FINAL/APPROVED 3-1-05

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

December 10, 2004
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of the Board of Pharmacy was called to order at 9:10 a.m.

PRESIDING: Mark A. Oley, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
Toni Aust
John O. Beckner
Willie Brown
Michelle R. Easton
Bobby Ison
Leo H. Ross

MEMBERS ABSENT:
Kimberly A. Anderson
Michael J. Ayotte

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Ralph A. Orr, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General
Donna M. Lee, Administrative Assistant

QUORUM: With eight members of the Board present, a quorum was established.

APPROVAL OF AGENDA: The agenda was amended to add the following topics: Discuss publishing a Notice of Periodic Review of the Collaborative Practice Agreement Regulations and a presentation by Neal Kauder on the Disciplinary Sanctions Study. The Board was also informed that the formal hearing for Mark Oliveira had been continued.

Mr. Beckner moved, and the Board voted unanimously to approve the amended agenda.

PUBLIC COMMENTS: No public comments were received at this time.

APPROVAL OF MINUTES: Mr. Oley called for changes or corrections to the Minutes of September 15, 2004. A copy of page 4 was missing from the agenda packet and was distributed to the Board for review at the

meeting and inserted into the agenda packet. The Minutes were approved as presented.

Mr. Oley called for changes or corrections to the Minutes of November 15, 2004 for the Regulation Committee. Hearing no changes, the Minutes were approved as presented.

ADOPTION OF AMENDMENT TO PROPOSED REGULATION FOR LIMITING SCHEDULE VI PRESCRIPTIONS TO ONE YEAR:

The Board reviewed a draft to amend the proposed regulation for limiting Schedule VI prescriptions to one year. The amendment was suggested by the Department of Planning and Budget and approved by the Executive Committee of the Board of Medicine. The amendment would make one year the default time limit, but would allow a prescriber to specify up to a two-year limit. After discussion, Mr. Ross moved, and the Board voted unanimously, to adopt the amended language as presented (Attachment 1).

ADOPTION OF GUIDANCE DOCUMENT REGARDING THE PROCESS FOR DELEGATION TO AN AGENCY SUBORDINATE-CONTINUED FROM LAST MEETING:

The Board reviewed the draft guidance document outlining the process for delegation of informal fact-finding to an agency subordinate to be used in implementing regulations adopted by the Board at its September 15, 2004 meeting. After discussion, Mr. Beckner moved, and the Board voted unanimously, to adopt the draft guidance document regarding the process for delegation to an agency subordinate (Attachment 2).

ADOPTION OF PROPOSED REGULATIONS FOR PHYSICIANS SELLING DRUGS:

The Board reviewed the draft proposed regulations for physicians selling drugs. After discussion, Mr. Brown moved, and the Board voted unanimously, to adopt the draft proposed regulations for physicians selling drugs (Attachment 3).

ADOPTION OF PORPOSED REGULATIONS FOR WHOLESALE DISTRIBUTORS:

The Board reviewed the draft proposed regulations for wholesale distributors. Ms. Russell explained to the Board that a subcommittee reviewed and worked on the draft regulations and considered the NABP Model Rules and federal rules as a guideline in drafting the regulations. Elizabeth A. Gallenagh, Healthcare Distribution Management Association, addressed the Board and stated that her organization supported the proposed regulations. After discussion, Ms. Easton moved, and the Board voted unanimously, to adopt the draft proposed regulations for wholesale distributors (Attachment 4).

APPROVAL OF PUBLICATION OF A NOTICE OF PERIODIC REVIEW FOR COLLABORATIVE

Ms. Russell advised the Board that the collaborative practice agreement regulations went into effect in 2001, but that the regulations needed to be reviewed by the Board and updated to coincide with current practices. Ms. Russell requested that the Board proceed with the Notice of Periodic Review. She also

PRACTICE AGREEMENT REGULATIONS:

recommended that an ad hoc committee, consisting of participants from the Board of Medicine and other interested parties, be established to review the regulations. Because these regulations were adopted jointly with the Board of Medicine, that board will also need to approve publication.

Mr. Beckner moved, and the Board voted unanimously, to proceed with publishing a Notice of Periodic Review for the Collaborative Practice Agreement Regulations and to appoint an Ad Hoc Committee to assist in updating the regulations. The Ad Hoc Committee members from the Board of Pharmacy will be appointed by the Board Chairman at a later date.

DRAFT LEGISLATIVE PROPOSAL FOR COMPOUNDING:

The Board reviewed a draft legislative proposal for amendments to the compounding law to respond to requests by various physician practices to remove preparation for administration from the definition of compounding. After discussion and suggested amendments, Mr. Ison moved, and the Board voted unanimously to approve the draft legislative proposal as presented and amended by the Board (Attachment 5). The Board will not seek introduction of the proposal.

GUIDANCE DOCUMENT TO ADDRESS A DISASTER PLAN FOR PHARMACIES:

Upon a request, the Board discussed drafting a guidance document to address a disaster plan for pharmacies. After discussion, Mr. Beckner moved, and the Board voted unanimously, to appoint a committee to draft a guidance document to present to the Board for approval. The Committee will be appointed by the Board Chairman at a later date.

ADOPTION OF GUIDANCE DOCUMENT TO ASSIST HOSPITALS IN RANDOM REVIEW OF WITHDRAWALS FROM AUTOMATED DISPENSING DEVICES:

During the public comment period when the current regulations were being promulgated, a request was made for a guidance document to assist hospitals in knowing how to conduct the required random audits. After discussion, the Board determined that the regulations were specific enough not to warrant a guidance document, and did not adopt a guidance document.

NEW BUSINESS:

- **LICENSE RENEWALS -2005**

Ms. Russell distributed a statistical chart as of December 7, 2004, that indicated the numbers of online renewals. For example, the chart shows that, for pharmacists, only 49% have renewed online, but that 93% did complete the online survey. Further, it indicated that only 35% of the pharmacy technicians have renewed online.

- **FINANCIAL**

Ms. Russell reminded the Board that they will be receiving

DISCLOSURE STATEMENTS: financial disclosure statements that must be completed and returned to the Director's office for submission to the Governor's Office.

- **PRESCRIPTION MONITORING PROGRAM:** Ms. Russell updated the Board on new legislation that will be introduced to expand the Prescription Monitoring Program to include Schedules II through IV drugs and that it will encompass the entire state instead of just southwest Virginia. The proposal will also allow pharmacists to query the system, and will have non-resident pharmacies report. Ms. Russell informed the Board that the Board of Directors for the Virginia Pharmacists Association supports the new legislation.

DISCIPLINARY SANCTIONS STUDY PRESENTATION: Neal Kauder gave a presentation outlining the study of previous disciplinary cases and decisions made by the Board and a new worksheet they may utilize to assist them in sanction determinations.

The Board deferred any action on the adoption of the worksheet until its March 1, 2005 Board meeting to provide review time for the board members.

CONFLICT OF INTEREST TRAINING: Emily Wingfield, Assistant Attorney General, provided training regarding the Virginia conflict of interest and procurement laws as it pertains to state employees and appointed Board members.

ADJOURN: With all business concluded, the meeting adjourned at 2:35 p.m.

Elizabeth Scott Russell
Executive Director

Donna M. Lee
Administrative Assistant

Mark A. Oley, Board Chairman

Date

Proposed Regulations – Regulations Governing the Practice of Pharmacy

Change to one year refill on S VI

18VAC110-20-320. Refilling of Schedule III through VI prescriptions.

