COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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Tentative Agenda of Regulation Committee Meeting

May 10, 2017

10AM

TOPIC	PAGES
Call to Order: Ryan Logan, Committee Chairman	
• Welcome & Introductions	
• Approval of Agenda	
Call for Public Comment	
Agenda Items	
• Continue Periodic Regulatory Review by Developing Draft Amendments to Chapter 20 *Regulations Governing the Practice of Pharmacy* Parts VI - VIII, X - XII and Chapter 50 *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers* Parts I-II	1-6 A-E 7-37
• Legislative Proposal for Dispensing of Schedule V Drugs to be Reported to the Prescription Monitoring Program	38-40
Adjourn	

****The Committee will have a working lunch at approximately 12pm. A quorum of the board will convene at 1pm for consideration of a possible summary suspension and a formal hearing. ****

Continue Periodic Regulatory Review by Developing Draft Amendments to Chapter 20 *Regulations Governing the Practice of Pharmacy* Parts VI-VIII, X-XII and Chapter 50 *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers* Parts I-II

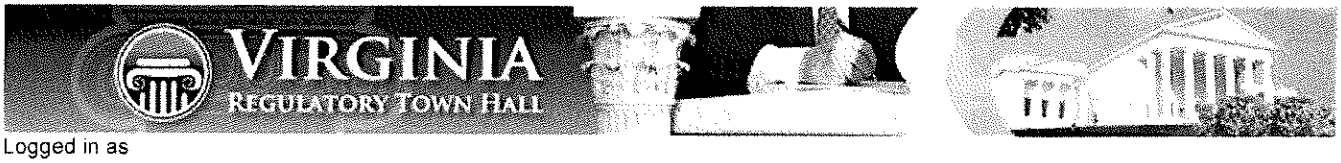
In agenda packet:

- Comments received on NOIRA during open comment period ending 8/10/2016
- Regulations identified in NOIRA that potentially need amending
- Suggested draft amendments

Committee action:

- Motion to recommend regulatory amendments as presented or amended to full board for adoption in June

Virginia.gov Agencies | Governor



Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Action	**Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25**
Stage	**NOIRA**
Comment Period	Ends 8/10/2016

All good comments for this forum **Show Only Flagged**

Back to List of Comments

Commenter: Dale StClair, PharmD (Remedi SeniorCare) 8/9/16 4:12 pm

NOIRA 18VAC110-20-240

This comment is being made in regards to the Notice of Intended Regulatory Action posted regarding changes to VAC 18VAC110-20-10 et seq. Specifically as outlined, the proposed update to 18VAC110-20-240 "Clarifying in subsection C that chart orders used in long term care facilities must include a quantity or duration of treatment." Currently Virginia regulations do not specifically require a quantity on any prescription regardless of it being considered a "Chart Order". The Board has already addressed this issue in Guidance Document 110-35 "While Virginia law does not specifically require that quantity be included on a prescription, written prescriptions must include some direction related to quantity to be dispensed, or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration. Federal regulations require that quantity be indicated on prescriptions for Schedule II-V controlled substances." Therefore, Remedi SeniorCare does not feel the proposed changes referenced above are necessary.

Commenter: Travain Sutphin, Pharm.D. 8/10/16 1:19 pm

NOIRA 18VAC110-20-240

This comment is being made regarding changes to 18VAC110-20-240 subsection C clarifying that chart order used in long term care facilities must include a quantity or duration of therapy. As a general rule, the current pharmacy practice for the skilled nursing setting uses chart orders in the form of 1) admission order/MD Plan of Care, or 2) individual chart orders (verbal orders). Most often the nurse contacts the Physician verbally to receive admission orders.

When the pharmacy dispenses the medications, the qty is generally driven by the payor source; shortened days supply for Medicare Part A Skilled residents and a full month supply for Medicare Part D or third party payer residents. Continual clinical oversight for medications is routinely occuring in the skilled facility settings. The skilled facility resident has licensed nursees monitoring

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the patients and there is a Consultant RPh reviewing medications monthly. The Physician also performs routine reviews through the recertification process (which could be monthly, every 3 or every 6 months) which are sent to the pharmacy with the physician signature once he has completed the review. The medication order is considered an active order until the pharmacy receives an order to modify or discontinue the order, or the patient is discharged from the LTC setting.

If this revision is adopted, admission orders received in the pharmacy without a qty or duration stipulated, will result in a delay of processing the medications until the requirements are met. The same would be true for ongoing orders or if new or changed orders were sent to the pharmcy without requirements. This has the potential to significantly delay therapy to residents, whom may have just been discharged from the hospital. This not only has the potential for significant harm to the patients, but it also has implications for the facility in regards to Federal CMS regulations specifically the following Federal Tags: F425 (Medication Availability is a recurring issues), F332 (Charting omissions/Med Errors per documetation/audit). This may also effect the CMS reimbursement and Five-Star Quality program ratings for the facility.

I would request that the board continue to allow Long Term Care pharmacies the use of chart orders without the requirement of quantity or duration of therapy, like hospitals and hospice programs, whom we are currently not facing this change. If you have any additional questions, please do not hesitate to contact me.

Commenter: Steve Ford, VHCA 8/10/16 4:04 pm

Comment on NOIRA

Please accept these comments to the NOIRA stage for the periodic review of pharmacy regulations on behalf of the Virginia Health Care Association-Virginia Center for Assisted Living (VHCA-VCAL), our members' 30,000 employees, and the 29,000 residents served in our over 280 nursing centers and assisted living facilities. VHCA-VCAL is proud of our role as the Commonwealth's largest association representing long term care. Our strength, effectiveness, and integrity are significantly enhanced by the diversity of our membership, which includes proprietary, non-profit, and government-operated facilities dedicated to providing the highest quality of care.

As this is only a NOIRA, it is difficult to interpret precisely what the Board intends to change. However, VHCA-VCAL wants to express our general concern that any changes made to 18VAC110-20-240 do not diminish the fact that chart orders remain a valid prescribing method and that regulatory changes do not obstruct the availability/timeliness of medications nor staff resources for direct clinical care of nursing facility residents and patients. As you are aware, regulations already require periodic order review for nursing facility residents which reconfirm any continued need for medication(s).

Thank you for the opportunity to comment. Please direct any questions to Steve Ford, SVP, Policy and Reimbursement, at steve.ford@vhca.org or (804) 212-1695.

