COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Tentative Agenda of Regulation Committee Meeting

November 4, 2021

9AM

TOPIC	**PAGES**

Call to Order: Dale St.Clair, Jr., Committee Chair

- Welcome & Introductions
- Approval of Agenda

Call for Public Comment

Agenda Items

Adjourn

******The Board will have a working lunch at approximately 12pm.******

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**
As of October 22, 2021

Board of Pharmacy

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Reporting of immunizations to VIIS [Action 5598] Emergency - *Register Date: 10/12/20 Expires 3/21/22*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Implementation of 2021 legislation for pharmacists initiating treatment [Action 5861] Emergency/NOIRA - *AT Attorney General's office*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Use of medication carousels and RFID technology [Action 5480] Proposed - *Register Date: 8/16/21* [Stage 9236]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Implementation of legislation for pharmacists initiating treatment [Action 5604] Proposed - *At Secretary's Office for 127 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 1248 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Deletion of scheduling of certain chemicals now scheduled in Schedule I in the Code [Action 5846] Final - *AT Attorney General's Office*
[18 VAC 110 - 21]	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians	Implementation of legislation for registration of pharmacy technicians [Action 5603] Proposed - *At Secretary's Office for 127 days*
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	Limited license for prescribing Schedule VI drugs in non-profit clinics [Action 5605] Proposed - *Register Date: 8/16/21 Comments closed: 10/15/21*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Response to petition for rulemaking [Action 5611] NOIRA - *Register Date: 3/1/21* [Stage 9081]

Agenda Item: Consideration of Final Regulations – Medication carousels

Included in your agenda package are:

Notice from the Va. Regulatory Townhall

Copy of comments on proposed regulations

A copy of the proposed regulations

Committee action:

Consider the comments and recommend action on final regulations (Amend or adopt as proposed)

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VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

Chapter Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]

Action: Use of medication carousels and RFID technology

Proposed Stage

Action 5480 / Stage 9236

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	8/10/2021 9:52 am	Sync Text with RIS
Agency Background Document	3/24/2021	Upload / Replace
Attorney General Certification	4/19/2021	
DPB Economic Impact Analysis	6/2/2021	
Agency Response to EIA	7/22/2021	Upload / Replace
Governor's Review Memo	7/22/2021	
Registrar Transmittal	7/22/2021	

Status	
Incorporation by Reference	No
Exempt from APA	No, this stage/action is subject to Article 2 of the *Administrative Process Act*
Attorney General Review	Submitted to OAG: 3/24/2021 Review Completed: 4/19/2021 Result: Certified
DPB Review	Submitted on 4/19/2021 Economist: Jini Rao Policy Analyst: Jerry Gentile Review Completed: 6/2/2021
Secretary Review	Secretary Review Completed: 7/5/2021
Governor's Review	Review Completed: 7/22/2021 Result: Approved
Virginia Registrar	Submitted on 7/22/2021 The Virginia Register of Regulations Publication Date: 8/16/2021 Volume: 37 Issue: 26
Public Hearings	09/24/2021 9:10 AM
Comment Period	Ended 10/15/2021 2 comments

Contact Information	
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This person is the primary contact for this chapter.

This stage was created by Elaine J. Yeatts on 03/24/2021 at 9:00am
This stage was last edited by Elaine J. Yeatts on 03/24/2021 at 9:00am

Comment- Public Hearing
Medication carousels

Virginia Society of Health-System Pharmacists
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September 23, 2021

Ms. Caroline Juran
Executive Director, Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233

Dear Ms. Juran:

On behalf of the Virginia Society of Health-System Pharmacists (VSHP), this written comment is to provide a high level overview of medication carousel technology and its role within the health-system pharmacy environment, as well as to clarify our requests for considerations for the Board to review.

We hope to provide more insight to the efficiencies and patient safety strategies that are availability from this technology to mitigate potential errors stemming from inventory, filling and dispensing process.

We also include requests of the Board of Pharmacy to consider proposed revised language with regards to the proposed regulatory language for **18VAC110-20-425**. Robotic pharmacy systems concerning medication carousel technology.

Medication Carousel Technology

This type of automated technology utilizes barcode scanning technology and electronic interfaces for safe and accurate storage, filling, and final verification of medications for dispensing. A summary comparison of specific actions and technology functions are described below. For more detailed steps, please refer to Appendix A, which includes language included in an approved pilot by the Board.

Using Carousel Technology	Without Using Carousel Technology
Inventory Management	
□ Maintains electronic inventory with associated min/max inventory levels	□ On-hand inventory is manual and often on paper.
□ Since inventory is electronic, items are separated throughout the carousel in individually located bins, and not side-by-side.	□ Items are located on shelves, often in alphabetical order.
□ Inventory may also include electronic tracking of expiration dating.	□ Expiration dating is manually tracked.
Medication Procurement	
□ Reordering occurs through electronic interface with wholesaler for products below suggested MIN levels	□ Reordering occurs through assessing inventory manually, and then entering each item into ordering system.

