacy technician to scan one unit of each drug and visually verify the remaining drug product. Therefore, the board adopted language that requires the pharmacy technician to scan "each drug unit" to verify the accuracy of the drug. 2) The board concluded that no additional clarification was necessary if errors are identified during the 5% check for RFID technology.

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, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of this background document.

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, email or fax to Elaine Yeatts, 9960 Mayland Drive, Henrico, VA 23233; phone: (804) 367-4688; fax: (804) 527-4434; elaine.yeatts@dhp.virginia.gov. 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	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
425		Sets out the requirements for use of a robotic pharmacy system in a hospital or long-term care facility	Subsection A is amended to delete #8, the requirement for maintenance and storage of records. The requirements are moved to subsection D to clarify that record-keeping requirements are applicable to the entire section. Subsection C is added to set out the requirements for use of a medication carousel. *Change from draft published with the NOIRA: medication carousels are not always a component of a robotic pharmacy system in a hospital, so the wording was changed to say that medication carousels may be utilized if they function with or without a robotic system.*

			#1 provides that a pharmacist must enter drug information into the barcode database for a barcode to be assigned to an individual drug. *The accuracy of that information is essential to the safe delivery of drug or else a pharmacy technician may not be able to accurately verify a drug when scanning the drug's barcode. Thus, a pharmacist must verify the accuracy of the barcode assignment.* #2 states that it is not necessary for a pharmacist to verify the accuracy of a patient-specific drug removed from the carousel if: 1) a pharmacist has verified the accuracy of entry of the order for a patient-specific drug into the dispensing software, and 2) each drug unit removed from the carousel by a pharmacy technician has been scanned prior to dispensing and a nurse has scanned the barcode technology to verify the accuracy prior to administration to a patient. *Change from draft published with the NOIRA: Language in subdivision b required technician to scan "each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug." Comment to the Board indicates that this did not accurately describe how a carousel system works, so the language was changed to require the technician to scan "each drug unit." Scanning each drug unit is consistent with the previous board-approved innovative pilot programs for use of a medication carousel.* #3 provides that under certain conditions, a pharmacist is not required to verify the accuracy of a drug removed from the carousel that is to be placed in an automated drug dispensing system. *Change from draft published with the NOIRA: Comment to the Board indicated that the drug may be distributed to another entity legally authorized to possess the drug, such as an off-site unit away from the main hospital, so that provision was added in the proposed regulation.* The conditions that must exist if the pharmacist is not verifying the accuracy of a drug removed are: 1) the list of drugs to be removed from the carousel for loading or replenishing an automated dispensing system is electronically transmitted to the carousel; and 2) the drugs removed are verified for accuracy by a pharmacy technician by scanning each drug unit prior to leaving the pharmacy and there are additional scans for accuracy at the point of dispensing and administration. *Changes from draft published with the NOIRA: The same changes as described above were included in b.*

			#4 requires that a pharmacist must verify the accuracy of all drugs prior to dispensing or leaving the pharmacy if the drugs are manually removed from the carousel by a technician without the use of barcode scanning technology. #5 (added after NOIRA) requires the pharmacist to perform a daily random check for verification of accuracy of 5% of drugs prepared that day utilizing the medication carousel technology. A record of that random check information must include the date, a description of discrepancies, and the initials of the pharmacist. *The random check is currently required for all innovative pilot programs, so it is consistent with the process used by hospital system that have permission to utilize medication carousel technology.* Subsection D is identical to the record-keeping requirement that was deleted from #8 in subsection A, but it was moved to be inclusive of records required in subsection C.
500		Sets out the rules for a pharmacy preparing drugs for EMS agencies	Subsection A is amended to include the allowance for use of RFID in the preparation of a drug kit to be used by an EMS agency. A pharmacist is not required to check each kit if it is prepared in accordance with provisions of section 505.
	505	Sets out requirements for a hospital pharmacy in the preparation of kits for floor stock in the hospital or kits for EMS agencies through the use of radio-frequency identification (RFID)	Section 505 authorizes a hospital pharmacy to use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for licensed emergency medical services or other kits used as floor stock throughout the hospital if the following conditions are met: #1 delineates the tasks for which a pharmacist is responsible for performing and verifying the accuracy: a. The addition, modification, or deletion of drug information into the RFID database for assignment of a RFID tag to an individual drug; and b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags. #2 specifies that a pharmacy technician may place the RFID tag on the drugs, and then a pharmacist must verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory. #3 provides that a pharmacy technician may remove RFID-tagged drugs from the pharmacy's

			inventory whose RFID tags have been previously verified for accuracy by a pharmacist, and place the drugs into the kit's container. A pharmacy technician may then place the container into the pharmacy's device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database. #4 requires that a pharmacist perform a daily random check for verification of the accuracy of 5% of all kits prepared that day utilizing the RFID technology. A manual or electronic record from which information can be readily retrieved. The record must include: a. The date of verification; b. A description of all discrepancies identified, if any; and c. The initials of pharmacist verifying the accuracy of the process. #5 allows pharmacies engaged in RFID tagging of drugs to be exempt from the requirements in subsection C of 18VAC110-20-490, subsection A of 18VAC110-20-460, and subsection A of 18VAC110-20-355. #6 requires all records to be maintained for a period of one year from the date of verification by the pharmacist. *This new section was added to incorporate another technology already approved for innovative pilot programs – the use of radio-frequency identification to verify the accuracy of drugs placed into a kit for licensed emergency medical services personnel or other kits used as floor stock throughout a hospital. The regulations specify the responsibilities of a pharmacist and the duties of a pharmacy technician in the use of RFID technology.* *There were no changes from the text that was published with the NOIRA.*