A. A prescription for a drug listed in Schedule III, IV, or V shall not be dispensed or refilled more than six months after the date on which such prescription was issued, and no such prescription authorized to be filled may be refilled more than five times.

1. Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with §54.1-3412 and 18VAC110-20-255, initialed and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.

2. The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that:

a. Each partial dispensing is recorded in the same manner as a refilling;

b. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and

c. No dispensing occurs after six months after the date on which the prescription order was issued.

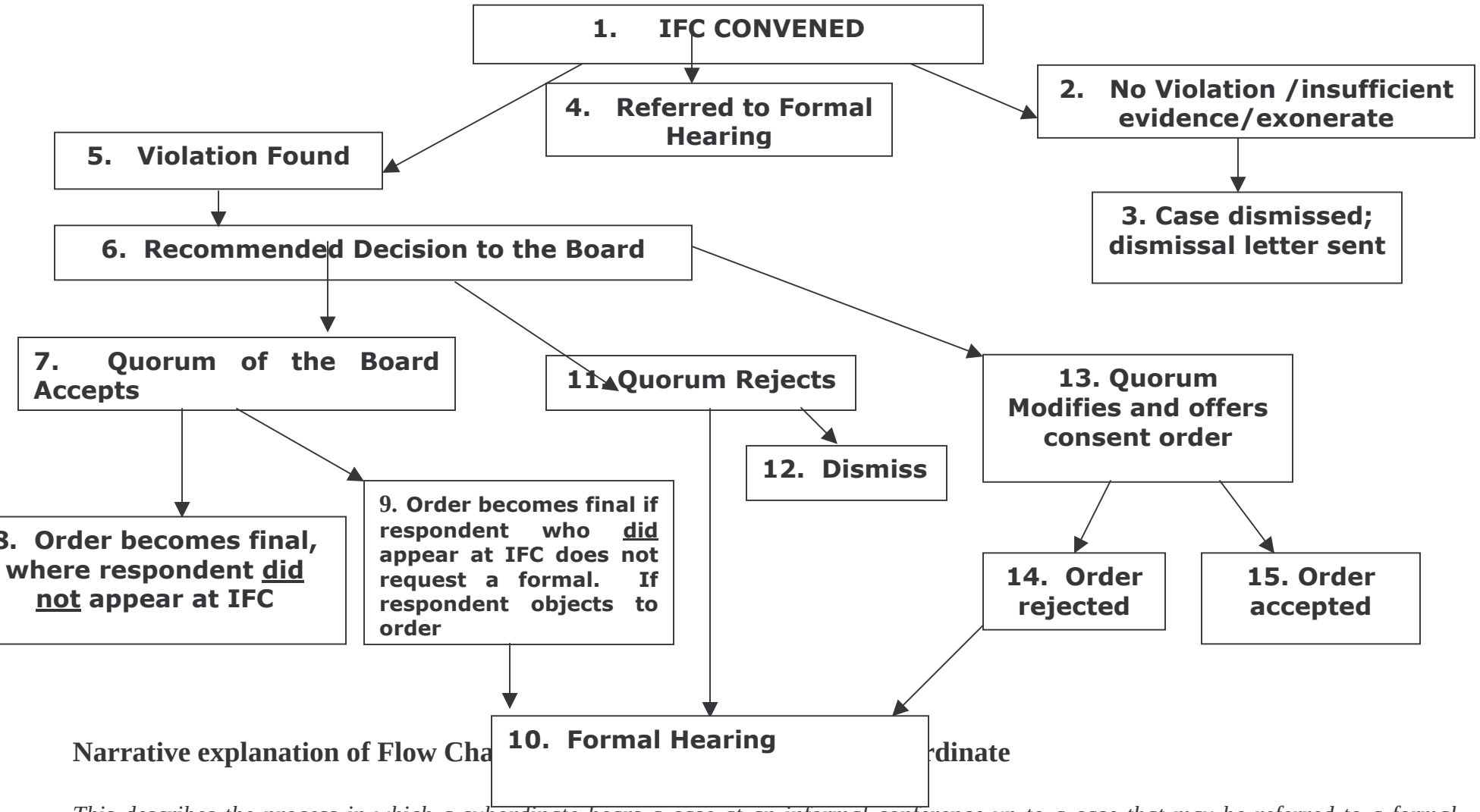
B. A prescription for a drug listed in Schedule VI shall be refilled only as expressly authorized by the practitioner. If no such authorization is given, the prescription shall not be refilled, except as provided in §54.1-3410 C or subdivision 4 of §54.1-3411 of the Code of Virginia.

A prescription for a Schedule VI drug or device shall not be dispensed or refilled more than ~~two years~~ one year after the date on which it was issued, unless the prescriber specifically authorizes dispensing or refilling for a longer period of time not to exceed two years.

C. As an alternative to all manual recordkeeping requirements provided for in subsections A and B of this section, an automated data processing system as provided in 18VAC110-20-250 may be used for the storage and retrieval of all or part of dispensing information for prescription drugs dispensed.

D. Authorized refills of all prescription drugs may only be dispensed in reasonable conformity with the directions for use as indicated by the practitioner; if directions have not been provided, then any authorized refills may only be dispensed in reasonable conformity with the recommended dosage and with the exercise of sound professional judgment.

Guidance for Conduct of an Informal Conference by an Agency Subordinate of a Health Regulatory Board at the Department of Health Professions



Narrative explanation of Flow Cha rdinate

This describes the process in which a subordinate hears a case at an informal conference up to a case that may be referred to a formal hearing.

1. Pursuant to a notice, the designated agency subordinate ("subordinate") will convene the informal conference ("IFC"). An IFC before a subordinate is conducted in the same manner as an IFC before a committee of the board. Following the presentation of information by the parties, the subordinate will consider the evidence presented and render a recommended decision regarding the findings of fact, conclusions of law, and if appropriate, the sanction to be imposed.

2. The subordinate may recommend that the respondent be exonerated, that there be a finding of no violation, or that insufficient evidence exists to determine that a statutory and/or regulatory violation has occurred.

3. If the subordinate makes such a finding, the case is dismissed and a dismissal letter is issued to the respondent notifying him of the determination.

4. The subordinate may decide that the case should be referred to a formal hearing. A hearing before the board would then be scheduled and notice sent to the respondent.

5. The subordinate may determine that a violation has occurred and recommend the findings of fact and conclusions of law along with an appropriate sanction.

6. With the assistance of APD, the subordinate drafts a recommended decision, which includes the findings of fact, conclusions of law and sanction. The recommendation is provided to the respondent and to the board and must be ratified by a quorum of the board.

7. If a quorum of the board accepts the recommended decision and:

8. If the respondent <u>did not appear</u> at the IFC, the board's decision becomes a final order that can only be appealed to a circuit court; or

9-10. If the respondent <u>did appear</u> at the IFC and objects to the order, he may request a formal hearing before the board. A case referred to a formal hearing proceeds in the same manner as cases considered by special conference committees convened pursuant to Va. Code § 54.1-2400(10). If the respondent who appeared at the IFC does not request a formal hearing, the order becomes final after a specified timeframe.

11. A quorum of the board may reject the recommended decision of the subordinate, in which case:

The board may decide to refer the case for a formal hearing **(10)**; or the board may decide

to dismiss the case and a dismissal letter is issued to the respondent notifying him of the decision of the board **(12)**.

13. A quorum of the board may modify the subordinate's recommended decision, and a consent order reflecting the modified decision is presented to the respondent:

If the respondent accepts the consent order, it is duly entered **(15)**; or if the respondent rejects the consent order **(14)**, the case proceeds to a formal hearing before the board **(10)**.

