PART I. GENERAL PROVISIONS

18 VAC 110-20-10. 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 these regulations, shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the American Council on Pharmaceutical Education.

“Acquisition” of an existing entity permitted, registered or licensed by the board means (i) the purchase 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 or change in partnership composition; (iii) the acquiring of fifty 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; or (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.

"Aseptic processing" means the technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Class 100 environment" means an atmospheric environment which contains less than 100 particles, 0.5 microns in diameter, per cubic foot of air.

"Closed system transfer" means the movement of sterile products from one container to another in which the container-closure system and transfer devices remain intact throughout the entire transfer process, compromised only by the penetration of a sterile, pyrogen-free needle or cannula through a designated stopper or port to effect transfer, withdrawal, or delivery, to include the withdrawal of a sterile solution from an ampul in a Class 100 environment.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Cytotoxic drug" means a drug which has the capability of killing living cells.

"DEA" means the United States Drug Enforcement Administration.

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

"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.

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

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

"Floor stock" means a supply of drugs which have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Generic drug name" means the non-proprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hermetic container" means a container that is impervious to air or any other gas under the ordinary or customary conditions of handling, shipment, storage, and distribution.

"Home infusion pharmacy" means a pharmacy which compounds solutions for direct parenteral administration to a patient in a private residence, long term care facility or hospice setting.

"Hospital" or "nursing home" means those facilities as defined in Title § 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Light resistant container" means a container that protects the contents from the effects of light by virtue of the specific properties of the material of which it is composed, including any coating applied to it. Alternatively, a clear and colorless or a translucent container may be made light-resistant by means of an opaque covering, in which case the label of the container bears a statement that the opaque covering is needed until the contents have been used. Where a monograph directs protection from light, storage in a light-resistant container is intended.

"Long term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On-duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Open-system transfer" means the combining of products in a non-sealed reservoir before filling or when a solution passes through the atmosphere during a transfer operation.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Personal supervision" means the pharmacist 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 rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

“Pharmacy closing” means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

”PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for continuous monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"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.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

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

"Safety closure container" means a container which meets the requirements of the Federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is non-contiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug 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.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Sterile pharmaceutical product" means a dosage form free from living microorganisms.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).
2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" is a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77° F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Tight container" means a container that protects the contents from contamination by extraneous liquids, solids, or vapors, from loss of the drug, and from efflorescence, deliquescence, or evaporation under the ordinary or customary conditions of handling, shipment, storage, and distribution, and is capable of tight reclosure. Where a tight container is specified, it may be replaced by a hermetic container for a single dose of a drug and physical tests to determine whether standards are met shall be as currently specified in United States Pharmacopoeia-National Formulary.

"Unit-dose container" means a container that is a single-unit container, as defined in United States Pharmacopoeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

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

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18 VAC 110-20-20. Fees.

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

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

~~1. The application fee for a pharmacist license shall be $180.~~

~~2. The fees for taking all required examinations shall be paid directly to the examination service as specified by the board.~~

~~3. The application fee for a person whose license has been revoked or suspended indefinitely shall be $500.~~

~~C. Renewal of pharmacist license.~~

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

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

~~3. If a pharmacist fails to renew his license within the Commonwealth by the renewal date, he must pay the back renewal fee and a $30 late fee within 60 days of expiration.~~

~~4. Failure to renew a pharmacist license within 60 days following expiration shall cause the license to lapse and shall require the submission of a reinstatement application, payment of all unpaid renewal fees, and a delinquent fee of $70.~~

~~D. Other licenses, permits or facility registrations.~~

~~1. The following fees shall be required upon submission of a new facility application, change of ownership of an existing facility, or annual renewal:~~

~~a. Pharmacy permit ..... $270~~

b. Permitted physician to dispense drugs $270

c. Nonrestricted manufacturing permit $270

d. Restricted manufacturing permit $180

e. Wholesale distributor license $270

f. Warehouser permit $270

g. Medical equipment supplier permit $180

h. Licensed humane society permit $20

i. Non-resident pharmacy $270

j. Non-resident wholesale distributor $270

2. The following fees shall be required for facility changes:

a. Application for a change of the pharmacist-in-charge $50

b. Application for a change of location or a remodeling which requires an inspection $150

3. The following fees shall be required for late renewals or reinstatement:

a. If a facility fails to renew a required license, permit or registration prior to the expiration date, a late fee shall be assessed as follows:

1) For a resident or non-resident pharmacy, permitted physician, non-restricted manufacturer, resident or non-resident wholesale distributor, or warehouser, the late fee shall be $90.

2) For a restricted manufacturer or medical equipment supplier, the late fee shall be $60.

b. If a required license, permit or facility registration is not renewed within 60 days after its expiration, the license or permit shall lapse, and continued practice or operation of business with a lapsed license or permit shall be illegal. Thereafter, reinstatement shall be at the discretion of the board upon submission of an application accompanied by all unpaid renewal fees and a delinquent fee of $150.

E. Controlled substances registration

1. The application and annual fee for a controlled substances registration as required by § 54.1-3422 of the Code of Virginia shall be $90.

2. If a registration is not renewed within 60 days of the expiration date, the back renewal fee and a $30 late fee shall be paid prior to renewal.

3. If a controlled substance registration has been allowed to lapse for more than 60 days, all back renewal fees and a $35 delinquent fee must be paid before a current registration will be issued.

Engaging in activities requiring a controlled substance registration without holding a current registration is illegal and may subject the registrant to disciplinary action by the board. Reinstatement of a lapsed registration is at the discretion of the board and may be granted by the executive director of the board upon completion of an application and payment of all fees.