Using Carousel Technology	Without Using Carousel Technology
□ Once ordered, there is an electronic purchase order receiving process for what was ordered, and what is fulfilled by the wholesaler.	□ Purchase order, invoices, and receiving is manually verified.
□ When receiving the order, staff scan the individual product, and the carousel spins to the appropriate shelf and indicates location of bin to restock/receive the medication.	□ Items are placed back into appropriate bins without any barcode validation.
□ Staff electronically receive the medication to adjust inventory levels, and load the medication into the indicated location.	
Medication Dispensing for Restock or Patient-Specific	
□ Automated Dispensing Cabinets and Electronic Health Systems interface with carousels to indicate needed medication.	□ Items needed for dispensing are indicated by physical labels or paper reports.
□ The carousel spins to the appropriate shelf and indicates location of bin for staff to pick medications.	□ Staff go to the location of the medication, and manually match the label to the medication.
□ Staff remove the medication quantity and visually inspects the medication for integrity and expiration date.	□ Staff remove the medication quantity and visually inspects the medication for integrity and expiration date.
□ Staff scan the barcode of the product, which validates the accuracy of the medication and adjusts the electronic inventory.	□ There is no barcode validation that the correct product was obtained.
□ The technician then places the medication in the plastic bag with the label and provides it to the pharmacist for verification.	□ The technician then places the medication in the plastic bag with the label and provides it to the pharmacist for verification.
If dispensed to the **patient**, the medication is then administered by a nurse or other licensed health professional as defined by their scope of practice. This may or may not include a barcode scanning requirement. Note that per administration requirements, any health care professional that administers a drug should be performing the appropriate review regarding the rights of administration (i.e., right patient, right drug, right dose, right time, right route, right indication, and right documentation). Many health-systems have adopted barcode scanning technology for administration as another layer of safety.	
If dispensed to the **automated dispensing cabinet**, the pharmacy technician refilling the automated dispensing cabinet scans the drug prior to filling each pocket/ drawer. Upon refiling they perform a visual inspection of inventory being added to the pocket/drawer and existing inventory to ensure medication accuracy and that there are no expired medications. Only designated healthcare professionals may access these medications.	

NOTE: When a community pharmacy utilizes barcode technology for filing medications, each tablet or capsule is not "scanned," as the bottle is usually scanned. Visual inspection is still expected by the pharmacy technician and pharmacist at each of these steps to ensure the accuracy of medication prepared and dispensed. In addition, upon returning unused stock to the original bottle, there is no scanning involved; visual inspection is how the correct tablet or capsule is returned to the original bottle. We believe that the multiple layers of checks from the point of ordering, restocking, filling, dispensing, and ultimate verification by a licensed healthcare professional authorized to administer medications complement safety checks within the medication use system.

Advantages Of Utilizing Carousel Technology

1. **Patient Safety**
    - **Utilization of barcode technology at receiving, restocking, and patient order fulfillment ensures accurate medication distribution processes**
        - **This technology allows utilization of barcodes from receiving through administration.**
    - **Electronic inventory and dispensing allow for:**
        - **Separating different concentrations of the same medication**
        - **Separating sound-alike or look-alike medications (thus you are not defined by having to store medications in alphabetical order)**
        - **Limited access to entire inventory compared to inventory located on shelves**
    - **Password-protected access allows for security and traceability: pharmacists and pharmacy technicians must log onto the medication carousel technology to log their actions**
    - **Controlled database management allows for safe ordering and dispensing through accurate medication and barcode inputs**

2. Inventory Management
    - Integration with wholesaler to improve accurate order of medications (for example, the system can order up to the designated MAX/PAR and submit through the medication carousel technology, eliminating the need for a pharmacy technician to manually enter in the order, thus make errors. This function has been critical to staying abreast with drug shortage management)
    - Real-time inventory management
    - Simplified barcode restocking
    - Reduction of inventory waste by allowing for analytical review of inventory turns and expiration dating
    - Cycle Counting: During downtimes, pharmacy technicians will review assigned medication bins and assess accuracy of the quantity in the system as well as review for expired medications for removal. This ensures the medication stored in the bin matches what is designated by the medication carousel technology.

3. Efficient Use of Limited Space
    - Vertical carousel spinning allows for more medications in a confined space as well as improved design to access of fast-mover vs. slow-mover medications

VSHP respectfully asks the following:

ASK#1: Amend and approve the proposed language, per the recommendation below. VSHP supports the Board's intent to bring the practices and experiences through the pilots on medication carousel technology into regulation as the technology is widely utilized across many health-systems. Based on the discussions so far, we believe that the language as written supports *specific* health-systems who are able to scan every single unit bar code per medication order for patient-specific orders or refilling automated dispensing cabinets.

There is one clarification to the medication administration language that VSHP would like the Board to consider:

- Section C, Subsection 2, Statement b and Section C, Subsection 3, Statement b: replace "a nurse or other person authorized to administer drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient" with "**a nurse or other person authorized to administer medications, will verify the accuracy of the drug prior to administration of the drug to the patient according to their scope of practice.**"

Reasoning:

- Many institutions have adopted bedside barcode scanning medication administration technology as an added error mitigation strategy in addition to the current requirements of medication verification prior to administration. In addition, there may be scenarios where the nurse may be withdrawing a medication in the event of an emergent event such as a Code Blue, and there is no time for medication scanning. They are still required to review the 7 rights of administration prior to administration.
- This recommended language reflects the current state where the barcode is the validation of accuracy by a pharmacist within medication carousel technology. Pilots have been able to demonstrate the safety utilizing the barcode scanning elements performed by a pharmacy technician to validate the accuracy of the medication product for the order in lieu of the visual inspection by a pharmacist.

ASK#2: Although we support the Board of Pharmacy's efforts, we believe that there is still opportunity to amend the language to support feasibility for all health-system pharmacy practice.

To make this applicable for all hospitals, we recommend adding the following language to the following sections:

- Section C, Subsection 2, Statement c: If a hospital does not have the capability for the patient-specific drug removed from the medication carousel by a pharmacy technician to be verified for accuracy by scanning each drug unit, then the hospital will utilize a secondary pharmacy technician check: the first pharmacy technician removing the patient-specific drug from the medication carousel performs a visual inspection for accuracy and then double checks the accuracy by scanning an individual unit dose of the order; a second, different pharmacy technician then performs a visual inspection double check and then shall scan an individual unit dose of the order for final verification. A nurse or other person authorized to administer the drug then provides the medication administration. Bar code scan verification at the point of administration is encouraged, but not required.

