

DRAFT/UNAPPROVED

**VIRGINIA BOARD OF PHARMACY  
MINUTES OF REGULATION COMMITTEE FOR DRUG DIVERSION AND  
RESPONSIBILITY OF PHARMACIST-IN-CHARGE TO PROVIDE ADEQUATE  
SAFEGUARDS**

November 25, 2013  
Second Floor  
Board Room 2

Perimeter Center  
9960 Mayland Drive  
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:05AM.

PRESIDING: Cynthia Warriner, Committee Chairman

MEMBERS PRESENT: R. Crady Adams  
Empsy Munden  
Dinny Li  
Rebecca Thornbury

STAFF PRESENT: Caroline D. Juran, Executive Director  
J. Samuel Johnson, Jr., Deputy Executive Director  
Elaine J. Yeatts, Senior Policy Analyst, DHP

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented. (motion by Munden, second by Li)

The committee discussed concerns regarding drug diversion and the responsibility of the pharmacist-in-charge (PIC) to provide adequate safeguards to protect the controlled substances. The committee reviewed the information in the agenda packet from the NABP Taskforce on the Control and Accountability of Prescription Medications and the various state regulations regarding PIC responsibilities. It was noted that certain state(s) require as a prerequisite to assuming the role of PIC the passing of a Board-approved test, completion of additional training, and a minimum number of years of practice.

**MOTION: The Committee voted unanimously to recommend to the full board for its consideration a requirement to list the name of the pharmacist-in-charge in the Findings of Fact for disciplinary cases involving drug diversion and to amend Guidance Document 110-27, as indicated in Attachment 1, by adding a new section regarding diversion, theft, and loss of controlled substances, including best practices for safeguarding against diversion. (motion by Thornbury, second by Adams)**

ADJOURN: With all business concluded, the meeting adjourned at 10:55AM.

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Cynthia Warriner, Committee Chairman

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Caroline D. Juran, Executive Director

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Date

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Date

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## Attachment 1

### Guidance Document 110-27

## Virginia Board of Pharmacy PIC Responsibilities

This document is intended to assist a new pharmacist-in-charge (PIC) as a reminder of some of the responsibilities, and some "do's" and "don'ts". It is not intended to be a comprehensive list of all responsibilities and is not intended to negate individual responsibility of any other pharmacist practicing at the location. **Pharmacists should not be fearful that, by merely being the PIC of a pharmacy, they will be the subject of Board action for circumstances which are beyond their control.**

### New Pharmacies:

- It is your responsibility to ensure that your pharmacy is ready to be inspected on the date assigned. At least 24 hours prior to a scheduled opening make sure that the pharmacy is ready, i.e. all enclosures to the prescription department are in place with appropriate locks on entrances, all counters and shelving are in place, hot and cold running water, refrigerator/freezer is working and at proper temperature with monitoring thermometer if drugs requiring storage at these temperatures plan to be stored, all minimum equipment is in place, and the alarm system is functional and fully protects the prescription department. Please note that Regulation 18 VAC 110-20-180 requires that the alarm device must be capable of detecting breaking by any means when activated, monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. The system must be approved prior to stocking drugs. On the opening inspection, the inspector will "walk test" the system to ensure that there are no areas within the prescription department uncovered by the alarm. For example, if an inspector can stand in a corner of a bay and move his arms without setting off the alarm, the alarm will not pass. In most cases, more than one sensor is necessary to provide complete coverage. The inspector will also want assurances of monitoring and the ability to alert the monitoring company if the alarm system is breached even when the communication line is cut. Although not required, some PICs find it very helpful to have an alarm technician present at the time of the inspection to answer any questions the inspector may have or to make any adjustments or additions necessary to bring the system into compliance which may negate the need for a reinspection.
- If the new pharmacy will not be ready, you or the owner should notify the inspector as soon as it is known to prevent the inspector from making an unnecessary trip. If the inspector is not notified and the pharmacy cannot reasonably be inspected, a \$150 reinspection fee will be assessed in order to schedule and conduct the reinspection.
- As PIC of a new pharmacy, you should be present at the opening inspection of the pharmacy. If you are not able to be present at the opening, you need to notify the Board prior to the date of the inspection with the reason why you are not able to be present. Additionally, you must ensure that another Virginia licensed pharmacist is present if you are absent. If deficiencies are noted on the opening inspection, drugs may not be stocked and the permit will not be issued until you assure the Board in writing that the deficiencies have been corrected and the Board gives approval.

- If any deficiencies are noted on the opening inspection, as the PIC, you must personally notify the Board of corrections made prior to a permit being issued. Therefore, you should personally inspect any corrections to be sure they have been made properly before contacting the Board.