F. Other fees.

1. A request for a duplicate wall certificate shall be accompanied by a fee of $25.

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

3. The fee for board approval of an individual CE program is $100.

4. The fee for board approval of a robotic pharmacy system shall be $150.

5. The fee for a board-required inspection of a robotic pharmacy system shall be $150.

G. Approval of new process or procedure in pharmacy.

1. The fee for filing an application for board review of a new process, procedure or pilot project in pharmacy pursuant to § 54.1-3407.2 of the Code of Virginia shall be $250. The initial application shall specify each pharmacy location in which the pilot is to be implemented.

2. The fee for an inspection of a pilot process or procedure, if required by the informal conference committee, shall be $150 per location.

3. 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 be paid by the applicant.

4. The fee for a change in the name of the pharmacist responsible for the pilot program shall be $25.

5. Continued approval.

a. In the initial order granting approval, the informal conference committee shall also set an approval period with a schedule for submission of reports and outcome data. The frequency for submission of required reports shall not exceed four times per year.

b. The committee shall determine the appropriate fee for continued approval, which shall be based on the requirements for review and monitoring but which shall not exceed $200 per approval period.

H. Pharmacy Technicians.

1. The application fee for initial registration as a pharmacy technician shall be $25.

2. The application fee for a person whose registration has been suspended or revoked shall be $125.

3. The annual fee for renewal of a pharmacy technician registration shall be $25.

4. If a pharmacy technician fails to renew his registration within the Commonwealth by the renewal date, he must pay the back renewal fee and a $10 late fee within 60 days of expiration.

~~5. Failure to renew a pharmacy technician registration within 60 days following expiration shall cause the registration to lapse and shall require the submission of a reinstatement application, payment of all unpaid renewal fees, and a delinquent fee of $25.~~

6. ~~The application fee for approval of a training program for pharmacy technicians shall be $150.~~

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. Medical equipment supplier permit $180

11. Humane society permit $20

12. Non-resident pharmacy $270

13. Non-resident wholesale distributor $270

14. Controlled substances registrations $90

15. Robotic pharmacy system approval $150

16. 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. Medical equipment supplier permit $180

11. Humane society permit $20

12. Non-resident pharmacy $270

13. Non-resident wholesale distributor $270

14. Controlled substances registrations $90

15. 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. Medical equipment supplier permit $60

11. Humane society permit $5

12. Non-resident pharmacy $90

13. Non-resident wholesale distributor $90

14. 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. Medical equipment supplier permit $210

h. Humane society permit $30

i. Non-resident pharmacy $115

j. Non-resident wholesale distributor $115

k. 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 II. LICENSURE REQUIREMENTS FOR PHARMACISTS

18 VAC 110-20-30. Requirements for practical experience.

A. Each applicant for licensure by examination shall have gained practical-experience in the practice of pharmacy, to include no less than 300 hours in the area of prescription compounding and dispensing within a pharmacy.

B. An applicant who graduated from an approved school of pharmacy after January 1, 2003 shall accumulate a minimum of 1,500 hours of practical experience, of which at least 300 hours shall be gained outside of a school of pharmacy practical experience program. For purposes of this regulation, credit will not be given for more than 50 hours in any one week. ~~Students enrolled in a school of pharmacy prior to January 1, 1999 are required to have a minimum of 1,000 hours.~~ Applicants who graduated from an approved school of pharmacy prior to January 1, 2003 shall have gained at least 1,000 hours of practical experience.

C. All practical experience credit required shall only be gained after completion of the first professional year in an approved school of pharmacy.

D. Practical experience gained in a school of pharmacy which has a program designed to provide the applicant with practical experience in all phases of pharmacy practice and which program is approved by the American Council on Pharmaceutical Education will be accepted by the board for the time period during which the student is actually enrolled. The applicant will be required to gain any additional experience outside the school program as needed to meet the requirements of subsections A and B of this section.

E. In accordance with § 54.1-3312 of the Code of Virginia all practical experience required by this section shall be gained within the United States.

18 VAC 110-20-40. Procedure for gaining practical experience.

A. Each pharmacy student or graduate of an approved school of pharmacy, who desires to gain practical experience in a pharmacy within the Commonwealth, shall register with the board on a form provided by the board prior to becoming so engaged as a pharmacy intern. This requirement shall also apply to students gaining practical experience within the Commonwealth for licensure in another state.

B. The applicant shall be supervised by a pharmacist who holds an unrestricted license and assumes full responsibility for the training, supervision and conduct of the intern. The supervising pharmacist shall not supervise more than one pharmacy intern during the same time period.

C. The intern registration of a pharmacy student shall be valid only while the student is enrolled in a school of pharmacy. The registration card issued by the board shall be returned to the board upon failure to be enrolled.

D. Practical experience gained within any state must be registered with and certified by the board of that state in order to be accepted or certified by this board. In the event that a state does not use internships to gain practical experience in pharmacy but relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of experience gained in the United States may be accepted in lieu of board certification.

E. All practical experience of the pharmacy intern shall be evidenced by an affidavit, which shall be filed prior to or with the application for examination for licensure.

F. ~~An applicant for examination shall file the affidavits or certificates of experience on a form prescribed by the board no less than 30 days prior to the date of the examination.~~ An applicant for licensure by endorsement may provide verification acceptable to the board of practical experience hours worked as a pharmacist in another state within the United States in lieu of intern hours in order to meet the practical experience requirement.

18 VAC 110-20-60. Content of the examination and grades required; limitation on admittance to examination.

A. Prior to admission to any examination required for licensure, the applicant shall have met all other requirements, but in no case shall the applicant be admitted if grounds exist to deny licensure under § 54.1-3316 of the Code of Virginia.

B. The applicant shall achieve a passing score as determined by the board on the licensure examination which is approved by the board and which shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy.

C. The applicant shall also achieve a passing score as determined by the board on an examination, which tests the candidate's knowledge of federal and state laws related to pharmacy practice.