Commenter: H. Otto Wachsmann 8/10/16 4:52 pm

Comments on background document on upcoming proposals Board of Pharmacy

To: Members and staff of the Virginia Board of Pharmacy

From: H. Otto Wachsmann, Jr

Subject: Comment period for proposed regulatory changes.

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Date: August 10, 2016

At this time I would like to express some concerns with the background document I received as a member of the Virginia Pharmacists Association. I regret my comments are at the very end of the comment period however my scheduled vacation and an inability to discuss with the document further with VPhA as their telephone lines were impacted by a storm, I am just now able to provide some hastily prepared thoughts on the document.

In reading the document, I find it is difficult to respond. While it provides subject material under consideration, it is difficult for me to have a full understanding on which direction many of these proposals are going.

An area that I initially agreed with was siting the CDC vaccine storage recommendations as the new guidelines for pharmacy refrigerators. I have googled CDC Vaccine Storage and discovered a CDC web page which provided various discussions on the subject but wasn't necessarily clear. For example, it discussed how dorm refrigeration units were less than ideal, but didn't exclude their use except for the freezer compartment. It discussed advantages and disadvantages of traditional household refrigerators vs especially made units but didn't necessarily exclude either one. When discussing certified recording thermometers I wasn't certain if there was a specific certification. In attempting to conduct an internet search for these devices, I saw prices ranging from $800.00 to $1800.00 for the thermometer. I am aware of one doctor's office that recent purchased a specialty refrigeration that cost thousands of dollars. I question with today's reimbursements how a small business such as a family owned pharmacy might be able to purchase something of this magnitude without adequate notice. It is also possible that I may have read a CDC recommendation/guideline page that was different than what the Board of Pharmacy is referencing. I also question the validity of using vaccine storage requirements and how they may or may not relate to a pharmacy such as mine that does not store vaccines. Then there is the question if we would need to have a complaint freezer if we do not stock zostavax?

In reading the section on the physical barrier for the pharmacy department and the front door, I am hopeful this will not require a complete barrier for the pharmacy floor to ceiling in the event the pharmacy department which is already secured and separately alarmed is only open when the rest of the building is open. The cost associated with constructing these barriers will be burdensome for family owned pharmacies. I anticipate this remodel will also require the pharmacy to pay for a re-inspection which further creates a financial burden.

Regarding the landline security system. This appears to be going backwards from the Board of Pharmacy requiring cell phone systems. I wonder how may alarm companies deactivated the old hard line phone system when pharmacies were required to install cell phone systems a few years ago. For pharmacies that fall into this category, this will require these small businesses to pay to have the alarm companies come back into the pharmacy to reattach the landline. I expect since this would be a change to the security system, will this not also require the pharmacy owner to have the pharmacy department re-inspected at an additional fee which may well be two inspections and two fees for those who will not be able to coordinate the alarm company at the same time period as the contractor installing the security barrier. Has the Board of Pharmacy seen a substantial number of cases where these items were an issue? My experience has been the existing alarm systems work effectively but the police response times cannot keep up with the professional burglars committing the crimes. Making it too difficult to gain access to a pharmacy after hours is also likely to create a more dangerous situation where the criminals increase the amount of armed robberies occur. This will results in pharmacy staff and our patients being placed in harms way.

I do not wish to complain about areas in which the Board of Pharmacy promotes to increase patient safety. That is certainly an important and complex task. I only wish to provide the perspective of a practicing community pharmacist of some unintended consequences that some of these areas may create. If I might suggest, it may be helpful to provide some discussion in the

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Board's quarterly newletter for additional thoughts and suggestions while providing a better understanding of the issues for practicing pharmacists. It's quickly becoming quite impossible to keep up with all the state/federal/PBM requirement changes that are going which practitioners are forced to keep up with. Add to that we are doing these at our expense in a market where stores are closing due to reimbursement issues. There is less and less time/resources left to actually take care of the patient.

Thanks

Otto Wachsmann

Commenter: Bill Irvin, CVS Health 8/10/16 5:39 pm

NOIRA 18VAC110-20 Regulations Governing the Practice of Pharmacy

CVS Health appreciates the opportunity to submit comments regarding the proposed Notice of Intended Regulatory Action (NIORA) regarding 18VAC110-20, Regulations Governing the Practice of Pharmacy. The goal of this communication is to provide the Board of Pharmacy (the "Board") with additional information regarding 18VAC110-20-240 and 18VAC110-20-280 for consideration and incorporation into the final proposal.

Comments:

18VAC110-20-240(C), Manner of maintaining records, prescriptions, inventory records. The Board proposes to add language to clarify subsection (C) that chart orders used in long term care facilities must include a quantity or duration of treatment.

CVS Health recommends the proposed change to 18VAC110-20-240(C) be removed from the proposal to afford the pharmacist the opportunity to continue leveraging good professional judgment as well as the guidance noted in 110-35. Pursuant to the Virginia Board of Pharmacy Guidance Documents 110-35, a chart order should contain directions for use as it relates to the quantity to be dispensed or authorized duration of therapy that the pharmacist can reference in calculating the quantity of medication to be dispensed to the patient. CVS Health believes that this guidance coupled with professional judgment provides pharmacists the best opportunity to serve the elderly population residing in long-term care facilities.

18VAC110-20-280(A)(4)(C), Transmission of a prescription order by facsimile machine. The Board is considering whether there is value in the allowance for residents of long term care facilities and provider pharmacies or if it should be removed.

CVS Health strongly opposes any consideration which would remove the ability for practitioners' authorized agents to transmit a written prescription from a long-term care facility to a pharmacy provider. Transmission of prescription information by a practitioner's authorized agent is a long-standing and commonly accepted pharmacy practice and legal principle recognized by the healthcare industry.

The current rule language in 18VAC110-20-280(A)(4)(C) is critical for long-term care facilities to successfully transmit chart orders to provider pharmacies and promotes the most expeditious dispensing and medication delivery model for the facility. The majority of long term care facilities in the state of Virginia still primarily rely on facsimile because more advanced technological solutions may be unattainable due to cost, available resources, IT integration challenges, or other operational barriers. Placing further restriction on the manner in which long term care facilities transmit prescription medication orders will create a significant burden on long term care facility providers, practitioners, and pharmacies. Removal of the facsimile transmission process by practitioners' authorized agents in the long-term care facility may lead to unintended consequences such as delays in processing chart orders, delays in medication administration, and

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jeopardize timely initiation of drug therapy.