- Section C, Subsection 3, Statement c: The drug removed from the medication carousel is verified for accuracy first through visual inspection followed by the pharmacy technician by scanning an individual unit dose of the automated drug dispensing system restock order prior to leaving the pharmacy and delivering the drug to the automated drug dispensing system or distributed to another entity, and a nurse or other person authorized to administer the drug then provides the medication administration. Bar code scan verification at the point of administration is encouraged, but not required. In this case, an individual unit dose of the restock order must be scanned prior to restocking to the automated drug dispensing system pocket or drawer prior to withdrawal by a nurse or other person authorized to administer the drug for medication administration.

Reasoning: Our concerns stem from the undue burden of the requirement to scan every single unit dose.

- The requirement to scan every single barcode is not realistic for health-systems with larger order volumes. For instance, if a health-system dispenses an average of 14,000 doses per day for inpatient and ambulatory units, and each patient-specific or restock order has 2 to 20 unit doses, the range in volume for scanning can increase to the range of 28,000 to 280,000 scans per day, requiring additional hours from a pharmacy technician to support this model.
- Bar code scanners are not ergonomically designed for high volume, consecutive scanning such as scanning 20 unit doses of a medication order. This may lead to higher incidences of hand injuries within the workplace and may cause long-term damage such as carpel tunnel syndrome.
- This requirement may also lead to alert fatigue. This may redirect the pharmacy technician's attention from the visual inspection elements to ensuring that the correct number is scanned; or encourage workarounds due to human factors engineering elements for higher volume processes.

- Medications dispensed from medication carousel technology are ultimately administered by a licensed healthcare professional who must perform the 7 rights of administration as part of their scope of practice for medication administration. The use of barcode scanning technology is another added "forcing function" strategy that most health-systems have adopted for added patient safety strategies. Note that additional administration strategies at the point of administration include independent double checks (by another licensed healthcare professional) or requirements for provider-level administration for certain high alert medications.

We would like to further emphasize the current strategies <u>already employed</u> to ensure patient safety:

- Pharmacist validates barcode of a medication prior to its addition into inventory
    - Note: Verification by scanning the bar code has been demonstrated to be more accurate than visual inspection by the human eye.
- Medication restocking – information for restocking is already automated, allowing for technician scanning and visual inspection of accuracy, quantity, and expiration dating
- Medication storage – medications that can be potentially confused (such as different concentrations of the same medications, sound alike or look alike medications) can be physically separated and do not need to be stored next to each other
- Intentional medication filling processes: Medication orders are filled each drug at a time
- Medication inventory management: cycle counting practices
- Analytical reporting – cycle count, expired medications and near misses reporting are possible reporting functions for quality improvement opportunities
- Medications dispensed from medication carousels are administered by licensed healthcare professionals when intended for patient-specific orders and automated dispensing system fills

<u>ASK#3:</u> We understand the Board's role in protecting the public within the medication use process.

We also recommend the additional language to support the quality assurance strategies to ensure patient safety. In addition to the pharmacist 5% check, we recommend the following additions if the previous addition is supported:

- <u>Section C, Subsection 6:</u> The hospital will also perform quality assurance surveillance to ensure the integrity of the medication carousel process by performing at a minimum monthly cycle counts (which include confirmation of the correct drug in the storage bin, correct quantity and appropriate expiration dating). A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:
    - a. The date of verification
    - b. A description of all discrepancies identified, if any; and
    - c. The initials of pharmacist or pharmacy technician verifying the accuracy of the process.

- <u>Section C, Subsection 7:</u> If the hospital is utilizing this process to restock automated drug dispensing systems, a pharmacist or pharmacy technician shall perform a monthly random check for verification of the accuracy of 5% of drugs dispensed to an automated drug dispensing system. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:
    - a. The date of verification
    - b. A description of all discrepancies identified, if any; and
    - c. The initials of pharmacist or pharmacy technician verifying the accuracy of the process.

As described previously, medication carousel technology adds additional layers of safety, allowing for accurate dispensing when the barcode scanning is utilized during the medication restocking process, filling process, and verification process.

Thus, we strongly encourage the Board to consider the implications of the current language of the proposed regulations on medication carousel technology and its impact to all health-system pharmacies across the Commonwealth of Virginia.

We appreciate the Board's consideration of amendments to incorporate changes currently in approved as pilots for medication carousel technology and its application to all hospitals within the Commonwealth of Virginia.