D. When an applicant for licensure by examination fails to meet the passing requirements of the board-approved integrated pharmacy examination on three occasions, he shall not be readmitted to the

examination until he has completed an additional ~~six months~~ 1,000 hours of practical experience as a pharmacy intern as set forth in 18 VAC 110-20-40.

18 VAC 110-20-70. Requirements for foreign trained applicants.

A. Applicants for licensure who were trained in foreign schools of pharmacy shall meet the following additional requirements prior to being allowed to take the examinations required by 18 VAC 110-20-60:

1. Obtain verification from the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy (NABP) that the applicant is a graduate of a foreign school of pharmacy. ~~verification of the following:~~

~~a. That the applicant is a graduate of a foreign school of pharmacy.~~

~~b. That the applicant has received a score acceptable to the board on the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).~~

~~c. That the applicant has received a score acceptable to the board on the Test of English as a Foreign Language (TOEFL).~~

2. Complete and receive a score acceptable to the board on the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).

3. Complete and receive a score acceptable to the board on the Test of English as a Foreign Language (TOEFL).

~~2~~ 4. Complete the Test of Spoken English (TSE) as given by the Educational Testing Service with a score acceptable to the board.

~~3~~ 5. Fulfill the requirements for practical experience as prescribed in subsections A, ~~and~~ B and E of 18 VAC 110-20-30 and ~~all of~~ subsections A, B, D, E and F of 18 VAC 110-20-40.

~~4~~ B. Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations ~~Fulfill the requirements for the examination and passing grade~~ as prescribed in 18 VAC 110-20-60.

18 VAC 110-20-80. Renewal and reinstatement of license.

A. Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and statement of compliance with continuing education requirements.

B. A pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.

C. A pharmacist who fails to renew his license by the expiration date may renew his license at any time within one year of its expiration ~~has 60 days in which to renew~~ by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.

D. ~~Failure to renew within the 60 days of expiration shall cause his license to lapse.~~ A pharmacist who fails to renew his license for more than one year following expiration and who wishes to reinstate

such license shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement. ~~upon completion of an application for reinstatement of license, the payment of all back renewal fees and a delinquent fee, and submission of a statement of compliance with continuing education requirements. Practice of pharmacy with a lapsed license shall be illegal and may subject the licensee to disciplinary action by the board~~

E. A pharmacist who has been registered as inactive for more than one year must apply for reinstatement, ~~comply with CE~~ submit documentation showing compliance with continuing education requirements, and pay the current year active renewal fee in order to resume active licensure.

F. In order to reactivate or reinstate a license to active status, a pharmacist who holds an inactive license, who has allowed his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEU's or hours equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 60 hours of CE.

G. A pharmacist whose license has been lapsed, in inactive status, or suspended or revoked for more than five years shall, as a condition of reinstatement in addition to 60 hours CE, take and receive a passing score on the board-approved law examination and furnish acceptable documentation of one of the following:

1. Active pharmacy practice within the past five years as a properly licensed pharmacist in another state; or

2. Practical experience as a pharmacy intern registered with the board of at least 160 hours within six months immediately prior to being reinstated.

H. The practice of pharmacy without a current, active pharmacist license is unlawful and shall constitute grounds for disciplinary action by the board.

~~F~~ I. It shall be the duty and responsibility of each licensee to inform the board of his current address. A licensee shall immediately notify the board in writing of any change of an address of record. All notices required by law or by these rules and regulations are deemed to be legally given when mailed to the address given and shall not relieve the licensee of the obligation to comply.

18 VAC 110-20-90. Requirements for continuing education.

A. On and after December 31, 1993, a ~~licensee~~ pharmacist shall be required to have completed a minimum of 1.5 CEU's or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEU's or hours in excess of the number required for renewal may not be transferred or credited to another year.

B. A pharmacy education program approved for continuing pharmacy education is:

1. One that is approved by the American Council on Pharmaceutical Education (ACPE);

2. One that is approved as a Category I Continuing Medical Education (CME) course, the primary focus of which is pharmacy, pharmacology or drug therapy; or

3. One that is approved by the board in accordance with the provisions of 18 VAC 110-20-100.

C. The board may grant an extension pursuant to § 54.1-3314 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

D. ~~Licensees~~ Pharmacists are required to attest to compliance with CE requirements in a manner approved by the board at the time of ~~on~~ their annual license renewal. Following ~~the~~ each renewal period, the board may conduct an audit of the immediate past two years CE documents ~~of licensees~~ to verify compliance with requirements. Pharmacists are required to maintain, for two years following renewal, the original certificates documenting successful completion of CE, showing date and title of the CE program or activity, the number of CEU's or contact hours awarded, and a certifying signature or other certification of the approved provider. ~~Licensees~~ Pharmacists selected for audit must provide these original documents to the board ~~certifying that they have fulfilled their CE requirements~~ by the deadline date ~~as~~ specified by the board in the audit notice.

~~E. All licensees are required to maintain original documents verifying the date and subject of the program or activity, the CEU's or contact hours , and certification from an approved provider. Original documents must be maintained for a period of two years following renewal in a file available to inspectors at the pharmacist's principal place of practice or if there is not principal place of practice, at the pharmacist's address of record.~~

~~F. A pharmacist who holds an inactive license, who has allowed his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEU's or hours equal to the requirements for the number of years in which his license has not been active.~~

PART III. REQUIREMENTS FOR PHARMACY TECHNICIAN REGISTRATION.

18 VAC 110-20-105. Renewal and reinstatement of registration

A. Pharmacy technician registrations expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee and renewal form. A pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Failure to receive the application for renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.

B. A pharmacy technician who fails to renew his registration by the expiration date may renew his registration at any time within one year of its expiration ~~has 60 days in which to renew~~ by submission of the renewal fee and late fee, renewal form, and proof of required continuing education.