As a leader in the long term care pharmacy industry and an advocate for increased patient access to prescription medication, CVS Health recommends the Board reconsider the proposal to 18VAC110-20-280(C) and allow the current language to remain as written.

In closing, CVS Health appreciates the opportunity to provide these comments to the Board of Pharmacy for their review and consideration regarding this proposal and look forward to a favorable outcome for the patients of the Commonwealth of Virginia.

Sincerely,

Bill Irvin, R.Ph.

Director, Pharmacy Regulatory Affairs

CVS Health

13 Commerce Avenue

Londonderry, NH 03053

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Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

As part of the periodic review, the Board has determined that provisions in Chapter 20 relating to the licensure of pharmacists and registration of pharmacy technicians should be re-promulgated into a separate chapter, Chapter 25, to reduce the size and complexity of this chapter. Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated. Additionally, section 15, *Criteria for delegation of informal fact-finding proceedings to an agency subordinate,* will be moved into a separate chapter, Chapter 16, because it applies to all types of licensees, registrants, and permit holders regulated by the board.

Amendments to the following sections of Chapter 20 (or the new chapter 25) will be considered in the promulgation of proposed regulations:

PART I. General Provisions.

18VAC110-20-10. Definitions

- Modifying definition for "robotic pharmacy system."

18VAC110-20-20 Fees

- Changing the renewal for pharmacist licenses and pharmacy technician registrations to a date different from December 31st, but retain the facility renewal dates for facilities. (Note: a change in renewals for pharmacists and pharmacy technicians necessitates amendments of 18VAC110-20-80 A and B and 18VAC110-20-105.)

18VAC110-20-21 Public address

- Adding requirement for notification to the board if there is a name change and specify documentation that must be submitted. Consider a specific timeframe for notification.

18VAC110-20-25 Unprofessional conduct

- Adding failure to submit corrective action related to inspection deficiency within a specified time frame.
- Adding dispensing any controlled substance with the intent or knowledge that it will be used otherwise than medicinally, for accepted therapeutic purposes, or with the intent to evade any law with respect to the sale or use of such drug.

PART II. Licensure Requirements for Pharmacists.

18VAC110-20-60 Content of the examination and grades required; limitation on admittance to examination

- Specifying a timeframe for validity of law exam score to 2 years, consistent with requirements for record retention.

18VAC110-20-80 Renewal and reinstatement of license

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- Specifying acceptable refrigeration facilities based on Center for Disease Control guidance for vaccine storage, require calibrated thermometer, weekly temperature logs or documentation; exemption of sink requirement if pharmacy does not stock prescription drugs.

18VAC110-20-180 Security system

- Requiring security system to have at least one hard wired communication method for transmitting breaches is required for wholesale distributors.
- Clarifying that monitoring entity shall notify PIC or pharmacist practicing at the pharmacy; simply notifying non-pharmacist manager is insufficient.

18VAC110-20-190

- Amending physical requirements for a prescription department's enclosure.
- Amending requirement for locking of enclosure if front door to pharmacy is locked and the entire pharmacy is covered by the security system.

18VAC110-20-200 Storage of drugs, devices, and controlled paraphernalia; expired drugs

- Adding language from Guidance Document 110-40 regarding dispensation of Schedule II drugs.

PART VI. Drug Inventory and Records.

18VAC110-20-240 Manner of maintaining records, prescriptions, inventory records

- Adding language in subsection A from Guidance Document 110-16 regarding clarifications for performing inventories.
- Deleting language in subsection B regarding the red "C" unless this is based on federal rules.
- Clarifying in subsection C that chart orders used in long term care facilities must include a quantity or duration of treatment.

PART VII. Prescription Order and Dispensing Standards.

18VAC110-20-270 Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians

- Separating subsections A and B from the rest of the regulation.
- Addressing concern in subsection B by the Virginia Pharmacist Association with pharmacists not being provided adequate pharmacy technician support.
- Reviewing appropriateness of requiring pharmacists to not return a forged prescription.
- Regarding subsection F and on-hold prescriptions, revising requirement for pharmacy to pull the originally filed prescription and refile it.
- Adding language from Guidance Document 110-32 regarding use of drop boxes into a new subsection G, but the last sentence regarding a prohibition for patients to leave containers which contain drug or drugs should be reworded to regulate pharmacists, not the consumer.

18VAC110-20-275 Delivery of dispensed prescriptions

- Addressing concerns with white bagging and brown bagging.

B

- Revising section 275 for more clarity.

18VAC110-20-277 Prescription Requirements

- Adding new regulation in section 277 to clarify that prescriptions, unless electronically transmitted, must include manual signature and that all prescriptions must include a quantity or duration of treatment.

18VAC110-20-280 Transmission of a prescription order by facsimile machine

- Clarifying that a requirement for a signature to be manual for written prescriptions unless electronically transmitted is unnecessary if proposed 18VAC110-20-277 is adopted.
- Considering whether there is value in the allowance in 18VAC110-20-280 A, 4, C for residents of long term care facilities and provider pharmacies or if it should be removed.

18VAC110-20-290 Dispensing of Schedule II drugs

Adding language from Guidance Document 110-41 regarding allowable changes to a Schedule II.

PART VIII. Labeling and Packaging Standards for Prescriptions.

18VAC110-20-355 Pharmacy repackaging of drug; records required; labeling requirements

Amending requirement for how to identity pharmacist verifying accuracy of the process.

PART X. Unit Dose Dispensing Systems.

18VAC110-20-425 Robotic Pharmacy Systems

- Streamlining robotic pharmacy system regulations by striking #5 and simplifying #4.
- Strengthening requirements for pharmacist accountability in assigning bar codes.

Part XI Pharmacy Services to Hospitals

18VAC110-20-470 Emergency room

In #2, consider changing "practitioner" to "prescriber"

18VAC110-20-490 Automated devices for dispensing and administration of drugs

- Streamlining requirements for automated dispensing devices in hospitals.
- Clarifying that drug for emergency use may include drugs for first doses.
- Clarifying drugs stored in automated dispensing device for emergency purposes not restricted to quantities for emergency boxes.

Part XII Pharmacy Services to Long-Term Care Facilities

18VAC110-20-530 Pharmacy's responsibility to long-term care facilities

Allowing a pharmacy providing services to a long-term care facility to provide prescription information of Schedule VI drugs to a "back-up" pharmacy without constituting the transfer of a prescription. In addition to section 530, the Board will also consider amending section 515 on

C

Remote prescription order processing for hospitals and long-term care facilities and section 360 on Issuing a copy of a prescription that can be filed or refilled to address this same issue..