Sincerely,

Craig Kirkwood, PharmD, MS

Virginia Society of Health-System Pharmacists (VSHP) President

Appendix A

1. Method of ensuring accurate packaging and loading of the carousel

1. Upon receiving the daily medication purchase order, the Purchaser signs for the product and sequesters it from the current pharmacy inventory. Purchases are already segregated by tote as to which inventory location it will eventually go to.
2. The purchaser or a pharmacy technician scans each medication to ensure that it is scanable and recognized in the pharmacy's medication database.
    a. If the drug is recognized by the scanner and is found in the pharmacy medication database, this medication is then ready to move to step 3.
    b. If the drug is not recognized by the scanner or is not found in the pharmacy medication database, a pharmacist is contacted.
        i. If it is a completely new product, the IS Pharmacist must be contacted to build the new drug entry into the medication database.
        ii. If it is a new barcode of an existing product (example: new generic manufacturer), a pharmacist can link the new barcode to an existing medication in the database.
3. After the product has been identified by the scanner, it is placed in the pharmacy inventory:
    a. If the product is packaged and can be scanned at the product's lowest unit of measure (LUM), then it is ready to move to step 4.
    b. For bulk packages, they can go through one of two pathways:
        i. Slow moving bulk items have their own carousel inventory location and can be placed in inventory similar to a LUM product.
        ii. Fast moving bulk items will be set aside to be prepacked. Once they are prepacked, they will then go through the process beginning at step 2.
4. Below is a description for loading packaged medications in to the Carousel.
    a. After logging into the system and selecting the restock function, the User will be prompted to scan the medication to be restocked.
    b. After scanning the bar code on the medication The Carousel will rotate to the appropriate location and the position and depth indicators illuminate.
        i. If the item is stocked outside of the Carousel device in another location (static shelving or the refrigerator), the User will obtain location information from the Restock Location field. The other locations do not have lights that display the position of the medication; the Restock Location field will tell the User exactly where the medication is located.
    c. The User will:
        i. Enter the quantity to be restocked in Restock Qty field.
        ii. Enter the earliest expiration date found on items to be restocked and already in the bin into the Expires field.
        iii. Count the medications in the bin to verify that the quantity equals the display in the Inventory field.
    d. The End Inventory field automatically updates based on the Restock Qty entered. However, if necessary, the User will enter a different number in the End Inventory field to correct the total quantity in the bin.
    e. The User will then scan the label on the side of the bin. The application automatically saves the restocking information.
        i. The label on the side of each medication bin is specifically associated with the bar code on each product's lowest unit of measure.

2. Procedures for conducting quality control checks of final dispensing for accuracy

1. When dispensing drugs from the Carousel, there are 4 methods in place: First dose dispensing, Cartfill dispensing, and Automated Dispensing Cabinet (ADC) batch/stock-out dispensing, and Manual dispensing.

a. **First Doses** are dispensed as follows:
   i. After an order has been entered by the pharmacist for a First Dose, the dispense request appears on the Carousel Order queue
   ii. When the technician processes the dispense request, a drug-patient specific label (adjacent to the Carousel) prints. The Carousel will rotate to the appropriate location and the position and depth indicators illuminate.
   iii. If the item is stocked in another location (static shelving or the refrigerator), the technician will obtain location information from the Location field.
   iv. The technician will scan the individual medication to be dispensed and then scan the patient-specific label.
   v. The drug will then be placed by the technician in a clear bag with the order-specific label affixed to it.
   vi. Simultaneously following the scan of the drug-patient specific label, the next dispense request (if one exists) in the queue will appear to be processed.
   vii. The medication is then ready to be transported by the pneumatic tube system or delivery to the specific unit.

b. **Cartfill doses** are dispensed as follows:
   i. The technician processes the Cartfill Batch in the RxIS.
   ii. Patient specific dispense requests appear on the Carousel Order queue
   iii. When the technician processes the dispense request, a drug-patient specific label (adjacent to the Carousel) prints. The Carousel will rotate to the appropriate location and the position and depth indicators illuminate.
   iv. If the item is stocked in another location (static shelving or the refrigerator), the technician will obtain location information from the Location field.
   v. The technician will scan the individual medication to be dispensed and then scan the patient-specific label.
   vi. The technician will then look for a confirmation message to ensure that scanned medication is correct. If incorrect medication is scanned, a warning message appears and flashes.
   vii. The drug will then be placed by the technician in a clear bag with the order-specific label affixed to it.
   viii. Simultaneously following the scan of the drug-patient specific label, the next dispense request (if one exists) in the queue will appear to be processed.
   ix. The medication is then ready to be transported by the pneumatic tube system or delivery to the specific unit.

c. **ADC Batch and Stockouts** are dispensed as follows:
   i. The ADC sends batch refill information or stockout information directly to the Carousel Dispense queue via an electronic interface.
   ii. The technician processes the batch and stockout dispense in the Carousel Order queue.
   iii. When the technician processes the dispense request, an ADC restock label (adjacent to the Carousel) prints. The Carousel will rotate to the appropriate location and the position and depth indicators illuminate.
   iv. If the item is stocked in another location (static shelving or the refrigerator), the technician will obtain location information from the Location field.
   v. The technician will scan the individual medication to be dispensed and then scan the ADC restock label.
   vi. The technician will then look for a confirmation message to ensure that scanned medication is correct. If incorrect medication is scanned, a warning message appears and flashes.
   vii. The drug will then be placed by the technician in a clear bag with the label affixed to it.
   viii. Simultaneously following the scan of the drug-patient specific label, the next dispense request (if one exists) in the queue will appear to be processed.

ix. The medication is then ready to be delivered to the specific ADC.

d. **A Manual dispense** may be needed for a variety of reasons: Emergent need for a dose which has not been entered via the electronic medical record, filling of the trauma boxes for the local EMS teams, pulling stock that has been recalled or expired, or replenishing floor stock requisitions. Manual dispense doses are dispensed as follows:

i. In order to fulfill the requested order the User will log into the Carousel software and select Manual Pick.

1. In the **Search** field, type in the first few letters of the generic name of the medication and Enter. This will give the User a list of medications that fit the generic description.
2. The User will then **carefully** select the medication that they wish to obtain from the list by highlighting that drug.
3. In the **Pick Quantity** field, type the quantity to be dispensed and press Enter.
4. The Carousel will spin to the correct shelf. The position and depth lights will illuminate on the posting board indicating the medication's location. The system will automatically subtract the quantity picked from the **Current inventory** count, and display the new inventory value in the **New Inventory Count** field.
5. The Technician will then **scan the barcode on the medication being dispensed.**
6. The technician will then look for a confirmation message to ensure that scanned medication is correct. If incorrect medication is scanned, a warning message appears and flashes.

2. **Prior to dispensing a medication to the patient on the patient care unit, the nurse, using the scanner, will scan the patient's wrist band to verify the patient, and then scan the bar code on the medication to verify that the drug is indeed on the patient's profile to be administered and that it is the right dose, route and time.**

a. **This process will chart the medication on the patient's electronic medical record as given.**

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Agency Department of Health Professions

Board Board of Pharmacy

Chapter Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]

Action	Use of medication carousels and RFID technology
Stage	Proposed
Comment Period	Ends 10/15/2021 (today!)