C. ~~Failure to renew within the 60 days of expiration shall cause his registration to lapse.~~ A pharmacy technician who fails to renew his registration for more than one year following expiration and who wishes to reinstate such registration shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement ~~upon completion of an application for reinstatement of registration, the payment of all back renewal fees and a delinquent fee, and submission of original continuing education certificates~~. Conducting tasks associated with a pharmacy technician with a lapsed registration shall be illegal and may subject the registrant to disciplinary action by the board.

D. A person who fails to reinstate a pharmacy technician registration within five years of expiration, shall not be eligible for reinstatement and shall repeat an approved training program and repeat and pass the examination, or hold current PTCB certification, before applying to be re-registered.

PART IV. PHARMACIES.

18 VAC 110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than ~~one pharmacy~~ two pharmacies.

B. The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the ~~pharmacist-in-charge~~ PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

C. When the ~~pharmacist-in-charge~~ PIC ceases practice at a pharmacy or no longer wishes to be designated as ~~pharmacist-in-charge~~ PIC, he shall take a complete and accurate inventory of all Schedule II through V controlled substances on hand and shall immediately return the pharmacy permit to the board. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board, returning the permit, and taking the required inventory. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

D. An application for a permit designating the new ~~pharmacist-in-charge~~ PIC shall be filed with the required fee on a form provided by the board within 14 days of the original date of resignation or termination of the PIC. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline, unless the board receives a request for an extension prior to the deadline. The executor director for the board may grant an extension for up to an additional 14 days for good cause shown.

18 VAC 110-20-120. Special or limited-use pharmacy permits.

For good cause shown, the board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. 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. A policy and procedure manual detailing the type and method of operation, hours of operation, schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing pharmacist control must accompany the application.

3. The issuance and continuation of such permits shall be subject to continuing compliance with the conditions set forth by the board.

18 VAC 110-20-121. Innovative program approval.

A. An informal conference committee of the board may approve an innovative or pilot program in accordance with §54.1-3307.2 of the Code of Virginia upon receipt of an application and fee specified in 18 VAC 110-20-20 .

B. If the informal conference committee determines that an inspection is necessary to adequately consider an application, it may require that the applicant pay a fee specified in 18 VAC 110-20-20 to cover the cost of the inspection.

C. If the informal conference committee determines that a technical consultant is necessary in order for the board to make an informed decision on approval of a program, the applicant shall pay a consultant fee, not to exceed the actual cost of the consultation.

D. In the initial order granting approval of a program, the informal conference committee shall set the approval period with a schedule for submission of required reports and outcome data. The frequency of required reports shall not exceed four times a year.

E. The informal conference committee shall determine the appropriate fee for continued approval of the program based on the requirements for review and monitoring. Such renewal fee shall not exceed $200 per approval period.

18 VAC 110-20-130. Pharmacy closings, going out of business, and change of ownership.

A. At least 14 days prior to the date a pharmacy closes in accordance with § 54.1-3434.01 of the Code of Virginia or goes out of business, the owner shall notify the board. The proposed disposition of all Schedule II through VI drugs, prescription dispensing records, patient information records, and other required records shall be reported to the board. If the pharmacy drug stock and records are to be transferred to another licensee, the owner shall inform the board of the name and address of the licensee to whom the drugs and records are being transferred and the date of transfer.

B. Exceptions to the public notice as required in § 54.1-3434.01 of the Code of Virginia and the notice required in subsection A of this section shall be approved by the board and may include sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the pharmacy is not able to meet the notification requirements of § 54.1-3434.01, the owner shall ensure that the board and public are properly notified as soon as he knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

C. In the event of an exception to the notice as required in § 54.1-3434.01 of the Code of Virginia and subsection A of this section, the ~~pharmacist-in-charge~~ PIC or owner shall provide notice as far in advance of closing as allowed by the circumstances.

D. At least 14 days prior to any change in ownership of an existing pharmacy, the owner shall notify the board of the pending change.

1. Upon any change in ownership of an existing pharmacy, the prescription dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of pharmacy services.

2. The previous owner shall be held responsible for assuring the proper and lawful transfer of records on the date of the transfer.

3. The format of the prescription dispensing records, which are transferred to a new owner, shall comply with the requirements of Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia, and this chapter. Failure to comply with this regulation during a change in ownership shall be deemed to be a closing of the existing pharmacy for which the existing pharmacy owner shall be required to provide notice to the board and public in accordance with § 54.1-3434.01 of the Code of Virginia and subsection A of this section.

18 VAC 110-20-135. Change of hours in an existing pharmacy.

~~A.~~ The owner of the pharmacy shall be responsible for providing notice for a change in the hours of operation ~~shall be given~~ to the public and to the board in accordance with § 54.1-3434 of the Code of Virginia unless the change is necessitated by emergency circumstances beyond the control of the ~~pharmacist-in-charge or~~ owner, or unless the change will result in an expansion of the current hours of operation. If the pharmacy is not able to post the changes 14 days in advance as required by § 54.1-3434, ~~it~~ the owner shall ~~notify~~ ensure that the board is notified as soon as he knows of the change and disclose the emergency circumstances preventing the required notification.

18 VAC 110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.

A. Any person wishing to open a new pharmacy, engage in the acquisition of an existing pharmacy, change the location of an existing pharmacy, ~~or~~ move the location or make structural changes to an existing prescription department, or make changes to a previously approved security system shall file an application with the Board.

B. In the acquisition of an existing pharmacy, if prescription records are to be available to anyone other than authorized persons at the permitted pharmacy acquiring the records, the owner of the pharmacy acquiring the records shall disclose such information in writing to each patient 14 days prior to the acquisition.

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

1. Pharmacy permit 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 dispensing area shall comply with 18 VAC 110-20-150 through 18 VAC 110-20-190.

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 110-20-20 prior to a reinspection being conducted.