Virginia Administrative Code

CHAPTER 30
REGULATIONS FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES

Part I
Definitions And Fees

18VAC110-30-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

"Board" means the Virginia Board of Pharmacy.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act.

"Licensee" means a practitioner who is licensed by the Board of Pharmacy to sell controlled substances.

"Personal supervision" means the licensee must be physically present and render direct, personal control over the entire service being rendered or acts being performed. Neither prior nor future instructions shall be sufficient nor shall supervision be rendered by telephone, written instructions, or by any mechanical or electronic methods.

"Practitioner" means a doctor of medicine, ~~osteopathy~~ osteopathic medicine or podiatry who possesses a current active license issued by the Board of Medicine.

"Sale" means barter, exchange, or gift, or offer thereof, and each such transaction made by any person, whether as an individual, proprietor, agent, servant or employee. It does not include the gift of manufacturer's samples to a patient.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the controlled substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"U.S.P.-N.F." means the United States Pharmacopeia-National Formulary.

18VAC110-30-15. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Fee for initial license for a practitioner of the healing arts to sell controlled substances.

1. The application fee for initial licensure shall be ~~$200~~ 240.

2. The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500.

C. Renewal of license for a practitioner of the healing arts to sell controlled substances.

1. The annual fee for renewal of an active license shall be $90.

2. The annual fee for renewal of an inactive license shall be $45.

3. The late fee for renewal of a license within ~~60 days~~ one year after the expiration date is $30 in addition to the annual renewal fee.

4. The ~~delinquent~~ fee for reinstatement of a ~~lapsed~~ license expired for more than one year ~~is $70 in addition to all unpaid renewal fees~~ shall be $210.

D. The fee for reinspection of any facility shall be $150.

Part II
Licensure Requirements

18VAC110-30-20. Application for licensure.

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license.

B. In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine issued by the Virginia Board of Medicine. Any disciplinary action taken by the Board of Medicine against the practitioner's license to practice medicine shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

C. For good cause shown, the board may issue a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. The license to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion must accompany the application. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice;

2. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board~~; and~~

~~3. Application for a limited-use license is contingent on the practitioner selling only controlled substances which have been received prepackaged in ready-to-dispense quantities and containers needing only the addition of required labeling~~.

18VAC110-30-30. Renewal of license.

A. A license so issued shall be valid until December 31 of the year of issue. Renewal of the license shall be made on or before December 31 of each year.

B. If a practitioner fails to renew his license to sell within the Commonwealth by the renewal date, he must pay the renewal fee plus the late fee. He may renew his license by payment of these fees for ~~60 days~~ one year from the date of expiration.

C. Failure to renew the license to sell within ~~60 days~~ one year following expiration shall cause the license to lapse. The selling of controlled substances with a lapsed license shall be illegal and may

subject the practitioner to disciplinary action by the board. To reinstate a lapsed license, a practitioner shall submit an application for reinstatement and pay the reinstatement fee, plus the reinspection fee if a reinspection is required as set forth in subsection D of this section. Reinstatement is at the discretion of the board and may be granted by the executive director on the board's behalf ~~upon submission of a reinstatement application, payment of all unpaid renewal fees, and the delinquent fee~~ provided no grounds exist to deny said reinstatement.

D. Prior to reinstatement of a license that has been lapsed for more than one year, a reinspection of the storage and selling area shall be conducted unless another practitioner at the same location has held an active license to sell controlled substances during that period. A practitioner seeking reinstatement shall not stock drugs until approved by the board or its authorized agent.

E. The selling of controlled substances without a current, active license is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-30-35. ~~Inactive status.~~ Repealed

~~A. A licensee who intends to cease selling controlled substances may take inactive status. An inactive license may be reactivated by applying to the board for reactivation and paying any unpaid portion of the current renewal fee for an active license.~~

~~B. A licensee with inactive status shall not engage in the sale of controlled substances. Engaging in the sale of controlled substances with an inactive license shall constitute grounds for disciplinary action by the board.~~

8VAC110-30-40. Acts to be performed by the licensee.

A. The selection of the controlled substance from the stock, any preparation or packaging of a controlled substance or the preparation of a label for a controlled substance to be transferred to a patient shall be the personal responsibility of the licensee.

1. Any compounding of a controlled substance shall be personally performed by the licensee or a registered pharmacy technician under the supervision of the licensee.

2. ~~Only one person who is not a licensee may be present in the storage and selling area at any given time for the purpose of assisting the licensee in the preparation, packaging and labeling of a controlled substance.~~ A licensee may supervise one person who may be present in the storage and selling area to assist in performance of pharmacy technician tasks, as set forth § 54.1-3321 of the Code of Virginia, provided such person is either:

a. A pharmacy technician registered with the board; or

b. A licensed nurse or physician assistant who has received training in technician tasks consistent with training required for pharmacy technicians.

3. Unless using one of the board-approved training courses for pharmacy technicians, a licensee who uses a nurse or physician assistant to perform pharmacy technician tasks shall develop and maintain a training manual and shall document that such licensee has successfully completed general training in the following areas:

a. The entry of prescription information and drug history into a data system or other recordkeeping system;

b. The preparation of prescription labels or patient information;

c. The removal of the drug to be dispensed from inventory;

d. The counting or measuring of the drug to be dispensed to include pharmacy calculations;

e. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

f. The stocking or loading of automated dispensing devices or other devices used in the dispensing process, if applicable; and

g. Applicable laws and regulations related to dispensing.

4. A licensee who employs or uses pharmacy technicians, licensed nurses or physician assistants to assist in the storage and selling area shall develop and maintain a site-specific training program and manual for training to work in that practice. The program shall include training consistent with that specific practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used in the practice in performing technician duties, and pharmacy calculations consistent with the duties in that practice.

5. A licensee shall maintain documentation of successful completion of the site-specific training program for each pharmacy technician, nurse or physician assistant for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed persons shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

B. Prior to the dispensing, the licensee shall:

1. Conduct a prospective drug review and offer to counsel a patient in accordance with provisions of § 54.1-3319 of the Code of Virginia; and

2. Inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction.

C. If the record of sale is maintained in an automated data processing system as provided in 18VAC110-30-200, the licensee shall personally place his initials with each entry of a sale as a certification of the accuracy of, and the responsibility for, the entire transaction.

18VAC110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.

A. Any licensee who intends to cease selling controlled substances shall notify the board 10 days prior to cessation and surrender his license, and his license will be placed on ~~an inactive~~ expired status ~~or may be surrendered~~.

B. Any Schedule II through V controlled substances shall be inventoried and may be disposed of by transferring the controlled substance stock to another licensee or other person authorized by law to possess such drugs or by destruction as set forth in this chapter.

C. The licensee or other responsible person shall inform the board of the name and address of the licensee to whom the controlled substances are transferred.

D. A licensee who has surrendered his license pursuant to this section may request that it be made current again at anytime within the same renewal year without having to pay an additional fee, provided the licensee is selling from the same location or from another location that has been inspected and approved by the board.

18VAC110-30-60. [Repealed]

Part III
Inspection Requirements, Standards, and Security for Storage Areas; Disposal of Controlled Substances

18VAC110-30-70. Maintenance of a common stock of controlled substances.