18VAC110-20-550 Stat-drug box

- Clarifying in 5, b whether one unit of liquid is allowable in each drug schedule.
- Clarifying that a facility may possess multiple stat drug boxes and that contents do not have to be uniform between boxes.

18VAC110-20-555 Use of automated dispensing devices

Considering whether requirements in 18VAC110-20-490 and 18VAC110-20-555 should be similar.

PART XIII Other Institutions and Facilities

18VAC110-20-580 Humane societies and animal shelters

- Amending regulation based on recent amendments to §54.1-3423; changing term for humane societies to public or private animal shelters.

PART XV Medical Equipment Suppliers (MES)

18VAC110-20-630 Issuance of a permit as a medical equipment supplier

- Adding requirement that applications must include name of responsible party
- Requiring MES to notify the Board within 14 days of a change in the responsible party

18VAC110-20-680 Medical equipment suppliers

- Adding language from Guidance Document 110-19 for MES to transfer prescriptions.
- Adding requirement to provide Board with hours of operation and notification to board and public when hours change.

PART XVI Controlled Substance Registration for Other Persons or Entities

18VAC110-20-710 Requirements for storage and security for controlled substance registrants

- Amending schedules to include Schedule I

The Board considered whether there is a better method for identifying the responsible pharmacist as initials are required 23 times throughout regulations of the Board. It is likely the Board review all regulations that require a pharmacist's initials to determine if there is a better method for identifying the responsible pharmacist.

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

Part I General Provisions

18VAC110-50-40 Safeguards against diversion of drugs

- Amending B, 2 that communication line must be hardwired, but sensors may be wireless.

- Amending B, 3 to require the security system to be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operable.

Part II Wholesale Distributors

18VAC110-50-60 Special or limited-use licenses

- Expanding ability to issue limited use for other entities such as third party logistic providers if law passed during 2016 General Assembly session to create this licensing category.

18VAC110-50-70 Minimum required information

- Placing information from Guidance Document 110-34 regarding submission of social security number or control number into regulation.

18VAC110-50-80 Minimum qualifications, eligibility, and responsible party

- Requiring federal criminal history record check, not simply the Virginia Central Criminal Records Exchange since Virginia database would likely not have information on responsible parties for nonresident wholesale distributors.

For consistency, the Board will consider requirements similar to those in sections 70 through 140 for manufacturers.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The Regulation Committee of the Board of Pharmacy conducted a thorough review of regulations and recommended a number of amendments. Each section was discussed for clarity and the need to amend to address any issues or inconsistencies with its provisions. Staff of the Board also brought recommendations for amendments. In some cases, the Committee did not recommend amendments but identified the need for additional research and review.

For example, in section 50, the Committee considered striking subsection B to eliminate language for "first" professional degree; staff was asked to do further research on implications of this recommendation. At a subsequent meeting, staff recommended that reference to a "first" professional degree should remain; curricular elements of a non-traditional PharmD program are not identical to that of traditional programs; many schools of non-traditional PharmD programs rely on state licensure, but licensure requirements vary among the states.

The Committee also discussed amendments to regulation (such as the ability to carry over hours of continuing education) but concluded that a statutory change would be necessary. The Committee attempted to identify every regulatory section that should be included in the NOIRA document in order to solicit public comment on any intended regulatory change.

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Periodic Review – Suggested Draft Amendments for Chapter 20 Parts VI - VIII, X - XII and Chapter 50 Parts I -II

Extra notes:

Strike fees for humane society permits.

18VAC110-20-10. Definitions.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

18VAC110-20-50. Curriculum and approved schools of pharmacy.

A. The following minimum educational requirements for the specified periods shall be recognized by the board for the purpose of licensure.

1. On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy awarded.

2. On and after June 1, 1964, the applicant for licensure shall have been graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded.

B. In order to be licensed as a pharmacist within this Commonwealth, the applicant shall have been granted the first professional degree from a program of a school of pharmacy which meets the requirements of §54.1-3312 of the Code of Virginia.

18VAC110-20-112. Supervision of pharmacy technicians.

A. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time.

B. In addition to the acts restricted to a pharmacist in §54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

Part VI. Drug Inventory and Records

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

A. Each pharmacy shall perform and maintain the inventories and records of drugs as follows:

1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. Inventories of drugs in Schedules I and II shall be performed by physically counting the drugs. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed which accurately indicates the physical count of each Schedule II drug "on-hand" at the time of performing the inventory. The perpetual inventory shall include a ~~with~~ reconciliation of each Schedule II drug at least monthly with a written explanation for any difference between the physical count and the theoretical count. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

2. Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy. Inventories of drugs in Schedules III-V may be performed by estimating drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules or there has been a theft or any other unusual loss of drug and the exact kind and quantity of the drug loss is unknown.

3. All executed order forms, prescriptions, and inventories of Schedule II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to Schedule II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

4. All inventories required by § 54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

5. Invoices or other records showing receipts of Schedule VI drugs shall be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

6. All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

B. Prescriptions.

1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing or by date of initial entry into the automated data processing system in compliance with 18VAC110-20-250 if such a system is employed by the pharmacy.

2. Schedule II drugs. Prescriptions for Schedule II drugs shall be maintained in a separate prescription file.

3. Schedule III through V drugs. Prescriptions for Schedule III through V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one-inch high and filed in the prescription file for drugs listed in the usual consecutively numbered prescription file for Schedule VI drugs. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

C. Chart orders.

1. A chart order written for a patient in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to §54.1-3408.01 A of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:

a. This information is contained in other readily retrievable records of the pharmacy; and

b. The pharmacy maintains a current policy and procedure manual that sets out where this information is maintained and how to retrieve it and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.

2. A chart order may serve as the hard-copy prescription for those patients listed in subdivision 1 of this subsection.

3. Requirements for filing of chart orders.

a. Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.

b. If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor stocked, but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.

Part VII. Prescription Order and Dispensing Standards

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; ~~supervision of pharmacy technicians.~~

A. ~~In addition to the acts restricted to a pharmacist in §54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.~~

~~B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time.~~

In addition to the requirements in §54.1-3408.01 of the Code of Virginia for an oral prescription or written prescription, including those transmitted via facsimile or electronically, a prescription shall include a quantity, or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use. Except for prescriptions transmitted electronically in compliance with 18VAC110-20-285, written prescriptions shall also include the prescriber's manual signature.