D. ~~Upon completion of the inspection, the Executive Director of the board shall review the findings of the inspection.~~ Drugs shall not be stocked within the proposed pharmacy or moved to a new location until approval is granted ~~or the permit is issued by the Executive Director of the board or his designee~~ by the inspector or board staff.

18 VAC 110-20-150. Physical standards for all pharmacies.

A. The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

B. Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to the effective date of this regulation. (November 3, 1993)

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

D. The entire area of the location of the pharmacy practice, including all areas where drugs are stored shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet U.S.P.-N.F. specifications for drug storage.

E. The prescription department counter workspace shall be used only for the compounding and dispensing of drugs and necessary record keeping.

F. A sink with hot and cold running water shall be within the immediate compounding and dispensing area.

G. Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department, if the pharmacy stocks such drugs.

18 VAC 110-20-160. Sanitary conditions.

A. The entire area of any place bearing the name of a pharmacy shall be maintained in a clean and sanitary manner and in good repair and order.

~~B. The prescription department and work counter space and equipment in the dispensing area shall be maintained in a clean and orderly manner.~~

~~C~~ B. Adequate trash disposal facilities and receptacles shall be available.

18 VAC 110-20-170. Required minimum equipment or resources.

The ~~pharmacist-in-charge~~ PIC shall be responsible for maintaining the following ~~equipment~~:

1. A current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy.

2. A set of prescription balances, sensitive to 15 milligrams, and weights or an electronic scale if the pharmacy engages in dispensing activities that require the weighing of components.

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

~~4~~ 3. Other equipment, supplies, and references consistent with the pharmacy's scope of practice and with the public safety.

18 VAC 110-20-180. Security system.

A device for the detection of breaking shall be installed in each prescription department of each pharmacy. 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 and shall have an auxiliary source of power.

3. The device shall fully protect the prescription department and shall be capable of detecting breaking by any means when activated.

4. Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy, except for access by other persons in accordance with 18 VAC 110-20-190 B 2~~;~~, and the system shall be activated whenever ~~those areas are~~ the prescription department is closed for business.

5. This regulation shall not apply to pharmacies which have been granted a permit prior to the November 4, 1993 provided that a previously approved security alarm system is in place, that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and provided further that a breaking and loss of drugs does not occur.

6. If the prescription department was located in a business with extended hours prior to November 4, 1993 and had met the special security requirements by having a floor to ceiling enclosure, a separately activated alarm system shall not be required.

7. This section shall not apply to pharmacies, which are open and staffed by pharmacists 24 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the ~~pharmacist-in-charge~~ PIC or owner must immediately notify the board and have installed within 72 hours a security system, which meets the requirements of 1 through 4 of this section.

18 VAC 110-20-190. Prescription department enclosures; access to prescription department.

A. The prescription departments of each pharmacy shall be provided with enclosures subject to the following conditions:

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

2. The enclosure shall be of sufficient height as to prevent ~~anyone~~ a person from reaching over to gain access to the drugs.

3. Entrances to the enclosed area must have a door with no more than a six-inch gap from the floor and which is at least as high as the adjacent structure. The requirement for a maximum six-inch gap shall not apply to those pharmacies in existence prior to February 3, 1999, with the exception of any pharmacy, which experiences a related diversion or theft.

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

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

1. Only pharmacists practicing at the pharmacy and authorized by the ~~pharmacist-in-charge~~ PIC shall be in possession of any keys to or other means of opening the locking device on the door to such enclosure, or to the alarm access code.

2. The pharmacist may place a key or other means of opening the locking device and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault within the pharmacy or other secured place. This key or code shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with paragraph D of this section. In lieu of the pharmacist'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 prescription department.

C. The prescription department is restricted to pharmacists ~~and interns~~ who are practicing at the pharmacy. ~~Clerical assistants and~~ Interns, pharmacy technicians, and other persons designated by the pharmacist may be allowed access by the pharmacist but only during the hours the pharmacist is on duty.

D. Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:

1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;

2. Alternate pharmacist coverage cannot immediately be obtained;

3. The technician is accompanied by a member of the pharmacy's management or administration, and

4. All requirements of subsection E of this section are met.

E. Requirements for entry into the prescription department in the absence of a pharmacist.

1. The requirements for prescriptions awaiting delivery in subsection A of 18 VAC 110-20-200 are followed;

2. Prior to entry into the prescription department, the pharmacy technician shall obtain verbal permission from the PIC or another pharmacist regularly employed by that pharmacy to obtain and use the emergency key or other access and alarm access code and enter the pharmacy;

3. A record shall be made by the pharmacy technician of the entry to include the date and time of entry, the name and signature of the pharmacy technician, the name, title, and signature of the person accompanying the pharmacy technician, the pharmacist's name granting permission to enter and telephone number where the pharmacist was reached; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department;

4. The pharmacy technician shall reseal the key and alarm access code after the pharmacy is re-secured, and the PIC shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.

5. All records related to entry by a pharmacy technician shall be maintained for a period of one year on premises.

18 VAC 110-20-200. Storage of drugs, devices, and controlled paraphernalia.

A. Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a secure place outside of the prescription department and access to the prescriptions restricted by the pharmacist to designated clerical assistants. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy which detail security of the dispensed prescriptions and a method of compliance with counseling requirements of § 54.1-3319 of the Code of Virginia. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription number(s), date of delivery, and the signature of the person receiving the prescription. Such log shall be maintained for a period of one year.

B. Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

C. Safeguards for controlled paraphernalia. Controlled paraphernalia shall not be placed ~~on open display or~~ in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

D. Expired drugs; security. Any drug, which has exceeded the expiration date, shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

18 VAC 110-20-210. Disposal of drugs by pharmacies.

If a ~~pharmacist-in-charge~~ PIC wishes to dispose of unwanted drugs, he shall use one of the following procedures:

1. Transfer the drugs to another person or entity authorized to possess or provide for proper disposal of such drugs; or

2. Destroy the drugs by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations. If Schedule II through V drugs are to be destroyed, the following procedures shall apply:

   a. At least 14 days prior to the destruction date, the ~~pharmacist-in-charge~~ PIC shall provide a written notice to the Board office; the notice shall state the following:

      (1) Date, time, manner, and place of destruction.