2 comments

All good comments for this forum Show Only Flagged

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Commenter: Tyler Martinson Sentara Virginia Beach General Hospital 8/17/21 11:59 am

Fully Support amendments

After reviewing the amendments, I fully support this regulation change to bring Virginia into line with many other states that already allow the use of both technologies. This regulation will allow us to apply the skills of our technicians to make sure we provide the correct drugs and free up pharmacists to assist with more clinical based needs of our patients. We have been using RFID tagging for our OR/Code carts/RSI boxes as a pilot program for over 5 years and never had any safety issues. The scanning technology within carousels, and ADDs, has grown significantly, and barcode scanning by nursing prior to administration is a Leap Frog measure that will make sure our nursing partners are validating for patient safety. Thank you for the work you do and moving Virginia pharmacy in the correct direction!

CommentID: 99769

Commenter: Catherine Floroff - Sentara Norfolk General Hospital 8/22/21 2:59 pm

Support this regulation

I fully support this regulation change. It is in line with the skills of our technician staff. This would allow the pharmacist to assist with more complex, clinical needs. We have been using RFID tagging for our OR/Code carts/RSI boxes as a pilot program for over 5 years and never had any errors or safety issues.

CommentID: 99858

Project 6271 - Proposed

Board Of Pharmacy

Use of medication carousels and RFID technology

18VAC110-20-425. Robotic pharmacy systems.

A. Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in barcoded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply:

1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.

2. The packaging, repackaging, stocking, and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.

3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards.

4. A written policy and procedure must be maintained and complied with and shall include at a minimum procedures for ensuring:

a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter and assigned barcodes;

b. Accurate stocking and restocking of the robotic pharmacy system;

c. Removing expired drugs;

d. Proper handling of drugs that may be dropped by the robotic pharmacy system;

e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

f. Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;

g. Accurate recording of any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution;

h. Appropriately performing an analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

i. Maintaining quality assurance reports.

5. All manual picks shall be checked by pharmacists.

6. If it is identified that the robot selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot. An investigation of

the cause of the event shall be completed, and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format.

7. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include a summary indicating the date and description of all discrepancies that include discrepancies involving the packaging, repackaging, and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

~~8. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.~~

B. Intravenous admixture robotics may be utilized to compound drugs in compliance with § 54.1-3410.2 of the Code of Virginia and 18VAC110-20-321; however, a pharmacist shall verify the accuracy of all compounded drugs pursuant to ~~18VAVC110-20-270~~ 18VAC110-20-270 B.

C. Medication carousels functioning with or without a robotic pharmacy system in a hospital may be utilized to store and guide the selection of drugs to be dispensed or removed from the pharmacy under the following conditions:

1. The entry of drug information into the barcode database for assignment of a barcode to an individual drug shall be performed by a pharmacist who shall verify the accuracy of the barcode assignment.

2. A pharmacist is not required to verify the accuracy of a patient-specific drug removed from a medication carousel if:

a. The entry of the order for a patient-specific drug into the pharmacy's dispensing software is verified by a pharmacist for accuracy and is electronically transmitted to the medication carousel; and

b. The patient-specific drug removed from the medication carousel by a pharmacy technician is verified for accuracy by the pharmacy technician who shall scan each drug unit removed from the medication carousel prior to dispensing, and a nurse or other person authorized to administer the drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient.

3. A pharmacist is not required to verify the accuracy of the drug removed from the medication carousel by a pharmacy technician if that drug is intended to be placed into an automated drug dispensing system as defined in § 54.1-3401 of the Code of Virginia or distributed to another entity legally authorized to possess the drug if:

a. The list of drugs to be removed from the medication carousel for loading or replenishing an individual automated dispensing system is electronically transmitted to the medication carousel; and

b. The drug removed from the medication carousel is verified for accuracy by the pharmacy technician by scanning each drug unit removed from the medication carousel prior to leaving the pharmacy and delivering the drug to the automated drug dispensing system or distributed to another entity, and a nurse or other person authorized to administer the drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient. If the drug is placed into an automated drug dispensing system located within a hospital, or the entity receiving the distributed drug, wherein a nurse or other person authorized to administer the drug will not be able to scan each drug unit using barcode

technology to verify the accuracy of the drug prior to patient administration, then a second verification for accuracy shall be performed by a pharmacy technician by scanning each drug unit at the time of placing the drugs into the automated dispensing system.

4. A pharmacist shall verify the accuracy of all drugs that are manually removed from the medication carousel by a pharmacy technician without the use of barcode scanning technology to verify the accuracy of the selection of the drug product prior to dispensing those drugs or those drugs leaving the pharmacy.

5. A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of drugs prepared that day utilizing the medication carousel technology. A manual or electronic record, from which information can be readily retrieved, shall be maintained and shall include:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of the pharmacist verifying the accuracy of the process.

D. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible, provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent of the board.

18VAC110-20-500. Licensed emergency medical services (EMS) agencies ~~program~~.

A. The pharmacy may prepare a kit for a licensed EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this kit. ~~A~~ Except as authorized in 18VAC110-20-505, a pharmacist shall check each kit after filling and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The kit is sealed, secured, and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection of theft or loss.

a. The hospital pharmacy shall have a method of sealing the kits such that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.

c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.

3. Drugs and devices may be administered by an EMS provider upon an oral or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The EMS provider shall make a record of all drugs and devices administered to a patient.

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the

pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

5. Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year:

a. The record of filling and verifying the kit to include the drug contents of the kit, the initials of the pharmacist verifying the contents, the date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit, which shall be no later than the expiration date associated with the first drug or device scheduled to expire.

b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.

6. Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation shall be maintained in the pharmacy for a period of two years from the date of destruction.

7. The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

8. Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.

9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.

B. A licensed EMS agency may obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.

1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.

2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.

3. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.

4. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge, which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

5. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs or devices, Schedule II, III, IV, or V drugs shall remain in a separate, sealed container and shall only be exchanged in accordance with provisions of subsection A of this section.

18VAC110-20-505. Use of radio-frequency identification.

A hospital pharmacy may use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for licensed emergency medical services pursuant to 18VAC110-20-500 or other kits used as floor stock throughout the hospital under the following conditions:

1. A pharmacist shall be responsible for performing and verifying the accuracy of the following tasks:

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. A pharmacy technician may place the RFID tag on the drugs, and a pharmacist shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.

3. 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. A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of all kits prepared that day utilizing the RFID technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:

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. Pharmacies engaged in RFID tagging of drugs shall 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. All records required by this subsection shall be maintained for a period of one year from the date of verification by the pharmacist.

Agenda Item: Periodic Review of Chapters 20, 21, 30, 40, and 50

Included in Agenda Package:

- Draft decisions for Chapters 20, 21, 30, and 50 regarding regulatory sections that the Board will consider amending during the current periodic review
    - Items in black were previously recommended by the Board
    - Items in red are staff suggestions for Board consideration
- No regulatory sections have been identified in Chapter 40

Staff note:

The amendments recommended by the Committee will be included in the Report of Findings for each chapter. Those reports will then be distributed to interested parties on the Board's Public Participation Guidelines list for an opportunity to offer additional amendments or comment on the recommendations. At its March 2022 meeting, the Board will need to promulgate amendments by either a fast-track action or publication of a Notice of Intended Regulatory Action.

Committee Action:

Motion to recommend to the Board that it report the result of its periodic review of Chapters 20, 21, 30 and 50 with a decision to continue the chapters with amendments and the result of its periodic review of Chapter 40 with a decision to continue without amendment.

protecting the public by scheduling dangerous chemicals in Schedule I, by setting rules for the safety, efficacy, and integrity of prescription medications, and by updating rules as new technologies and techniques are introduced in the practice of pharmacy. Whenever amendments are promulgated, language is reviewed to ensure that it is clearly written and easily understandable.

Chapter 20

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

The Board will amend the regulation. While there was no public comment on this chapter resulting from the Notice of Periodic Review, the Board has identified several sections that it will consider for amendments:

- Section 10, amend definition of "personal supervision" to allow audio-visual technology to supervision of compounding in retail pharmacies
- Section 25, amend to include the following:
    - engaging in a manner that discourages individuals from providing information regarding public safety concerns to the Board, other regulatory entities, or law enforcement;
    - assuming duties and responsibilities within the practice of pharmacy without adequate training or when competency has not been maintained
    - failure to provide a working environment for all pharmacy personnel that protects the health, safety and welfare of a patient including:
        - sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates an environment that jeopardizes patient care;
        - appropriate opportunities for uninterrupted rest periods and meal breaks;
        - adequate time for a pharmacist to complete professional duties and responsibilities including:
            - drug utilization review;
            - immunization;
            - counseling;
            - verification of the accuracy of a prescription
        - introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public;
        - incenting or inducing the transfer of a prescription absent professional rationale.
- Section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.
- Section 275, consider amending to require record for alternate delivery site further delivering drug to patient's home

- Section 290, shortening expiration date of Schedule II prescription
- Including a requirement for an e-profile identification number for facilities
- Section 110, extending timeframe beyond 14 days for notification of a change in the PIC
- Section 550, amending to remove the restriction that a stat-drug box contain no more than 20 solid dosage units per schedule of Schedules II through V drugs
- Section 110 (J) to include allowance to consider prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the practice of pharmacy by the pharmacist-in-charge or immediate family members of the pharmacist-in-charge, and owners, directors, or officers
- Section 690, amend to prohibit registration from being issued to private dwelling or residence
- Requiring application form for a new permit or nonresident registration or any change of ownership to include at least the following information:
- 1. The name, full business address, and telephone number of the applicant, registrant, or permit holder and name and telephone number of a designated contact person;
- 2. All trade or business names used by the applicant or licensee, registrant, or permit holder;
- 3. The federal employer identification number of the applicant or licensee, registrant, or permit holder;
- 4. The type of ownership and name of the owner of the entity, including:
- a. If an individual, the name, address, and social security number or control number;
- b. If a partnership, the name, address, and social security number or control number of each partner who is specifically responsible for the operations of the facility, and the name of the partnership and federal employer identification number;
- c. If a corporation:
- (1) The name and address of the corporation, federal employer identification number, state of incorporation, and the name and address of the resident agent of the corporation;
- (2) The name, address, social security number or control number, and title of each corporate officer and director who is specifically responsible for the operations of the facility;
- (3) For nonpublicly held corporations, the name and address of each shareholder that owns 10% or more of the outstanding stock of the corporation;
- (4) The name, federal employer identification number, and state of incorporation of the parent company;
- d. If a sole proprietorship, the full name, address, and social security number or control number of the sole proprietor and the name and federal employer identification number of the business entity;
- e. If a limited liability company, the name and address of each member, the name and address of each manager, the name of the limited liability company and federal employer identification number, the name and address of the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized;
- 5. Name, business address and telephone number, social security number or control number of the pharmacist-in-charge.
- 6. A list of all states in which the entity is licensed, registered, or permitted to practice pharmacy and into which it ships prescription drugs;

- 7. A list of all disciplinary actions imposed against the entity by state or federal regulatory bodies, including any such actions against the pharmacist-in-charge, other pharmacists practicing at this site, principals, owners, directors, or officers over the last seven years;
- 8. A full description, for nonresident pharmacies, including the address, square footage, security and alarm system description, temperature and humidity control, and other relevant information of the facility or space used for prescription drug storage and dispensing; and
- 9. An attestation providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts. Such attestation shall include the pharmacist-in-charge, pharmacists practicing at this site, principals, owners, directors, or officers.
- B. An applicant or licensee, registrant, or permit holder shall notify the board of any changes to the information required in this section within 30 days of such change.