Any two or more licensees who elect to maintain a common stock of controlled substances for dispensing shall:

1. Designate a licensee who shall be the primary person responsible for the stock, the required inventory, the records of receipt and destruction, safeguards against diversion and compliance with this chapter;

2. Report to the board the name of the licensee and the location of the controlled substance stock on a form provided by the board;

3. Upon a change in the licensee so designated, an inventory of all Schedule II through V controlled substances shall be conducted in the manner set forth in §54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board; and

4. Nothing shall relieve the other individual licensees who sell controlled substances at the location of the responsibility for the requirements set forth in this chapter.

18VAC110-30-80. Inspection and notice required.

A. The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the first license to sell controlled substances from that site. Inspection prior to issuance of subsequent licenses at the same location shall be conducted at the discretion of the board.

B. Applications for licenses which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice to the board is allowed prior to the requested inspection date.

C. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

D. At the time of the inspection, the controlled substance selling and storage area shall comply with 18VAC110-30-90, 18VAC110-30-100, 18VAC110-30-110, 18VAC110-30-120 and 18VAC110-30-130.

E. If an applicant substantially fails to meet the requirements for issuance of a license and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-30-15 prior to a reinspection being conducted.

~~E~~ F. No license shall be issued to sell controlled substances until adequate safeguards against diversion have been provided for the controlled substance storage and selling area and approved by the ~~board or its authorized agent~~ the inspector or board staff.

G. The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.

18VAC110-30-90. Physical standards.

Physical standards for the controlled substance selling and storage area:

1. The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted;

2. There shall be an enclosed area of not less than 60 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for the storage, preparation, dispensing, and record-keeping related to the sale of controlled substances. The work space used in preparation of the drugs shall be contained within the enclosed area. A controlled substance selling and storage area inspected and approved prior to November 3, 1993, shall not be required to meet the size requirement of this chapter;

3. Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be stored within the selling and storage area provided they are clearly separated from the stock maintained for sale;

4. The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner;

5. A sink with hot and cold running water shall be available within the immediate vicinity of the selling and storage area; and

6. The entire area described in this chapter shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage.

18VAC110-30-100. Access to selling area.

Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the licensee shall not be through the selling and storage area. The selling and storage area may be in an office that is exclusively used by the licensee and to which only the licensee has access provided the portion of the office used exclusively for controlled substances storage and preparation is at least 60 square feet; provided the drugs are stored in a cabinet, closet or other lockable area which can be locked when the practitioner is using the office for purposes other than dispensing; and provided the office meets all other requirements of 18VAC110-30-90, 18VAC110-30-120, and 18VAC110-30-130.

18VAC110-30-110. Minimum equipment.

The licensee shall be responsible for maintaining the following equipment in the designated area:

1. A current dispensing information reference source, either hard copy or electronic;

2. A refrigerator with a monitoring thermometer, located in the selling area, if any controlled substances requiring refrigeration are maintained;

~~3. A current copy of the Virginia Drug Control Act and board regulations;~~

~~4. A current copy of the Virginia Voluntary Formulary;~~

~~5~~ 3. ~~A laminar flow hood~~ Equipment consistent with requirements of §54.1-3410.2 of the Code of Virginia and USP-NF standards, if sterile products are to be prepared; ~~and~~

~~6~~ 4. Prescription balances, sensitive to 15 milligrams, and weights or an electronic scale, if the licensee is engaged in ~~extemporaneous compounding~~ dispensing activities that require the weighing of components~~.~~ ; and

5. Other equipment, supplies, and references consistent with the practitioner's scope of practice and with the public safety.

18VAC110-30-120. Safeguards against diversion of controlled substances.

A device for the detection of breaking shall be installed in the controlled substances selling and storage area. The installation and the device shall be based on accepted burglar alarm industry standards, and shall be 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 device shall be maintained in operating order;

3. The device shall fully protect the immediate controlled substance selling and storage areas and shall be capable of detecting breaking by any means whatsoever in the area when the area is closed;

4. The alarm system must have an auxiliary source of power;

5. The alarm system shall be capable of being activated and operated separately from any other alarm system in the area or the business in which the controlled substance selling and storage area is located;

6. The alarm system is controlled only by the licensee; and

7. An emergency key or access code to the system may be maintained as set forth in 18VAC110-30-130 B of this chapter.

18VAC110-30-130. Selling area enclosures.

A. The controlled substance selling and storage area of the licensee shall be provided with enclosures subject to the following conditions:

1. The enclosure shall be construed in such a manner that it protects the controlled substance stock from unauthorized entry and from pilferage at all times whether or not the licensee is on duty;

2. The enclosure shall be of sufficient height as to prevent anyone from reaching over to gain access to the controlled substances;

3. Entrances to the enclosed area must have a door which extends from the floor and which is at least as high as the adjacent counters or adjoining partitions; and

4. Doors to the area must have locking devices which will prevent entry in the absence of the licensee.

B. The door keys or other means of entry and alarm access code to the selling and storage area shall be subject to the following requirements:

1. Only the licensee shall be in possession of the alarm access code and any keys or other means of entry to the locking device on the door to such enclosure;

2. The selling and storage area must be locked when the licensee is not present and engaged in preparation or selling of drugs; and

3. The licensee may place a key or other means of opening the locking device and the alarm access code in a sealed envelope or other sealed container with the licensee's signature across the seal in a safe or vault within the office or other secured place for use by another licensee. In lieu of the licensee's signature across a seal, the executive director for the board may approve other methods of securing the emergency keys or access codes to the enclosed area.

C. The controlled substance selling and storage area is restricted to the licensee and one person designated by the licensee. The designated person may be present in the selling and storage area only during the hours when the licensee is on duty to render personal supervision.

18VAC110-30-140. Prescriptions awaiting delivery.

Prescriptions prepared for delivery to the patient may be placed in a secure place outside of the controlled substance selling area and access to the prescriptions restricted by the licensee to designated assistants. The prepared prescriptions may be transferred to the patient whether or not the licensee is on duty with prior approval of the licensee.

18VAC110-30-150. Expired controlled substances; security.

Any controlled substance which has exceeded the expiration date shall not be dispensed or sold and shall be separated from the stock used for selling ~~and may~~ but shall be maintained in ~~a designated~~ the selling and storage area ~~with the unexpired stock~~ prior to the disposal of the expired controlled substances.

18VAC110-30-160. Disposal of Schedule II through VI controlled substances.

A. If a licensee wishes to dispose of unwanted Schedule II through VI controlled substances, he shall use one of the following procedures:

1. Transfer the drugs to another person or entity authorized to possess Schedule II through VI drugs; or

2. Destroy the drugs by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations.

B. If Schedule II through V drugs are to be destroyed, the following additional procedures shall apply:

1. At least 14 days prior to the destruction date, the licensee shall provide a written notice to the board office. The notice shall state the following:

a. Date, time, manner, and place of destruction;

b. The names of the licensees who will witness the destruction process.

2. If the destruction date is to be changed or the destruction does not occur, a new notice stating the information required in subdivision 1 of this subsection shall be provided to the board;

3. The actual destruction shall be witnessed by the licensee conducting the destruction and another licensee of the board who is not employed by the licensee conducting the destruction;

4. At the conclusion of the destruction of the controlled substance stock, the DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the practitioner's office with other inventory records.

Part IV
Written Prescription and Record Keeping Standards

18VAC110-30-170. Sign and written prescription requirements.

~~A. The licensee shall provide the patient with a written prescription whether or not he intends to sell the controlled substance to the patient.~~

~~B~~ A. The licensee shall conspicuously display a sign in the public area of the office and in each patient examination room advising patients of their right to choose where they have their prescriptions filled.