      (2) The names of the pharmacists who will witness the destruction process.

   b. If the destruction date is to be changed or the destruction does not occur, a new notice shall be provided to the board office as set forth above in subdivision 2 of this subsection.

   c. The actual destruction shall be witnessed by the ~~pharmacist-in-charge~~ PIC and another pharmacist not employed by the pharmacy.

   d. 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 pharmacy with other inventory records.

PART V. NUCLEAR PHARMACIES

18 VAC 110-20-220. General requirements for pharmacies providing radiopharmaceutical services.

A. A permit to operate a pharmacy providing radiopharmaceutical services shall be issued only to a qualified nuclear pharmacist as defined in 18 VAC 110-20-230. In emergency situations, in the absence of the nuclear pharmacist, he may designate one or more other qualified pharmacists to have access to the licensed area. These individuals may obtain single doses of radiopharmaceuticals for the immediate emergency and shall document such withdrawals in the control system.

B. Pharmacies providing ordinary pharmacy services in addition to radiopharmaceutical services shall comply with all regulations applicable to pharmacies in general. Pharmacies providing only radiopharmaceutical services shall comply with all regulations related to physical standards, sanitary conditions and security.

C. ~~The nuclear pharmacy area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least 25 square feet of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance and office area.~~ Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided and in compliance with standards and requirements of the Nuclear Regulatory Commission (NRC) and the Virginia Department of Health.

D. Radiopharmaceuticals are to be dispensed only upon an order from a practitioner authorized to possess, use and administer radiopharmaceuticals.

1. Orders shall originate at an institution or healthcare facility licensed to receive and possess radiopharmaceuticals, and must contain all necessary information relative to the radiopharmaceutical, activity, time of calibration, and any special preparation or delivery instructions.

2. Orders for radiopharmaceuticals may be transmitted orally, by fax, or by electronic transmission by an authorized agent of the prescriber. If the fax or electronic transmission of the authorized agent is pursuant to an oral order from the prescriber, the transmitted document need not include the prescriber's signature, but must include the name of the agent.

~~D~~E. The immediate outside container of a radioactive drug to be dispensed shall also be labeled in accordance with requirements of § 54.1-3410.1 B of the Code of Virginia.

~~E~~F. The immediate inner container shall be labeled with: (i) the standard radiation symbol; (ii) the words "Caution--Radioactive Material"; and (iii) the serial number assigned to the order.

~~F~~G. The amount of radioactivity shall be determined by radiometric methods for each individual dose immediately prior to dispensing.

~~G~~H. Nuclear pharmacies may redistribute approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

PART VI. DRUG INVENTORY AND RECORDS

18 VAC 110-20-240. Manner of maintaining records, prescriptions, inventory records.

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

1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy.

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

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

4. In the event that an inventory is taken as the result of a theft of drugs pursuant to § 54.1-3404 of the Drug Control Act, 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.

5. All inventories required by § 54.1-3404 shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall

clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

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

B. Prescriptions.

1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing.

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

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

C. Chart Orders.

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

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

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

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

3. Requirements for filing of chart orders.

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

b. If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor-stocked, but is

dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.

18 VAC 110-20-250. Automated data processing records of prescriptions.

A. An automated data processing system may be used for the storage and retrieval of original and refill dispensing information for prescriptions instead of manual record keeping requirements, subject to the following conditions:

1. A hard copy prescription shall be placed on file as set forth in 18 VAC 110-20-240 B.

a. In lieu of a hard copy file for Schedule VI prescriptions, an electronic image of a prescription may be maintained in an electronic database provided it preserves and provides an exact image of the prescription which is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.

b. If the pharmacy system's automated data processing system fields are automatically populated by an electronic transmission, the automated record shall constitute the prescription and a hard copy or electronic image is not required.

c. Storing electronic images of prescriptions for Schedule II-V controlled substances instead of the hard copy shall only be authorized if such storage is allowed by federal law.

2. Any computerized system shall provide retrieval (via computer monitor display or printout) of original prescription information for those prescriptions which are currently authorized for dispensing.

3. Any computerized system shall also provide retrieval via computer monitor display or printout of the dispensing history for prescriptions dispensed during the past two years.

4. Documentation of the fact that the information entered into the computer each time a pharmacist fills a prescription for a drug is correct shall be provided by the individual pharmacist who makes use of such system by either maintaining a log or printout. If ~~the system provides a printout~~ a printout is maintained of each day's prescription dispensing data, the printout shall be verified, dated and signed by the individual pharmacist who dispensed the prescription. The individual pharmacist shall verify that the data indicated is correct and then sign the document in the same manner as his name appears on his pharmacist license (e.g., J.H. Smith or John H. Smith).

~~In place of such printout, the pharmacy shall maintain a~~ If a bound log book, or separate file is maintained rather than a printout, ~~in which~~ each individual pharmacist involved in dispensing shall sign a statement each day in the log, in the manner previously described, attesting to the fact that the dispensing information entered into the computer that day has been reviewed by him and is correct as shown.

B. Any computerized system shall have the capability of producing a printout of any dispensing data which the user pharmacy is responsible for maintaining under the Drug Control Act (§ 54.1-3400 et seq of the Code of Virginia) and such printout shall be provided within 48 hours of a request of an authorized agent.