After further opportunity for comment and recommendations for amendments, the Board will publish a Notice of Intended Regulatory Action.

Small Business Impact

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.

(1) There is a continued need for the regulation since the Code requires pharmacies and other entities to be permitted, registered or licensed by the Board;
(2) The Board has not received any of complaints or comments concerning the regulation;
(3) Practitioners do not find the regulation to be overly complex, but the Board will consider whether requirements could be simplified or clarified;
(4) There is no overlap duplication, or conflict with federal or state law or regulation; and
(5) As stated above, the chapter has been amended 40 times in the last five years and has five additions regulatory actions in process, including amendments to incorporate allowances for newer technology in hospital pharmacies. The last periodic review began in 2016, but was only finalized in 2019, so the Board has continually updated regulations while protecting the safety, integrity, and efficacy of dispensing medications.
In its review, the Board will consider any additional amendments that are recommended that will streamline or clarify regulations in order to minimize the economic impact on small businesses.

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

The Board will amend the regulation. While there was no public comment on this chapter resulting from the Notice of Periodic Review, the Board has identified several sections that it will consider for amendments:

- Section 90(A) by requiring FPGEC prior to obtaining pharmacist license through endorsement or score transfer and delete exemption from FPGEC in subsection D
- Section 80 by prohibiting a candidate from being readmitted to take the board-approved integrated pharmacy examination when the candidate fails to meet the passing requirements on 5 occasions

DRAFT

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

The Board will amend the regulation. While there was no public comment on this chapter resulting from the Notice of Periodic Review, the Board has identified several sections that it will consider for amendments:

- Section 80 to prohibit license and permit from being issued to private dwelling or residence

DRAFT

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

The Board will amend the regulation. While there was no public comment on this chapter resulting from the Notice of Periodic Review, the Board has identified several sections that it will consider for amendments:

- Requiring wholesale distributors and nonresident wholesale distributors to obtain and maintain the NABP Drug Distributor Accreditation (formerly VAWD)

Virginia Board of Pharmacy

Continuing Education Audit

Procedure for enforcement of CE requirements:

Following each renewal cycle, Board staff may audit the following persons for CE compliance:

- Persons checking "no" to the CE attestation on the annual license renewal form, either paper or online
- Persons who requested a continuance from the previous year
- Persons selected for random audit. The audit will be conducted pursuant to procedures established by the Department of Health Professions to ensure a statistically valid audit sample and randomness of those selected.

This procedure does not preclude the auditing and special handling of CE non-compliance as may be specified in a Board order.

If the response to the audit does not show compliance with CE requirements, Board staff will send a letter to the respondent offering resolution of the matter by consent, payment of an established monetary penalty, and proof of late compliance with CE requirements. The letter will also offer an additional opportunity for the respondent to furnish proof that CE requirements were actually met during the specified time period or the opportunity to request an informal conference. A signed letter will constitute an order of the Board and the licensee's consent to the imposition of a monetary penalty and an agreement to the submission of documentation of late CE compliance. If there is no response to the letter, within 30 days, an informal conference before an agency subordinate, or IFC if more expedient, will be scheduled.

The monetary penalty offered in the letter shall be $250 for each year a pharmacist does not meet CE requirements. Because the maximum audit period is 2 years, the maximum penalty would be $500. The monetary penalty offered for each year that a pharmacy technician does not meet CE requirements will be $50, for a maximum penalty of $100. Board-imposed penalties for CE non-compliance not resolved by consent may result in additional penalties following the informal conference proceedings.

Agenda Item: Consider Amending Guidance 110-9 to address Specific Compounding Deficiency

Background:

Should Guidance Document 110-9 include a deficiency and sanction when primary engineering controls with failed viable and nonviable environmental sampling tests are used for compounding prior to subsequent testing results confirming conditions have been corrected, a requirement of USP?

Included in Agenda Package:

- Guidance Document 110-9

Action Needed:

- Amend Guidance Document 110-9 to include a deficiency and recommended sanction, or advise staff on other actions to take when discovered during routine inspection.

Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	2000
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	54.1-3434 and 18VAC110-20-110		1000
3. Unregistered persons performing duties restricted to pharmacy technician without first becoming registered as a pharmacy technician trainee	54.1-3321 and 18VAC110-20-111	per individual	First documented occurrence = no penalty Repeat = $ penalty 250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-21-60, 18VAC110-21-110, and 18VAC110-21-170	per individual	First documented occurrence = no penalty Repeat = $ penalty 100
5. Pharmacy technicians, pharmacy interns, or pharmacy technician trainees performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320 18VAC110-20-112		500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320 18VAC110-20-112	per each technician over the ratio	First documented occurrence = no penalty Repeat = $ penalty 100
7. Change of location or remodel of pharmacy without submitting application or Board approval	18VAC110-20-140	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	First documented occurrence = no penalty; drugs may be embargoed Repeat = $ penalty 100 Drugs may be embargoed
9. The alarm is not operational. The enclosure is not locked at all times when a pharmacist is not on duty. The alarm is not set at all times when the pharmacist is not on duty.	18VAC110-20-180 and 18VAC110-20-190		1000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. The alarm system does not include a feature by which any breach shall be communicated to the PIC or a pharmacist working at the pharmacy.	18VAC110-20-180		First documented occurrence and no drug loss = no penalty Drug loss or repeat = $ penalty 250
10. Unauthorized access to alarm or locking device to the prescription department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		First documented occurrence and no drug loss = no penalty Drug loss or repeat = $ penalty 500
12. Storage of prescription drugs not in the prescription department	18VAC110-20-190		500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe, or maintained in a manner that combines the two methods.	18VAC110-20-200		First documented occurrence and no drug loss of Schedule II = no penalty Drug loss or repeat = $ penalty 250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 and 18VAC110-20-240	Cite Deficiency 113 if only expired drugs not included in inventory.	Over 30 days late and first documented occurrence = no penalty Over 30 days late and repeat = $ penalty 500
14. No incoming change of Pharmacist-in-Charge inventory, inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3434 and 18VAC110-20-240	Per occurrence. Cite Deficiency 113 if only expired drugs not included in inventory.	500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
15. Perpetual inventory not being maintained as required as it does not: • Include all Schedule II drugs received or dispensed; • Accurately indicate the physical count of each Schedule II drug "on-hand" at the time of performing the inventory; • Include a reconciliation of each Schedule II drug at least monthly; or • Include a written explanation of any difference between the physical count and the theoretical count. Monthly perpetual inventory is performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required.	18VAC110-20-240	Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 drugs not compliant.	250
16. Theft/unusual loss of drugs not reported to the Board as required	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant.	250
20a. Pharmacist not documenting verification of accuracy of non-sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355	10% threshold	500
20b. Pharmacist not documenting verification of accuracy of sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355		5000
21. No clean room	54.1-3410.2		10000
21a. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
21b. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better.	54.1-3410.2		500
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas	54.1-3410.2		2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		5000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
25a. No documentation of initial and semi-annual (6 months) media-fill testing or gloved fingertip testing for persons performing high-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the sixth month from the date the previous media-fill test and gloved fingertip testing was initiated.	5000
25b. High-risk compounded sterile preparations intended for use are improperly stored	54.1-3410.2		5000
25c. Documentation that a person who failed a media-fill test or gloved fingertip test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test	54.1-3410.2		5000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
26. No documentation of initial and annual (12 months) media-fill testing or gloved fingertip testing for persons performing low and medium-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved finger-tip testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test and gloved fingertip testing was initiated.	500
26a. Documentation that a person who failed a media-fill test or gloved fingertip test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test	54.1-3410.2		500
27. Compounding using ingredients in violation of 54.1-3410.2.	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50

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Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		First documented occurrence and no drug loss = no penalty Drug loss or repeat = $ penalty 500
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	18VAC110-20-555	Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C)	First documented occurrence and no known patient harm = no penalty Repeat = $ penalty 250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
34. Combined with Deficiency 142 – 12/2013.			
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	18VAC110-20-395		250

Other Deficiencies

If five (5) or more deficiencies in this category are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional deficiency cited in this category, over the initial five.

Deficiency	Law/Regulation Cite	Conditions
101. Repealed 6/2011		
102. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
103. Repealed 12/2013		
104. Sink with hot and cold running water not available within the prescription department.	18VAC110-20-150	
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
106. Prescription department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
107. Current dispensing reference not maintained	18VAC110-20-170	
108. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	

	Deficiency	Law/Regulation Cite	Conditions
109.	Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold
110.	Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
111.	Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	18VAC110-20-200	
112.	Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
113.	Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404, 54.1-3434 and 18VAC110-20-240	
114.	Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
115.	Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
116.	Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285 18VAC110-20-270	10% threshold
117.	Deficiency 117 combined with Deficiency 116 – 6/2011		
118.	Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3

Deficiency	Law/Regulation Cite	Conditions
119. Not properly documenting partial filling of prescriptions	54.1-3412, 18VAC110-20-255,18VAC110-20-310, and 18VAC110-20-320	
120. Offer to counsel not made as required	54.1-3319	
121. Prospective drug review not performed as required	54.1-3319	
122. Engaging in alternate delivery not in compliance	18VAC110-20-275	
123. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
124. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	18VAC110-20-340	
126. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions
127. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
128. Unit dose procedures or records not in compliance	18VAC110-20-420	
129. Robotic pharmacy systems not in compliance	18VAC110-20-425	

Deficiency	Law/Regulation Cite	Conditions
130. Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2	
130a Compounded products not properly labeled	54.1-3410.2	
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	54.1-3410.2	
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	54.1-3410.2	
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	54.1-3410.2	
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
135. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
136. After hours access to a supply of drugs or records not in compliance	18VAC110-20-450	10% threshold
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is

Deficiency	Law/Regulation Cite	Conditions
		taking to comply. Educate regarding requirements.
139. Emergency medical services procedures or records not in compliance	18VAC110-20-500	10% threshold
140. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
141. Maintaining floor stock in a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization	18VAC110-20-418	
143. Repealed 6/21/2018		
144. Repealed 6/21/2018		
145. Repealed 6/21/2018		
146. Repealed 6/21/2018		
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	

Deficiency	Law/Regulation Cite	Conditions
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy	54.1-3404 and 18VAC110-20-240	

NOTE: A "repeat" deficiency is a deficiency that was cited during the routine or focused inspection performed immediately prior to the current routine inspection and after July 1, 2018.

Examples:
Routine inspection on 7/1/18 – Cited for Deficiency 3. No monetary penalty.
Routine inspection on 7/1/20. Cited for Deficiency 3. Monetary penalty.

Routine inspection on 7/1/18 – Cited for deficiency 3. No monetary penalty.
Routine inspection on 7/1/20 – No deficiency.
Routine inspection on 7/1/22 – Cited for deficiency 3. No monetary penalty.
Routine inspection on 7/1/24 – Cited for deficiency 3. Monetary penalty.