~~C~~ B. The licensee ~~after delivery of the written prescription to the patient~~ shall~~, in each case,~~ advise the patient of their right to obtain the controlled substance from him or from a pharmacy.

C. If the patient chooses to obtain the controlled substance from a pharmacy, the licensee shall either provide the patient with a written prescription or transmit the prescription orally, electronically or by fax to a pharmacy of his choice.

D. If the patient chooses to purchase the controlled substance from the licensee, the licensee shall either:

1. Have the patient sign the written prescription ~~shall be returned~~ and return it to the licensee ~~and signed by the patient.~~ If the licensee chooses to use the hard copy prescription as his record of sale, he shall record all information and file as required by 18VAC110-30-190. If the licensee chooses to record the sale in book form or maintain it in an automated data system, he shall mark the prescription void, file chronologically, and maintain for a period of two years; or

2. In lieu of a written prescription, have the patient sign a separate waiver form to be maintained for at least two years, chronologically with other dispensing records according to date of dispensing. The waiver form may not be kept in the patient's chart.

18VAC110-30-180. Manner of maintaining inventory records for licensees selling controlled substances.

Each licensee shall maintain the inventories and records of controlled substances as follows:

1. Inventories and records of all controlled substances listed in Schedule II shall be maintained separately from all other records of the licensee;

2. Inventories and records of controlled substances listed in Schedules III, IV and V may be maintained separately or with records of Schedule VI controlled substances but shall not be maintained with other records of the licensee;

3. All records of Schedule II through V controlled substances shall be maintained at the same location as the stock of controlled substances to which the records pertain except that records maintained in an off-site database shall be retrieved and made available for inspection within 48 hours of a request by the board or an authorized agent;

4. In the event that an inventory is taken as the result of a theft of controlled substances pursuant to §54.1-3404 of the Drug Control Act of the Code of Virginia, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date; and

5. 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.

~~5~~ 6. All records required by this section shall be filed chronologically.

18VAC110-30-190. Manner of maintaining records for Schedule II through VI controlled substances sold.

A. A hard copy prescription shall be placed on file for every new prescription dispensed and be maintained for two years from date of last refill. All prescriptions shall be filed chronologically form date of initial dispensing. In lieu of a hard copy prescription, a licensee may have an alternative record of all drugs sold maintained for two years from date of dispensing or of refilling an order. Such record shall be in chronological order by date of initial dispensing with refills listed with initial dispensing information or by date of dispensing.

B. The hard copy prescription or records of sale for Schedule II controlled substances shall be maintained as follows:

1. They shall be maintained separately from other records; and

2. They shall be maintained in chronological order and shall show the selling date, a number which identifies the sale, the name and address of the patient, the name and strength of the controlled substance, the initials of the licensee, and the quantity sold.

~~B~~ C. The hard copy prescription or records of sale for Schedule III through V controlled substances shall be maintained as follows:

1. They shall be maintained in the manner set forth in subsection A of this section; and

2. The hard copy prescription or records of sale for Schedule III through V controlled substances may be maintained separately from other selling records or may be maintained with selling records for Schedule VI controlled substances provided the Schedule III through V controlled substance records are readily retrievable from the selling records for Schedule VI controlled substances. The records shall be deemed readily retrievable if a red "C" is placed uniformly on the record entry line for each Schedule III through V controlled substance sold. However, if the licensee employs an automated data processing system or other electronic recordkeeping system for prescriptions that 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 record with a red "C" is waived.

18VAC110-30-200. Automated data processing records of sale.

A. An automated data processing system may be used for the storage and retrieval of the sale of controlled substances instead of manual recordkeeping requirements, subject to the following conditions:

1. Any computerized system shall also provide retrieval via computer monitor display or printout of the sale of all controlled substances during the past two years, the listing to be in chronological order and shall include all information required by the manual method;

2. If the system provides a printout of each day's selling activity, the printout shall be verified, dated and signed by the licensee. The licensee shall verify that the data indicated is correct and then sign the document in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). In place of such printout, the licensee shall maintain a bound log book, or separate file, in which the licensee shall sign a statement each day, in the manner previously described, attesting to the fact that the selling information entered into the computer that day under his initials has been reviewed by him and is correct as shown; and

~~3. A hard copy prescription shall be placed on file chronologically and maintained for a period of two years.~~

B. Any computerized system shall have the capability of producing a printout of any selling data which the practitioner is responsible for maintaining under the Drug Control Act and such printout shall be provided within 48 hours of a request of an authorized agent.

Part V
Packaging, Repackaging and Label Standards

18VAC110-30-210. Repackaging of controlled substances; records required; labeling requirements.

A. A licensee repackaging controlled substances 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 controlled substances repackaged, strength, if any, quantity prepared, initials of the licensee supervising the process, the assigned control number, or the manufacturer's or distributor's name and control number, and an expiration date.

B. The controlled substance name, strength, if any, the assigned control number, or the manufacturer's or distributor's name and control number, and an appropriate expiration date determined by the licensee in accordance with USP-NF guidelines shall appear on any subsequently repackaged or reconstituted units ~~as follows:~~ .

~~1. If U.S.P.-N.F. Class B or better packaging material is used for oral unit dose packages, an expiration date not to exceed six months or the expiration date shown on the original manufacturing bulk containers, whichever is less, shall appear on the repackaged units;~~

~~2. If it can be documented that the repackaged unit has a stability greater than six months, an appropriate expiration date may be assigned; and~~

~~3. If U.S.P.-N.F. Class C or less packaging material is used for oral, solid medication, an expiration date not to exceed 30 days shall appear on the repackaged units.~~

18VAC110-30-220. Labeling of prescription as to content and quantity.

Any controlled substances sold by a licensee shall bear on the label of the container, in addition to other requirements, the following information:

1. The name and address of the practitioner and the name of the patient;

2. The date of the dispensing;

3. The drug name and strength, when strength is applicable:

a. For any drug product possessing a single active ingredient, the generic name of the drug shall be included on the label.

b. If a generic drug is dispensed when a prescription is written for a brand name drug, the label shall contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed, and ~~in accordance with §32.1-87 A of the Code of Virginia,~~ the label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed; and

4. The number of dosage units or, if liquid, the number of millimeters dispensed.

18VAC110-30-230. Packaging standards for controlled substance sold.

A controlled substance shall be sold only in packaging approved by the current U.S.P.-N.F. for the controlled substance. In the absence of such packaging standard for the controlled substance, it shall be dispensed in a well-closed container.

18VAC110-30-240. Special packaging.

A. Each controlled substance sold to a person in a household shall be sold in special packaging, except when otherwise requested by the purchaser, or when such controlled substance is exempted from such requirements promulgated pursuant to the Poison Prevention Packaging Act of 1970, 15 USC §§1471-1476.

B. Each licensee may have a sign posted near the compounding and selling area advising the patients that nonspecial packaging may be requested.

C. If nonspecial packaging is requested, a ~~signed~~ release of such request shall be obtained ~~pursuant to §54.1-3427 of the Code of Virginia~~ <u>from the patient or the patient's authorized agent</u> and maintained for two years from the date of dispensing.

Part VI

Patient's Choice of Supplier, Purchase of Drugs, and Return of Controlled Substances

18VAC110-30-250. Choice of controlled substance supplier.

A licensee shall neither interfere with the patient's right to choose his supplier of medication nor cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.

18VAC110-30-255. Purchase of drugs.

Except for an emergency purchase from another licensee or pharmacy, a licensee may only purchase Schedule II through VI drugs from a wholesale distributor licensed or registered by the board.

18VAC110-30-260. Returning of controlled substances.