PART VII. PRESCRIPTION ORDER AND DISPENSING STANDARDS

18 VAC 110-20-280. Transmission of a prescription order by facsimile machine.

A. Prescription orders for Schedule III through VI drugs may be transmitted to pharmacies by facsimile device (FAX) upon the following conditions:

1. The prescription shall be faxed ~~transmission shall occur~~ only to the pharmacy of ~~with permission of~~ the patient's choice.

2. A valid faxed prescription shall contain all required information for a prescription~~.~~. A written prescription shall include ~~including~~ the prescriber's signature.

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

~~3~~4. A faxed prescription shall be valid only if faxed from the prescriber's practice location, except for forwarding a faxed chart order from a long term care facility or from a hospice. ~~and only if the~~

5. The following additional information ~~is~~ shall be recorded on the faxed prescription ~~prior to faxing~~:

~~a. Documentation that the prescription has been faxed;~~

~~b~~ a. The date that the prescription was faxed;

~~c~~b. The printed name, address, phone number, and fax number of the authorized prescriber ~~and the pharmacy to which the prescription was faxed~~; and

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

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

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

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

18 VAC 110-20-285. Electronic transmission of prescriptions from prescriber to pharmacy.

A. Unless otherwise prohibited by law, prescriptions may be transmitted by electronic means from the prescriber, or an authorized agent as defined in § 54.1-3408.01 of the Code of Virginia for transmission of oral prescriptions directly to the dispensing pharmacy. For electronic transmission of Schedule II-V prescriptions, transmissions shall comply with any security or other requirements of federal law. All electronic transmissions shall also comply with all security requirements of state law related to privacy of protected health information.

B. In addition to all other information required to be included on a prescription, an electronically transmitted prescription shall include the telephone number of the prescriber, the full name of the prescriber's agent if other than the prescriber transmitting, and date of transmission~~, and the identity of the receiving pharmacy~~.

C. A pharmacy receiving an electronic transmission prescription shall ~~either receive the prescription in hard copy form or shall print out a hard copy of the prescription from the pharmacy's computer memory~~ maintain such prescription record in accordance with 18 VAC 110-20-250 (A). ~~Any hard copy of a prescription shall be maintained on paper of permanent quality and shall be placed on file in accordance with 18 VAC 110-20-240 B.~~

D. An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice.

PART VIII. LABELING AND PACKAGING STANDARDS FOR PRESCRIPTIONS

18 VAC 110-20-330. Labeling of prescription as to content and quantity.

Unless otherwise directed by the prescribing practitioner, any drug dispensed pursuant to a prescription shall bear on the label of the container, in addition to other requirements of §§ 544.1-3410 and 54.1-3463 of the Code of Virginia, the following information:

1. 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 the label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed.

   c. The requirements of paragraphs a and b of this subsection shall not apply to drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer.

2. The number of dosage units, or if liquid, the number of milliliters dispensed.

18 VAC 110-20-350. Special packaging.

A. Each drug dispensed to a person in a household shall be dispensed in special packaging except when otherwise directed in a prescription by a practitioner, when otherwise requested by the purchaser, or

when such drug is exempted from 16 CFR § 1702.1 et seq. promulgated pursuant to the Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476).

B. Each pharmacy may have a sign posted near the prescription department advising the patients that nonspecial packaging may be requested.

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

18 VAC 110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.

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

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

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 or reconstituted units~~.

C. ~~Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall record for each bin the drug name; strength, if any; the name of the manufacturer or distributor; manufacturer's control or lot number; any assigned lot or control number; and an expiration date which does not exceed six months from the date of repackaging and which also does not exceed the manufacturer's expiration date. A drug with two separate manufacturer's or assigned lot or control numbers may be mixed in the same bin provided the expiration date of the older lot is used for the record and provided that the device clears all of the older lot before a third lot is added.~~ Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:

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

a. The drug name and strength, if any;

b. The name of the manufacturer or distributor;

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

d. Any assigned lot number; and

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

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

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

4. If only one lot is added to a bin at one time, but a second lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed, the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot, and the bin shall be allowed to "run dry" where all product is completely removed prior to filling at least once every 60 days with a record made of the run dry dates.

PART IX. STANDARDS FOR PRESCRIPTION TRANSACTIONS.

18 VAC 110-20-360. Issuing a copy of a prescription that can be filled or refilled.

A. Consistent with federal laws and regulations, a copy of a prescription shall be given upon request by one pharmacy to another ~~pharmacist~~ pharmacy provided the drug can be filled or refilled pursuant to §§ 54.1-3410 and 54.1-3411 of the Code of Virginia and provided the patient has given permission for the transfer.

B. The transfer of original prescription information for a drug listed in Schedules III through VI for the purpose of ~~refill~~ dispensing is permissible between pharmacies if the transfer is communicated directly between the two pharmacies ~~pharmacists~~ either orally by direct communication between the transferring pharmacist and the receiving pharmacist, or by facsimile machine or by electronic transmission, ~~and~~ provided:

1. The transferring ~~pharmacist~~ pharmacy ~~records the following information~~:

~~1~~ a. Records the word "VOID" on the face of the invalidated prescription;

~~2~~ b. Records on the reverse of the invalidated prescription the name, address, and, except for a prescription for a Schedule VI drug, the ~~Drug Enforcement Administration (~~DEA~~), registry~~ number of the pharmacy to which it was transferred~~, except for a prescription for a Schedule VI drug~~, and for an oral transfer, the name of the pharmacist receiving the prescription information; ~~and~~

~~3~~ c. Records the date of the transfer and, in the case of an oral transfer, the name of the pharmacist transferring the information~~, or in the case of an electronic transmission, the name of the pharmacist releasing the information~~ ; and

~~C~~ 2. The ~~pharmacist~~ receiving pharmacy ~~the transferred prescription information shall reduce to writing the following~~:

~~1~~ a. ~~Write~~ Writes the word "TRANSFER" on the face of the transferred prescription.