~~C.~~B. After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which he is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years, unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.

~~D.~~C. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

~~E.~~D. If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist shall not return the forged prescription to the person presenting it. The forged prescription may

be given to a law-enforcement official investigating the forgery; or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigative or other legitimate purpose.

~~F.~~E. An on-hold prescription shall be entered into the automated data processing system, if such system is employed by the pharmacy, and the pharmacist on-duty shall verify the accuracy of the data entry at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date shall, at a minimum, conduct a prospective drug review consistent with § 54.1-3319 A of the Drug Control Act. If an on-hold prescription is returned to a patient prior to the initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system.

F. A pharmacy may utilize a drop box for the collection of written prescriptions and refill requests. The drop box shall be located in a visible area within the permitted facility and shall be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. Containers left in a drop box for refill shall not contain unused drugs.

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. The procedure for assuring confidentiality of patient information; and

e. The procedure for informing the patient and obtaining consent for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

18VAC110-20-280. Transmission of a prescription order by facsimile machine.

A. Unless otherwise prohibited by federal law, prescription orders for Schedule III through VI drugs may be transmitted to pharmacies by facsimile device (FAX) upon the following conditions:

1. The prescription shall be faxed only to the pharmacy of the patient's choice.

2. A valid faxed prescription shall contain all required information for a prescription.

3. An authorized agent, as defined in §54.1-3408.01 C of the Code of Virginia, may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription.

4. A faxed prescription shall be valid only if faxed from the prescriber's practice location, except in the following situations:

a. Forwarding a faxed chart order from a long-term care facility or from a hospice, including a home hospice;

b. Faxing an oral prescription by authorized agent under the conditions set forth in subdivision 3 of this subsection; or

c. Forwarding a written prescription by an authorized agent from a long-term care facility, provided the provider pharmacy maintains written procedures for such transactions, and provided the original prescription is obtained by the provider pharmacy within seven days of dispensing. The original prescription shall be attached to the faxed copy.

5. The following additional information shall be recorded on the faxed prescription:

a. The date that the prescription was faxed;

b. The printed name, address, phone number, and fax number of the authorized prescriber; and

c. The institution, if applicable, from which the prescription was faxed, including address, phone number and fax number.

B. Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for orders to be administered to long-term care facility and home infusion patients in accordance with §54.1-3408.01 B of the Code of Virginia and except for prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state, which may include home hospice. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's manual signature.

C. If the faxed prescription is of such quality that the print will fade and not remain legible for the required retention period the receiving pharmacist shall copy or transcribe the faxed prescription on paper of permanent quality.

D. Authorizations for refills may be faxed by the prescriber to the pharmacy provided the authorization includes patient name, address, drug name and strength, quantity, directions for use, prescriber's name, prescriber's manual signature or agent's name, and date of authorization.

18VAC110-20-290. Dispensing of Schedule II drugs.

A. A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than six months after the date on which the prescription was issued.

B. A prescription for a Schedule II drug shall not be refilled except as authorized under the conditions for partial dispensing as set forth in 18VAC110-20-310.

C. In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner;

3. If the pharmacist does not know the practitioner, he shall make a reasonable effort to determine that the oral authorization came from a practitioner using his phone number as listed in the telephone directory or other good-faith efforts to ensure his identity; and

4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 54.1-3410 of the Drug Control Act, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person, by mail postmarked within the seven-day period, or transmitted as an electronic prescription in accordance with federal law and regulation to include annotation of the electronic prescription with the original authorization and date of the oral order. Upon receipt, the dispensing pharmacist shall attach the paper prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to him. Failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing practitioner.

D. When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist is never permitted to make changes to the controlled substance prescribed, except for dispensing therapeutically equivalent drugs as permitted by law, or the prescriber's signature.

Part VIII. Labeling and Packaging Standards for Prescriptions

18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.

A. Pharmacies in which bulk reconstitution of injectable, bulk compounding or the repackaging or prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the drug(s) used; strength, if any; date repackaged; quantity prepared; initials or other form of identification of the pharmacist verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

B. The drug name; strength, if any; the assigned lot or control number or the manufacturer's or distributor's name and lot or control number; and an appropriate expiration determined by the pharmacist in accordance with USP guidelines shall appear on any subsequently repackaged or reconstituted units.

C. Repacking of drugs shall be performed in compliance with USP-NF standards.

C. Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:

1. A bin filling record shall be maintained, manually or in a computerized record for a period of one year from the date of filling from which information can be readily retrieved, for each bin including:

a. The drug name and strength, if any;

b. The name of the manufacturer or distributor;

c. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling;

d. Any assigned lot number;

e. An expiration date determined according to USP guidelines for repackaging;

f. The date of filling; and

g. The pharmacist's initials verifying the accuracy of the process.

2. If more than one lot is added to a bin at the same time, the lot which expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines.

3. Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.

4. If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed and the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot.

5. In the event of a drug recall involving one of multiple lots placed in a bin of an automated counting device in the last three months or if a recalled drug is known to remain in the bin, all drugs shall be removed from the bin and not used for patient care. The removal of drugs from the bin is not required if:

a. The technology of the automated counting device can ensure drugs in a particular lot have been cleared; or

b. The bin has been "run dry," with a record made of the "run dry" date, since the addition of the recalled lot number in which all drugs were completely removed prior to filling with a subsequent lot number.

6. An automated counting device shall be cleaned and maintained in accordance with recommended manufacturer guidelines and specifications.

D. A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to § 54.1-3411.1 A 3 of the Code of Virginia under the following conditions:

1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.

2. The restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210.

3. If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.

Part X. Unit Dose Dispensing Systems

18VAC110-20-425. Robotic pharmacy systems.

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 bar-coded 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 or otherwise identify himself on

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 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 bar codes;

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. Appropriately investigating, identifying and correcting sources of discrepancies or errors associated with the robotic pharmacy system; and

h. Maintaining quality assurance reports.

~~5. Pharmacists shall perform a daily random check of medications or compliance packaging picked by the robot for 5.0% of all patients' bins and 5.0% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.~~

6. All manual picks shall be checked by pharmacists.

7. If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all doses or compliance packages and shall immediately report the error to the board. The 100% check procedure shall continue until such time as the pharmacy provides documentation to the board showing that the cause of the error has been determined and addressed and that the robot is no longer making errors, and the board allows the pharmacy to return to a reduction in checking.

8. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include:

a. A summary indicating the date and description of all discrepancies that include but are not limited to 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.

b. The total number of doses packaged or compliance packages prepared for the robotic pharmacy system and total number of doses or compliance packages picked by the robot during the quarter.

c. The total number of doses or compliance packages picked by the robot that were checked in conducting the 5.0% checks.

d. Dates and time associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution.

9. All unanticipated downtime shall be immediately reported to the board.

10. 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.

Part XI. Pharmacy Services to Hospitals

18VAC110-20-470. Emergency room.

All drugs in the emergency department shall be under the control and supervision of the PIC and shall be subject to the following additional requirements:

1. All drugs kept in the emergency room shall be in a secure place from which unauthorized personnel and the general public are excluded.

2. Oral orders for medications shall be reduced to writing and shall be signed by the ~~practitioner~~ prescriber.

3. A medical practitioner may dispense drugs to his patients if in a bona fide medical emergency or when pharmaceutical services are not readily available and if permitted to do so by the hospital; the drug container and the labeling shall comply with the requirements of this chapter and the Drug Control Act.

4. A record shall be maintained of all drugs administered in the emergency room.

5. A separate record shall be maintained on all drugs, including drug samples, dispensed in the emergency room. The records shall be maintained for a period of two years showing:

a. Date and time dispensed;

b. Patient's name;

c. Prescriber's name;

d. Name of drug dispensed, strength, dosage form, quantity dispensed, and dose.

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A. A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable.

B. Policy and procedure manual; access codes.

1. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

2. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

C. Distribution of drugs from the pharmacy.

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution of drugs from the device.

1. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue.

2. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

E. Discrepancy reports.

A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

F. Reviews and audits.

1. The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures which are consistent with subsection A of § 54.1-3434.02 for security and use of the automated dispensing devices, to include procedures for timely termination of access codes, when applicable, and proper recordkeeping.

2. The PIC or his designee shall conduct at least a monthly audit to review distribution of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedule II-V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

3. The PIC or his designee shall conduct at least a monthly audit to review administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall include a review of administration records from each device per month for possible diversion by fraudulent charting. The review shall include all Schedule II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

b. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software which provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

(1) Peer-to-peer comparisons of use for that unit or department; and

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity which includes, but is not limited to, usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

4. The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

G. Inspections.

Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

a. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

b. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

c. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and

d. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

H. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

2. Distribution and delivery records and required initials may be generated or maintained electronically provided:

a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

b. The records are maintained in a read-only format that cannot be altered after the information is recorded.

c. The system used is capable of producing a hard-copy printout of the records upon request.

3. Schedule II through V distribution and delivery records may also be stored offsite or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

Part XII. Pharmacy Services to Long-Term Care Facilities

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

A. The pharmacy serving a long-term care facility shall:

1. Receive a valid order prior to the dispensing of any drug.

2. Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.

3. Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.

4. Ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.

5. Ensure that the storage area for patients' drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.

6. Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.

7. Provide for the disposition of discontinued drugs under the following conditions:

a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by §54.1-3411.1 and 18VAC110-20-400, or disposed of by appropriate means in compliance with 18VAC110-20-210 and any applicable local, state, and federal laws and regulations.

b. Drug destruction at the pharmacy shall be witnessed by the PIC and by another pharmacy employee. The pharmacy may transfer the drugs for destruction to an entity appropriately licensed to accept returns for destruction. Drug destruction at the facility shall be witnessed by the director of nursing or, if there is no director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.

c. A complete and accurate record of the drugs returned or destroyed or both shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

d. Long term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy within 30 days of the date the drug was discontinued.

8. Ensure that appropriate drug reference materials are available in the facility units.

9. Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title 63.2 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

B. The pharmacy providing services to the long term care facility may share a copy of a Schedule VI prescription or order with another pharmacy for the purpose of dispensing an immediate supply of drug, not to exceed a 7-day supply, without transferring the prescription pursuant to 18VAC110-20-360 if the following conditions are satisfied:

1. The pharmacy providing services to the long term care facility has a written contract with the other pharmacy outlining services to be provided and the responsibilities of each pharmacy; and,

2. The pharmacy providing services to the long term care facility provides a valid oral or written prescription or order to the other pharmacy.

18VAC110-20-550. Stat-drug box.

A. An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug

box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box shall be subject to the following conditions:

1. The box is sealed in such a manner that will preclude the loss of drugs.

a. The dispensing pharmacy must have a method of sealing such boxes so 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 and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

2. The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, the time and the name and quantity of item(s) removed. When the stat-drug box has been opened, it is returned to the pharmacy.

3. There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.

4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.

5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.

a. The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.

b. The stat-drug box shall contain no more than 20 solid dosage units per schedule of Schedule II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit in each drug schedule. If the unit of a liquid that may contain more than one dose is removed from the stat-box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.

B. The pharmacy may provide more than one stat-drug box to a long term care facility. Contents of the multiple boxes are not required to be uniform.

18VAC110-20-555. Use of automated dispensing devices.

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have on-line communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system.

3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:

a. A drug may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has on-line access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.

d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

4. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

5. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; nursing home; and a unique identifier for the specific device receiving drugs; and initials of pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

6. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

7. At the time of loading, the delivery record for all Schedule II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

8. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

9. The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

10. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

11. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

12. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper

storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

13. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically 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. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 13 a and b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained off site or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers

Part I. General Provisions

18VAC110-50-40. Safeguards against diversion of drugs.

A. The holder of the license as a wholesale distributor or permit as a manufacturer or warehouser shall restrict all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture, receipt, storage, distribution or quality

control of the controlled substance inventory, and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.

B. The holder of the license or permit, except for those distributors of only medical gases other than nitrous oxide, shall install an operable device for the detection of breaking subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The communication line installation shall be hard-wired and both the installation and device shall be based on accepted burglar alarm industry standards, to include wireless motion sensors.

3. The device shall be operable, centrally-monitored, ~~and~~ 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.

4. The device shall fully protect all areas where prescription drugs are stored and shall be reasonably capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to the person named on the application as the responsible party, or to persons specifically designated in writing in a policy and procedure manual.

6. The system shall be activated whenever the drug storage areas are closed for business.

C. Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.