Controlled substances shall not be accepted for return or exchange by any licensee for resale after such controlled substances have been taken from the premises where sold, unless such controlled substances are in the manufacturer's original sealed container or in a unit-dose container which meets the U.S.P.-N.F. Class A or Class B container requirement, have ~~not~~ been stored under conditions in which official compendium storage requirements can be assured ~~whereby they may have become contaminated~~, and provided such return or exchange is consistent with federal law and regulation.

Part VII

Grounds for Disciplinary Action

18VAC110-30-270. Grounds for disciplinary action.

In addition to those grounds listed in §54.1-3316 of the Code of Virginia, the board may revoke, suspend, refuse to issue or renew a license to sell controlled substances or may deny any application if it finds that the licensee or applicant has had his license to practice medicine, ~~osteopathy~~ osteopathic medicine or podiatry suspended or revoked in Virginia or in any other state or no longer holds a current active license to practice ~~medicine~~ in the Commonwealth of Virginia.

PROPOSED REGULATIONS ON WHOLESALE DISTRIBUTORS, MANUFACTURERS AND WAREHOUSERS

VIRGINIA BOARD OF PHARMACY
Proposed 12/10/04

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees

1. Pharmacist license $180

2. Pharmacy intern registration $15

3. Pharmacy technician registration $25

4. Pharmacy permit $270

5. Permitted physician licensed to dispense drugs $270

~~6. Nonrestricted manufacturer permit $270~~

~~7. Restricted manufacturer permit $180~~

~~8. Wholesale distributor license $270~~

~~9. Warehouser permit $270~~

~~10~~ 6. Medical equipment supplier permit $180

~~11~~ 7. Humane society permit $20

~~12~~ 8. Non-resident pharmacy $270

~~13. Non-resident wholesale distributor $270~~

~~14~~ 9. Controlled substances registrations $90

~~15~~ 10. Robotic pharmacy system approval $150

~~16~~ 11. Innovative program approval $250

If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.

17. Approval of a pharmacy technician training program $150

18. Approval of a continuing education program $100

D. Annual renewal fees:

1. Pharmacist active license $90

2. Pharmacist inactive license $45

3. Pharmacy technician registration $25

4. Pharmacy permit $270

5. Physician permit to practice pharmacy $270

~~6. Nonrestricted manufacturer permit $270~~

~~7. Restricted manufacturer permit $180~~

~~8. Wholesale distributor license $270~~

~~9. Warehouser permit $270~~

~~10~~ 6. Medical equipment supplier permit $180

~~11~~ 7. Humane society permit $20

~~12~~ 8. Non-resident pharmacy $270

~~13. Non-resident wholesale distributor $270~~

~~14~~ 9. Controlled substances registrations $90

~~15~~ 10. Innovative program continued approval based on board order not to exceed $200 per approval period

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license $30

2. Pharmacist inactive license $15

3. Pharmacy technician registration $10

4. Pharmacy permit $90

5. Physician permit to practice pharmacy $90

~~6. Nonrestricted manufacturer permit $90~~

~~7. Restricted manufacturer permit $60~~

~~8. Wholesale distributor license $90~~

~~9. Warehouser permit $90~~

~~10~~ 6. Medical equipment supplier permit $60

~~11~~ 7. Humane society permit $5

~~12~~ 8. Non-resident pharmacy $90

~~13. Non-resident wholesale distributor $90~~

~~14~~ 9. Controlled substances registrations $30

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license $210

2. Pharmacist license after revocation or suspension $500

3. Pharmacy technician registration $35

4. Pharmacy technician registration after revocation or suspension $125

5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Pharmacy permit $240

b. Physician permit to practice pharmacy $240

~~c. Nonrestricted manufacturer permit $240~~

~~d. Restricted manufacturer permit $ 210~~

~~e. Wholesale distributor license $240~~

~~f. Warehouser permit $240~~

~~g~~ c. Medical equipment supplier permit $210

~~h~~ d. Humane society permit $30

~~I~~ e. Non-resident pharmacy $115

~~j. Non-resident wholesale distributor $115~~

~~k~~ f. Controlled substances registration $180

G. Application for change or inspection fees for facilities or other entities

1. Change of pharmacist-in-charge $50

2. Change of ownership for any facility $50

3. Inspection for remodeling or change of location for any facility $150

4. Reinspection of any facility $150

5. Board-required inspection for a robotic pharmacy system $150

6. Board-required inspection of an innovative program location $150

7. Change of pharmacist responsible for an approved innovative program $25

H. Miscellaneous fees

1. Duplicate wall certificate $25

2. Returned check $25

Part XVI. ~~Manufacturers, Wholesale Distributors, Warehousers, and~~ Medical Equipment Suppliers

~~18VAC110-20-630. Licenses and permits generally.~~

~~A license or permit shall not be issued to any manufacturer, wholesale distributor, warehouser, or medical equipment supplier to operate from a private dwelling, unless a separate business entrance is provided, and the place of business is open for inspection at all times during normal business hours. The applicant shall comply with all other federal, state and local laws and ordinances before any license or permit is issued.~~

~~18VAC110-20-640. Safeguards against diversion of drugs.~~

~~The following requirements shall apply to manufacturers, wholesale distributors, or warehousers of prescription drugs:~~

~~1. The holder of the permit shall restrict all areas in which prescription drugs are manufactured, stored, or kept for sale, to only designated and necessary persons.~~

~~2. The holder of the permit shall provide reasonable security measures for all drugs in the restricted area.~~

~~3. The holder of the permit, except for those manufacturers or distributors of only medical gases other than nitrous oxide, shall install a device for the detection of breaking subject to the following conditions:~~

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

~~b. The installation shall be hard wired and both the installation and device shall be based on accepted burglar alarm industry standards.~~

~~c. The device shall be maintained in operating order and shall have an auxiliary source of power.~~

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

~~e. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.~~

~~4. The holder of the permit shall not deliver any drug to a licensed business at which there is no one in attendance at the time of the delivery nor to any person who may not legally possess such drugs.~~

~~18VAC110-20-660. 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.~~

~~18VAC110-20-670. Prescription drug marketing act.~~

~~A. The requirements for wholesale distribution of prescription drugs set forth in the federal Prescription Drug Marketing Act of 1987 (21 USC §321; 21 CFR 205) are adopted by reference.~~

~~B. Each wholesale distributor of prescription drugs shall comply with minimum requirements for qualifications, personnel, storage, handling, and records as set forth in the federal regulations referred to in subsection A of this section.~~

18VAC110-50-10 et seq. Wholesale Distributors, Manufacturers, and Warehousers

Part I. General Provisions

18VAC110-50-10. Definitions.

In addition to words and terms defined in §§54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"DEA" means the United States Drug Enforcement Administration.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"FDA" means the United States Food and Drug Administration.

"USP-NF" means the United States Pharmacopeia-National Formulary, current edition.

"Control number" means the unique identifying customer number assigned by the Virginia Department of Motor Vehicles to an individual when issuing a driver's license, learner's permit, or official identification card. This number is displayed on the driver's license or ID card in lieu of the Social Security Number.