#### Upon taking over responsibility as PIC:

- You are not a PIC until the Board approves your signed application. Make sure when you sign an application to be a PIC that you are not still on record with the Board as being a PIC for more than one other pharmacy. Once you are approved as PIC, the Board will issue a pharmacy permit in your name. This is your permit. It must be displayed where the public can read it. If you do not receive the permit within two weeks of sending in the application call the Board and check on the status (804)-367-4456. All pharmacy permits expire on 4/30 annually. Be sure that the permit is renewed each year.
- A PIC is required to be in "full and actual charge of the pharmacy" and "fully engaged in the practice of pharmacy at the location designated on the application". Never agree to sign a pharmacy permit application as PIC unless you intend to meet the requirement of being fully engaged in practice at that pharmacy. There is no minimum number of hours established to define "fully engaged etc."
- Take an incoming change of PIC inventory of all Schedule H—V II, III, IV, and V controlled substances, to include all expired drugs in Schedules II through V, on the date you first engage in business as the PIC. Sign and date the inventory and indicate whether the inventory was taken prior to the opening of business or after close of business that day. For a 24-hour pharmacy with no opening or closing of business, you must clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. If the pharmacy is a new pharmacy and you have no drugs on hand on opening date, you still "take" an inventory, and record a zero balance. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at [http://www.dhp.virginia.gov/pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm).
- Verify that every pharmacist working at your pharmacy holds a current license to practice pharmacy. Licensure can be verified by using the "license lookup" function on the Board's website at [www.dhp.virginia.gov/pharmacy](http://www.dhp.virginia.gov/pharmacy), calling the Board at (804) 367-4456, or if you know the license number or social security number of the individual, you may call (804) 270-6836 for automated verification.
- Verify via the methods listed in the previous item that every pharmacy technician working at your pharmacy holds a current registration, or that there is documentation on site showing enrollment in a Board approved training program for not more than 9 months.
- You are responsible for ensuring that the practice of pharmacy is in overall compliance with laws and regulations. You are not responsible for individual actions of practicing pharmacists. It is **strongly** recommended that you perform a routine self-inspection of the pharmacy using the most current pharmacy inspection report which may be downloaded from

[http://www.dhp.virginia.gov/Enforcement/enf\\_guidelines.htm](http://www.dhp.virginia.gov/Enforcement/enf_guidelines.htm). You should review pharmacy security equipment and procedures to ensure that they meet requirements, such as functional locks on enclosures, functional alarm systems, and access to keys and alarm restricted to pharmacists practicing at the location, including any emergency key kept in compliance with current regulations. Routinely check the refrigerator and freezer to ensure that there is a working thermometer placed within and that they are maintained at the required temperatures- between 36° and 46°F for refrigerators and between -4° and 14°F for freezers. Also review record keeping systems to make sure they meet current requirements and that staff pharmacists are aware of their responsibilities. Additionally, you should review the list of deficiencies that may result in a monetary penalty identified in guidance document 110-9 found at [http://www.dhp.virginia.gov/Pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm). You may choose to create a folder or notebook containing all required inventories, along with information indicating the location of all required documents for an inspector to review. This will ensure that all staff, even floater staff who may be on duty at the time of an unannounced inspection, know where to locate the required documents. Performing a self-inspection and staying organized will assist in identifying areas of non-compliance for which you should correct and will prevent the unnecessary citing of deficiencies.

- ~~• Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.~~
- Notify the Board of any known violation of law or regulation on the part of another individual in your pharmacy or of any inability to have known deficiencies corrected.

#### **Safeguards against Diversion of All Controlled Substances:**

- The PIC “shall provide safeguards against diversion of all controlled substances”. This responsibility should be taken very seriously. When an investigation involving the theft or loss of controlled substances is performed by the Board, the role of the PIC in providing safeguards against diversion is evaluated.
- The PIC shall ensure all security measures are in compliance and operational, e.g., locks to enclosures are functional, access to key and alarm code is restricted to pharmacists that practice at the location, emergency key and alarm code is securely stored;
- Ensure the biennial inventory of **all** drugs in Schedules II, III, IV, and V, to include any expired drugs in Schedules II-V, is performed on any date which is within two years of the previous biennial inventory. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at [http://www.dhp.virginia.gov/pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm)
- Ensure the pharmacy is in compliance each month with the perpetual inventory requirement of Schedule II drugs found in Regulation 18VAC110-20-240. Be sure to include **all** Schedule II drugs in the monthly perpetual inventory requirement, to include any drugs on-hand that were not dispensed during that month and any expired drugs. Additional guidance on performing the monthly perpetual inventory of Schedule II drugs may be found in Guidance Document 110-16 at [http://www.dhp.virginia.gov/pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm)

- Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.
- The Board also offers the following *suggested* best practices to safeguard against diversion of controlled substances:
  - Perform state and federal criminal background checks on all personnel with access to controlled substances;
  - Require periodic urine drug screening of all personnel with access to controlled substances;
  - Prohibit personal from bringing smocks or bags into the prescription department;
  - Prior to leaving the pharmacy, perform routine bag checks of all personnel with access to controlled substances;
  - Ensure all personnel with access to controlled substances are routinely made aware of policies and procedures to prevent, identify, and address internal and external theft, to include armed robberies, and loss of controlled substances;
  - In addition to the biennial inventory and perpetual inventory of Schedule II drugs, perform inventories, at least quarterly, of drugs at-risk for diversion and appropriately reconciling all discrepancies;
  - Do not delegate the management of drug inventory to solely one individual. Review the amount of drugs received and drugs dispensed to ensure no suspicious activity exists, and monitor any adjustments made to the ongoing inventory and any excessive ordering;
  - Install surveillance cameras to prevent and/or identify theft or loss of controlled substances;
  - In addition to the reporting requirements in §54.1-2400.6, notify the Board of any separation of employee for known or suspected drug diversion.

#### **Upon leaving as PIC:**

- Although not required by law or regulation, you have the right to take an outgoing change of pharmacist-in-charge inventory of all Schedule II-V controlled substances unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed. If you so take one, you should take a **copy** with you. Once you leave, you cannot ensure that the pharmacy will maintain it, and this inventory is your documentation of what drugs were on hand when you left if there is a subsequent diversion. If you request but are denied an opportunity to take this inventory, you should immediately report this to the Board.
- As you terminate your position as PIC, remove the pharmacy permit and return it directly to the Board office indicating the effective date of the termination of the PIC position. Do not leave it on the wall. Do not return it to a corporate or district office or a district manager. It is your permit and your responsibility to return it to the Board immediately. For your protection, we would suggest that you return it by certified mail, return receipt requested.