1. The holder of the license or permit shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs, and only at a time when someone authorized to possess such drugs is in attendance.

2. The holder of the license or permit shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.

3. Prescriptions drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the wholesale distributor, manufacturer, or warehouser, and provided the identity and authorization of the agent is verified, and such transfer is only used to meet the immediate needs of a patient or patients.

Part II. Wholesale Distributors.

18VAC110-50-60. Special or limited-use licenses.

The board may issue a limited-use wholesale distributor license, nonresident wholesale distributor registration, restricted or nonrestricted manufacturer permit to entities that do not engage in the wholesale distribution of prescription drugs except medical gases or entities that engage in wholesale distribution or manufacturing but do not stock drugs and may waive certain requirements of regulation based on the limited nature of such distribution. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board.

18VAC110-50-70. Minimum required information.

A. The application form for a new license or for registration as a non-resident wholesale distributor, or any change of ownership shall include at least the following information:

1. The name, full business address, and telephone number of the applicant or licensee and name and telephone number of a designated contact person;

2. All trade or business names used by the applicant or licensee;

3. The federal employer identification number of the applicant or licensee;

4. The type of ownership and name(s) of the owner of the entity, including:

a. If an individual: the name, address, 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, 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 non-publicly held corporations, the name and address of each shareholder that owns ten (10) percent 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, and social security number or control number, and documentation of required qualifications as stated in 18VAC110-50-80 of the person who will serve as the responsible party;

6. A list of all states in which the entity is licensed to purchase, possess and distribute prescription drugs, and into which it ships prescription drugs;

7. A list of all disciplinary actions, to include date of action and parties to the action, imposed against the entity by state or federal regulatory bodies, including any such actions against the responsible party, principals, owners, directors, or officers over the last seven years;

8. A full description, for non-resident wholesale distributors, including the address, square footage, security and alarm system description, temperature and humidity control, and other relevant information of the facility or warehouse space used for prescription drug storage and distribution; 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 responsible party, principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation.

B. An applicant or licensee shall notify the board of any changes to the information required in this section within 30 days of such change.

18VAC110-50-80. Minimum qualifications, eligibility, and responsible party.

A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors:

1. The existence of grounds to deny an application as set forth in §54.1-3435.1 of the Code of Virginia;

2. The applicant's past experience in the manufacture or distribution of drugs or devices;

3. Compliance with the recordkeeping requirements;

4. Prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the manufacturing, distribution, prescribing, or dispensing of drugs by the responsible party or immediate family members of the responsible party, and owners, directors, or officers; and

5. The responsible party's credentials as set forth in subsection B of this section.

B. Requirements for the person named as the responsible party:

1. The responsible party shall be the primary contact person for the board as designated by the wholesale distributor, who shall be responsible for managing the wholesale distribution operations at that location;

2. The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor licensed in Virginia or another state, where the person's responsibilities included, but were not limited to, managing or supervising the recordkeeping, storage, and shipment for drugs or devices;

3. A person may only serve as the responsible party for one wholesale distributor license at any one time;

4. The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor;

5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, vacation, or other authorized absence; and

6. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor and all applicable state and federal laws related to wholesale distribution of prescription drugs.

C. The person named as the responsible party on the application shall submit the following with the application:

1. A passport size and quality photograph taken within 30 days of submission of the application;

2. A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed;

3. An attestation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

4. A federal criminal history record check ~~through the Central Criminal Records Exchange~~; and

5. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning wholesale distribution of prescription drugs in which such businesses were named as a party.

D. Responsibilities of the responsible party

1. Ensuring that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs.

2. Requiring any employee who has access to prescription drugs to attest that he has not been convicted of any federal or state drug law or any law relating to the manufacture, distribution or dispensing of prescription drugs.

3. Maintaining current working knowledge of requirements for wholesale distributors and assuring continued training for employees.

4. Maintaining proper security, storage and shipping conditions for all prescription drugs.

5. Maintaining all required records.

E. Each non-resident wholesale distributor shall designate a registered agent in Virginia for service of any notice or other legal document. Any non-resident wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon who may be served all legal process in any action or proceeding against such non-resident wholesale distributor. A copy of any such service of legal documents shall be mailed to the non-resident wholesale distributor by the board by certified mail at the address of record.

18VAC110-50-90. Minimum requirements for the storage, handling, transport, and shipment of prescription drugs.

A. All locations where prescription drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

1. Be of suitable construction to ensure that all drugs and devices in the facilities are maintained in accordance with the labeling of such drugs and devices or with official USP-NF compendium standards;

2. Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

3. Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

4. Have a quarantine area for storage of drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;

5. Be maintained in a clean and orderly condition; and

6. Be free from infestation of any kind.

B. The facility shall provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information.

C. The facility shall provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs.

18VAC110-50-100. Examination of drug shipments and accompanying documents.

A. Upon receipt, each shipping container shall be visually examined for identity to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit, or damaged drugs, or drugs or devices that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, suspected counterfeiting, or other damage to the contents.

B. Upon receipt of drugs, a wholesale distributor must review records for accuracy, completeness, and the integrity of the drugs considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

C. Each outgoing shipment shall be carefully inspected for identity of the drugs and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

18VAC110-50-110. Returned, damaged and counterfeit drugs; investigations.

A. Any drug or device returned to a manufacturer or another wholesale distributor shall be kept under the proper conditions and documentation showing that proper conditions were maintained shall be provided to the manufacturer or wholesale distributor to which the drugs are returned.

B. Any drug or device that, or any drug whose immediate or sealed outer or secondary container or labeling, is outdated, damaged, deteriorated, misbranded, adulterated, counterfeited, suspected of being counterfeited or adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other drugs and devices until its appropriate disposition.

C. When a drug or device is adulterated, misbranded, counterfeited, or suspected of being counterfeit or when the immediate or sealed outer or secondary container or labeling of any drug or device is adulterated, misbranded other than misbranding identified by the manufacturer through a recall or withdrawal, counterfeited, or suspected of being counterfeit, the wholesale distributor shall:

1. Provide notice to the board and the manufacturer, and to the other wholesale distributor if applicable, from which such drug or device was acquired within three business days of that determination.

2. Maintain any such drug or device, its containers and labeling, and its accompanying documentation or any evidence of criminal activity until its disposition by the appropriate state and federal government authorities.