18VAC110-50-20. Fees

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Initial application fees

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180
3. Wholesale distributor license	$270
4. Warehouser permit	$270

5. Non-resident wholesale distributor $270

6. Controlled substances registration $90

C. Annual renewal fees

1. Nonrestricted manufacturer permit $270

2. Restricted manufacturer permit $180

3. Wholesale distributor license $270

4. Warehouser permit $270

5. Non-resident wholesale distributor $270

6. Controlled substances registration $90

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Nonrestricted manufacturer permit $90

2. Restricted manufacturer permit $60

3. Wholesale distributor license $90

4. Warehouser permit $90

5. Non-resident wholesale distributor $90

6. Controlled substances registration $30

E. Reinstatement fees.

1. Any entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration.

3. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Nonrestricted manufacturer permit $240

b. Restricted manufacturer permit $210

c. Wholesale distributor license $240

d. Warehouser permit $240

e. Non-resident wholesale distributor $240

f. Controlled substances registration $180

F. Application for change or inspection fees

1. Reinspection fee $150

2. Inspection for remodeling or change of location $150

3. Change of ownership fee $50

4. Change of responsible party $50

G. The fee for a returned check shall be $25.

18VAC110-50-30. Location of business, inspection required.

A. A license or permit shall not be issued to any wholesale distributor, manufacturer, or warehouser to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. The applicant shall comply with all federal, state and local laws and ordinances before any license or permit is issued.

B. If a wholesale distributor, manufacturer, or warehouser engages in receiving, possessing, storage, using, manufacturing, distribution, or otherwise disposing of any Schedule II – V controlled substances, it shall also obtain a controlled substances registration from the board in accordance with § 54.1-3422 of the Code of Virginia, and shall also be duly registered with DEA and in compliance with all applicable laws and rules for the storage, distribution, shipping, handling, and transporting of controlled substances.

C. The proposed location, structural changes, or security system changes shall be inspected by an authorized agent of the board prior to issuance of a license.

1. Applications which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

2. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

3. At the time of the inspection, the proposed prescription drug storage area shall comply with 18 VAC 110-50-40 and 18 VAC 110-50-50, and wholesale distributors shall meet the requirements of 18 VAC 110-50-80.

4. If an applicant substantially fails to meet the requirements for issuance of a permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18 VAC 110-50-20 prior to a reinspection being conducted.

D. Prescription drugs shall not be stocked within the proposed location or moved to a new location until approval is granted by the inspector or board staff.

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

A. The holder of the license shall restrict all areas in which prescription drugs are stored or kept for sale, to only designated and necessary persons and 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 a 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 installation shall be hard wired and both the installation and device shall be based on accepted burglar alarm industry standards.

3. The device shall be maintained in operating order and shall have an auxiliary source of power.

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

5. Access to the alarm system shall be restricted to only designated and necessary persons, and 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 on the premises of the holder of the license or permit provided the

identity and authorization of the agent is verified, and provided such delivery is only used to meet the immediate needs of a patient or patients.

18VAC110-50-50. Storage

A. All prescription drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements of USP-NF.

B. If no specific storage requirements are established for a drug or a device, it may be held at controlled room temperature, as defined in USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

C. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, and/or logs shall be utilized to document proper storage of prescription drugs.

D. Packaging of the prescription drugs should be in accordance with USP-NF standards.

E. Schedule II – V controlled substances shall be separated from Schedule VI prescription drugs and stored in a secure area in accordance with DEA security requirements and standards.

F. Any facility shall be of adequate size and construction and have the proper equipment necessary for the proper storage of prescription drugs and devices as set forth in this section.

Part II. Wholesale Distributors

18VAC110-50-60. Minimum required information.

A. Any person or entity wishing to obtain a new license as a wholesale distributor or register as a non-resident wholesale distributor, engage in the acquisition of an existing wholesale distributor, change the location or make structural changes to the prescription drug storage space of an existing wholesale distributor, or make changes to a previously approved security system shall file an application with the board on a form approved by the board.

B. Forms for new licenses or registration, 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, (includes “is doing business as,” and “formerly known as”) which cannot be identical to the name used by another unrelated wholesale distributor licensed to purchase or sell drugs in Virginia;

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, 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;

(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 18 VAC 110-50-70 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 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 (7) 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, owners, directors, or officers.

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

18VAC110-50-70. Minimum qualifications, eligibility, and responsible party.

A. The board shall use the following factors in determining the eligibility for and renewal of 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 C of this section.

B. The applicant shall provide a national criminal background check of the person named as the responsible party to assist the board in determining whether an applicant has committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state laws, at the applicant's expense, and will be sufficient to include all states of residence for the past 10 years or since the person has been an adult, whichever is less.

C. 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.

D. 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. 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 7 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; and

4. Any additional information deemed by the board to be relevant to determining eligibility of a responsible party.

E. Responsibilities of the responsible party

1. The responsible party shall ensure that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs.

2. The responsible party shall ensure that any employee who has access to prescription drugs has not been convicted of any federal or state drug law or any law relating to the wholesale distribution of prescription drugs.

3. The responsible party shall be responsible for maintaining current working knowledge of requirements for wholesale distributors and assuring continued training for employees.

4. The responsible party shall be responsible for maintaining proper security, storage and shipping conditions for all prescription drugs.

5. The responsible party shall be responsible for maintaining all required records.

F. 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.

18VAC110-50-80. 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.

18VAC110-50-90. 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. The drugs found to be unacceptable under paragraph A shall be quarantined from the rest of stock until the examination and determination is made that the drugs are safe for distribution.

D. 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.

18VAC110-50-100. 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. When drugs and devices are adulterated, misbranded, counterfeited, or suspected of being counterfeit:

1. Notice shall be provided to the board and the manufacturer or wholesale distributor from which it was acquired within three (3) business days of that determination.

2. Any drug or device that 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 it is returned to either the manufacturer or wholesale distributor from which it was acquired or until it is destroyed.

3. No drug or device, and its accompanying documentation, that is counterfeit or suspected of being counterfeit or otherwise deliberately tampered, or any evidence of criminal activity shall be destroyed until its disposition by the appropriate state and federal government authorities.

C. When the immediate or sealed outer or secondary containers or labeling of any drug and device are adulterated, misbranded other than misbranding identified by the manufacturer through a recall or withdrawal, counterfeited, or suspected of being counterfeit:

1. Notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting shall be provided to the board and manufacturer or wholesale distributor from which it was acquired within three (3) business days of that determination.

2. Any drug whose immediate or sealed outer or secondary container or labeling is adulterated, misbranded, counterfeited, or suspected of being counterfeited shall be quarantined and physically separated from other drugs or devices until it is returned to either the manufacturer or wholesale distributor from which it was acquired or until it is destroyed.

3. No immediate or sealed outer or secondary container or labeling that is suspected of being counterfeit, fraudulent, or tampered, and accompanying documentation, shall be destroyed until disposition by the appropriate state and federal authorities is authorized.

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.

18VAC110-50-110. 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 wholesale distribution 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.

18VAC110-50-120. Recordkeeping

A. All records described in this section shall be maintained and made available for inspection and photocopying by an authorized agent of the board for a period of 3 (three) years following the date the record was created or received by the wholesale distributor.

1. Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection at the time of inspection. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 48 hours of a request by an authorized agent of the board.

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

B. Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution, or other disposition of all prescription drugs. Such records shall include the dates of receipt and distribution or other disposition.

C. Wholesale distributors shall establish and maintain records documenting monitoring of environmental conditions to ensure compliance with the storage requirements as required in 18 VAC 110-50-50.

D. Documentation of visual inspection of drugs and accompanying documents required in 18VAC110-50-90 shall be maintained to include the date of such inspection and the identity of the person conducting the inspection.

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

F. Wholesale distributors shall maintain an ongoing list of persons or entities from whom they receive prescription drugs and persons or entities to whom they distribute prescription drugs.

G. All wholesale distributors shall comply with the requirements of §54.1-3404 of the Code of Virginia for the mandatory reporting of thefts or unusual losses of Schedule II-V controlled substances and maintain a copy of such report.

H. Wholesale distributors shall submit a written report to the board of any significant shortages or losses of prescription drugs and maintain a copy of such report.

18VAC110-50-130. 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 from the resident board or licensing agency;

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

4. A list of corporate officers;

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;

7. A statement as to whether and 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 (3) 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

18VAC110-50-140. 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.

§ 54.1-3401. Definitions.

As used in this chapter, unless the context requires a different meaning:
"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.
"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.
"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.
"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth.
"Animal" means any nonhuman animate being endowed with the power of voluntary action.
"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.
"Board" means the Board of Pharmacy.
"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.
"Change of ownership" of an existing entity permitted, registered or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.
"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed prescribing patterns; (ii) by or for a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.1 or Title 4.1.

"DEA" means the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (54.1-2729.1 et seq.) of this title and who, under the supervision of a licensed physician, nurse practitioner, physician assistant or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; or (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii) or (iii). "Drug" does not include devices or their components, parts or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

"Facsimile (FAX) prescription" means a written prescription or order, which is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the United States Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Label" means a display of written, printed or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any, of the retail package of such article, or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, oil or cake made from the seeds of such plant, unless such stalks, fiber, oil or cake is combined with other parts of plants of the genus Cannabis.

"Medical equipment supplier" means any person, as defined in § 1-13.19, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.

<u>"Medical practice location" means any office location where a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine is engaged in the practice of the respective branch of practice.</u>

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means: (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety

and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the United States Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.) of this chapter, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to, a controlled substance in the course of professional practice or research in this Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian or other practitioner, authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353 (b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug which is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug which may be dispensed only upon prescription or the label of which bears substantially the statement "Warning - may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the United States Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale

distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) of this title and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy" and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 of this title unless the context requires a different meaning.

§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

No written prescription order form shall include more than one prescription. However, this provision shall not apply to prescriptions written as chart orders for patients in hospitals and long-term-care facilities, patients receiving home infusion services or hospice patients, <u>patients receiving services from a pharmacy located within a medical practice location or practitioner licensed to dispense pursuant § 54.1-3304 or § 54.1-3304.1,</u> or to a prescription ordered through a pharmacy operated by or for the Department of Corrections or the Department of Juvenile Justice, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services.

B. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard copy form, and such facsimile copy shall be treated as a valid original prescription order. If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.

C. The oral prescription referred to in § 54.1-3408 shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § 54.1-3420.2.

A pharmacist may also provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision.

Pharmacists shall label all compounded products distributed to practitioners for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding. ~~maintain and comply with a policy and procedure manual when engaging in the levels of compounding of drug products associated with any of the following: (i) higher risk from contamination in compounding, such as the compounding of sterile injectable products, sterile ophthalmic or otic products, total parenteral nutrition products, chemotherapy injectable products and implants; (ii) radiopharmaceuticals; or (iii) preparation of dosage forms that are dose-critical or are specialized preparations, such as slow-release products or transdermal patches.~~

~~Such manual shall (i) be consistent with USP-NF standards and guidance for compounding; (ii) describe all significant procedures in compounding; and (iii) establish a quality assurance program to ensure accountability, accuracy, quality, safety, and uniformity.~~

~~A policy and procedure manual shall not be required for nonsterile compounding that only involves the mixing of two or more commercially available preparations, the mixing or reconstitution of a commercially available product in accordance with the manufacturer's instructions, preparation of injections for immediate administration using commercially available sterile products, preparation of other nonsterile dosage forms that are not dose-critical or specialized products, and the addition of flavoring.~~

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;

2. Are manufactured by an establishment that is registered by the FDA; or

3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal; or

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, or (iii) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products

are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and conducting in-process and final checks of compounded products.

2. In addition to the requirements of paragraph 1, ~~All compounding~~ records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include~~: (i) the date of the preparation; (ii) the generic name and~~ the name of the manufacturer of ~~the raw materials~~ each component or the brand name of ~~the raw materials~~ each component; ~~(iii)~~ the manufacturer's lot number and expiration date for each component~~, and,~~ or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; ~~(iv) the prescription number or~~ the assigned lot number ~~when compounding in anticipation of receiving a prescription; (v) the signature or initials of the pharmacist or other authorized person performing the compounding; (vi) the signature or initials of the pharmacist responsible for supervising support personnel and conducting in-process and final checks of compounded products when other authorized personnel perform the compounding function; (vii) the quantity in units of finished products or quantity of raw materials used in compounding the product; (viii)~~ if subdivided, the unit or package size and the number of units or packages prepared; and ~~(ix)~~ the beyond-use date. The criteria for establishing the beyond use date shall be available for inspection by the Board.~~; (x) for the levels of compounding described in subsection E, requiring the maintenance and compliance with a policy and procedure manual, a complete formula with compounding procedures, including, when appropriate, complete mixing instructions with the order of mixing, mixing temperatures or other environmental controls, duration of mixing, equipment needed, and other factors necessary to replicate the preparation as compounded; and (xi) documentation for the levels of compounding described in subsection E of any tests conducted on compounded products in accordance with the required policy and procedure manual~~.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ 54.1-3301, 54.1-3304 and 54.1-3304.1 shall comply with all provisions of this section and the relevant Board regulations, where such compounding is limited to drugs that are administered or dispensed at the location where the compounding occurs. Practitioners who are licensed pursuant to § 54.1-3304.1 may directly supervise compounding by pharmacy technicians, nurses, medical interns, or physician assistants who have received specific training in the type of compounding to be performed within the medical practice location, and who have

been assessed for competency in accordance with USP-NF standards. The practitioner or a pharmacist shall perform the final check for accuracy for any product compounded within a medical practice setting.

K. Compounding for immediate administration to a specific patient shall not be subject to the requirements of this section provided the following criteria are met:

1. The compounding only includes the reconstitution or dilution of a drug in accordance with manufacturer's instructions or the combining of no more than three commercially available drugs;

2. When such compounding is (i) performed by a person authorized by law to administer controlled substances and who will be personally administering the drug or drugs, or (ii) performed by a person authorized by law to administer controlled substances, a pharmacist, or pharmacy technician when the prescriber will immediately administer the drug or drugs; and

3. When there are no intervening tasks by the person compounding between the compounding and the administering to the patient, and the administration is reasonable concurrent with the compounding. For sterile products that are not compounded in accordance with USP-NF standards, administration shall begin no more than one hour following preparation, and, if infused over time, shall be completed within the timeframe established by USP standards.

§ 54.1-3420.2. Delivery of prescription drug order.

A. Whenever any pharmacy permitted to operate in this Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the following conditions shall be required:

1. Written notice shall be placed in each shipment alerting the consumer that under certain circumstances chemical degradation of drugs may occur; and

2. Written notice shall be placed in each shipment providing a toll-free or local consumer access telephone number which is designed to respond to consumer questions pertaining to chemical degradation of drugs.

B. If a prescription drug order is not personally hand delivered directly to the patient or the patient's agent, or if the prescription drug order is not delivered to the residence of the patient, the delivery location shall hold a current permit, license, or registration with the Board that authorizes the possession of controlled substances at that location. The Board shall promulgate regulations related to the security, access, required records, accountability, storage, and accuracy of delivery of such drug delivery systems.

C. A pharmacy may deliver a prescription drug order to a medical practice location when such prescription drug order is to be administered to the patient at the medical practice location within 48 hours of delivery.