D. The wholesale distributor shall fully cooperate with authorities conducting any investigation of counterfeiting or suspected counterfeiting to include the provision of any records related to receipt or distribution of the suspect drug or device.

18VAC110-50-120. Policies and procedures.

All wholesale distributors shall establish, maintain, and adhere to written policies and procedures for the proper receipt, security, storage, inventory, and distribution of prescription drugs. Wholesale distributors shall include in their policies and procedures at least the following:

1. A procedure for reporting thefts or losses of prescription drugs to the board and other appropriate persons;

2. A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this process provided the deviation is temporary and appropriate for the distribution;

3. A procedure for handling recalls and withdrawals of prescription drugs and devices;

4. Procedures for preparing for, protecting against, and handling emergency situations that affect the security and integrity of drugs or the operations of the wholesale distributor;

5. A procedure to ensure that outdated drugs are segregated from other drugs to include the disposition of such drugs;

6. A procedure to ensure initial and ongoing training of all employees;

7. A procedure for ensuring, both initially and on an ongoing basis, that persons with access to prescription drugs have not been convicted of a drug law or any law related to the manufacture, distribution, or dispensing of prescription drugs; and

8. A procedure for reporting counterfeit or suspected counterfeit prescription drugs or counterfeiting or suspected counterfeiting activities to the board and other appropriate law enforcement or regulatory agencies.

18VAC110-50-130. Recordkeeping.

A. All records and documentation required in this subsection shall be maintained and made available for inspection and photocopying by an authorized agent of the board for a period of three years following the date the record was created or received by the wholesale distributor. A wholesale distributor shall establish and maintain the following:

1. Inventories and records of all transactions regarding the receipt and distribution, or other disposition of all prescription drugs, including the dates of receipt and distribution or other disposition;

2. Records documenting monitoring of environmental conditions to ensure compliance with the storage requirements as required in 18VAC110-50-50;

3. Documentation of visual inspection of drugs and accompanying documents required in 18VAC110-50-100, including the date of such inspection and the identity of the person conducting the inspection;

4. Documentation of quarantine of any product and steps taken for the proper reporting and disposition of the product shall be maintained, including the handling and disposition of all outdated, damaged, deteriorated, misbranded, or adulterated drugs;

5. An ongoing list of persons or entities from whom it receives prescription drugs and persons or entities to whom it distributes prescription drugs; and

6. Copies of the mandated report of thefts or unusual losses of Schedule II-V controlled substances in compliance with the requirements of §54.1-3404 of the Code of Virginia.

B. Records shall be either (i) be kept at the inspection site or immediately retrievable by computer or other electronic means and made readily available at the time of inspection or (ii) if kept at a central location and not electronically retrievable at the inspection site, be made available for inspection within 48 hours of a request by an authorized agent of the board.

C. All facilities shall have adequate backup systems to protect against the inadvertent loss or deliberate destruction of data.

18VAC110-50-140. Due diligence.

A. Prior to the initial purchase of prescription drugs from another wholesale distributor not residing and licensed in Virginia, a wholesale distributor shall obtain, and update annually, the following information from the selling wholesale distributor:

1. A copy of the license to wholesale distribute from the resident state;

2. The most recent facility inspection report, if available;

3. A list of other names under which the wholesale distributor is doing business, or was formerly known as;

4. A list of principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation;

5. A list of all disciplinary actions by state and federal agencies;

6. A description, including the address, dimensions, and other relevant information, of each facility or warehouse used for drug storage and distribution; and

7. A listing of any manufacturers for whom the wholesale distributor is an authorized distributor of record.

B. If the selling wholesale distributor's facility has not been inspected by the resident board or the board's agent within three years of the contemplated purchase, the purchasing wholesale distributor may conduct an inspection of the wholesale distributor's facility prior to the first purchase of drugs or devices from another wholesale distributor, to ensure compliance with applicable laws and regulations relating to the storage and handling of drugs or devices. A third party may be engaged to conduct the site inspection on behalf of the purchasing wholesale distributor.

C. Prior to the first purchase of drugs from another wholesale distributor not residing in and licensed in Virginia, the purchasing wholesale distributor shall secure a national criminal background check of all of the wholesale distributor's owners, corporate officers, and the person named as the responsible party with the resident board or licensing agency.

Part III. Manufacturers.

18VAC110-50-150. Good manufacturing practices.

A. The Good Manufacturing Practice for Finished Pharmaceuticals regulations set forth in 21 CFR 211 are adopted by reference.

B. Each manufacturer of drugs shall comply with the requirements set forth in the federal regulations referred to in subsection A of this section.

Legislative Proposal for Dispensing of Schedule V Drugs to be Reported to the Prescription Monitoring Program (PMP)

In agenda packet:

- Excerpt from June 14, 2016 minutes of Board of Pharmacy full board meeting

Committee action:

- Motion to full board in June that it recommend to the PMP to advance a legislative proposal to amend the definition of "covered substance" in §54.1-2519 and its reference in §54.1-2520 to include Schedule V controlled substances; or,
- Take no action.

- RECOMMEND THAT PMP ADVANCE LEGISLATIVE PROPOSAL TO AMEND "COVERED SUBSTANCES" TO INCLUDE SCHEDULE V:

Ms. Shinaberry provided the board with background regarding the Regulation Committee's recommendation that the Prescription Monitoring Program (PMP) advance a legislative proposal to amend "covered substance" to include Schedule V. The Virginia Pharmacist Association (VPhA) offered comment at the March 25, 2016 board meeting requesting that the Board should consider deeming promethazine with codeine a drug of concern and require dispensers to report dispensations of the drug to the PMP. Promethazine with codeine is classified as a Schedule V drug and the abuse of the drug appears to have occurred periodically over recent years, not continuously. The law currently only requires drugs in Schedules II-IV be reported to the PMP. Virginia is one of 18 states that does not require the reporting of Schedule V drugs to the state PMP. Every state surrounding Virginia and the District of Columbia does require the reporting of Schedule V controlled substances. The Regulation Committee therefore, recommended that the board not deem promethazine with codeine as drug of concern at this time, but rather recommend that the PMP advance a legislative proposal to expand the definition of "covered substance" to include drugs in Schedule V.

MOTION:

The Board voted unanimously, as recommended by the Regulation Committee, to recommend to the Prescription Monitoring Program (PMP) that it advance a legislative proposal to amend the definition

of "covered substance" in §54.1-2519 and its reference in §54.1-2520 to include Schedule V controlled substances.