~~2~~ b. ~~Provide~~ Provides all information required to be on a prescription ~~and~~ to include:

~~a~~ (1). Date of issuance of original prescription;

~~b~~ (2). Original number of refills authorized on the original prescription;

~~c~~ (3). Date of original dispensing, if applicable;

~~d~~ (4). Number of valid refills remaining and date of last ~~refill~~ dispensing;

~~e~~ (5). Pharmacy name, address, DEA registry number except for Schedule VI prescriptions, and original prescription number from which the prescription information was transferred; and

~~f~~ (6). Name of transferring pharmacist, if transferred orally.

3. Both the original and transferred prescription shall be maintained for a period of two years from the date of last refill.

~~D~~ C. Nothing in this regulation shall prevent the giving of a prescription marked "For Information Only" to a patient.

~~E~~ D. ~~Pharmacists may use computer systems in lieu of recording on the hard copy prescription provided that the system used clearly meets all requirement of subsections B and C of this section while retaining all previous dispensing information.~~ In lieu of recording the required information in subsection B of this section on a hard copy prescription, a pharmacy may record all required information in an automated data processing system used for storage and retrieval of dispensing information in accordance with 18 VAC 110-20-250.

F. For prescriptions transferred between pharmacies using a common database, the pharmacy receiving the prescription shall not be required to maintain a hard copy pursuant to 18 VAC 110-20-240 B provided that the system used is capable of generating a hard copy of the transferred prescription upon request or except as required by federal law.

18 VAC 110-20-370. ~~Issuing a copy of a prescription that cannot be refilled.~~ (Repealed.)

~~A. A copy of a prescription for a drug which, pursuant to § 54.1-3411 of the Drug Control Act, cannot be refilled at the time the copy is requested, shall be given on request of a patient but such copy shall be marked with the statement "FOR INFORMATION ONLY," the patient's name and address, the date of the original prescription, and the date the copy was given.~~

~~B. A copy marked in this manner is not a prescription, as defined in § 54.1-3400 of the Drug Control Act, and shall not be refilled.~~

~~C. The original prescription shall indicate that a copy has been issued, to whom it was issued, and the issuing date.~~

~~D. Copies of prescriptions which cannot be refilled and which are transmitted electronically to another pharmacy shall meet all requirements of this section.~~

18 VAC 110-20-380. ~~Confidentiality of patient information.~~ (Repealed.)

~~A pharmacist shall not exhibit, dispense, or reveal any prescription or discuss the therapeutic effects thereof, or the nature or extent of, or the degree of illness suffered by or treatment rendered to, any patient served by the pharmacist with any person other than the patient or his authorized representative, the prescriber, or other licensed practitioner caring for this patient, or a person duly authorized by law to receive such information.~~

18 VAC 110-20-410. Permitted physician licensed by the Board.

A. Pursuant to §54.1-3304 of the Code of Virginia, ~~Permitted~~ physicians licensed by the board to dispense drugs, when pharmacy services are not reasonably available, shall be subject to the following sections of this chapter. For purposes of this section, the terms "pharmacist", "pharmacist-in-charge", and "PIC" in the sections listed below shall be deemed to mean the physician permitted by the board:

1. 18 VAC 110-20-110 (C) and (D);

2. 18 VAC 110-20-130 (A);

3. 18 VAC 110-20-140 (A), (C);

4. 18 VAC 110-20-150 except that these requirements shall not apply to physicians licensed prior to the effective date of this regulation (_____) unless the dispensing area is relocated or remodeled;

5. 18 VAC 110-20-160;

6. 18 VAC 110-20-180;

7. 18 VAC 110-20-190 (A), (B), and (C);

8. 18 VAC 110-20-200; and

9. 18 VAC 110-20-210;

10. 18 VAC 110-20-240 through 18 VAC 110-20-410.

B. A physician may apply for a special or limited use permit in accordance with 18 VAC 110-20-120.

PART X. COMPOUNDING STERILE PHARMACEUTICAL PRODUCTS

18 VAC 110-20-412. Policy and procedure manual.

A policy and procedure manual shall be prepared and maintained for the compounding, dispensing and delivery of sterile products that is consistent with USP-NF standards and guidance and shall include at least the following elements:

1. Personnel qualifications including initial and follow-up training and method of periodic re-evaluation of qualifications and performance;

2. Scope of compounding performed at the pharmacy and proper procedures for compounding to include maintaining suitable environmental conditions in the compounding area, wearing appropriate garb to reduce particulate matter and contamination of work area, performing aseptic procedures.

3. Procedures for maintaining and monitoring proper operating conditions for all equipment used in sterile compounding;

4. Guidelines for patient or caretaker education if products are dispensed for home use to include instructions concerning proper storage, aseptic manipulation of the product, proper administration and use of devices if applicable, recognizing signs of instability or incompatibility, and procedures in case of an emergency with the product;

5. Guidelines for assignment of beyond-use dates for all compounded sterile products and justification for any date chosen which exceeds the standard set forth in this regulation.

6. Separate procedures for handling cytotoxic drugs, if applicable, to include protective apparel; disposal procedures consistent with applicable local, state, and federal requirements; procedures for handling spills; special packaging and labeling requirements, and delivery procedures to minimize risks of accidental spills;

7. If applicable, separate procedures for compounding sterile products using non-sterile components or open system transfer techniques and for end-product sterilization of these products.

18 VAC 110-20-415. Quality assurance.

A. The ~~pharmacist-in-charge~~ PIC in a pharmacy compounding sterile products shall be responsible for maintaining and updating the policy and procedure manual as set forth in 18 VAC 110-20-411 in accordance with current acceptable standards, and for ensuring compliance with the policy and procedure manual.

B. All laminar flow hoods or other environmental control devices shall be certified according to accepted standards for operational efficiency by a qualified independent contractor initially, at least every six months or after relocation.

PART XI. UNIT DOSE DISPENSING SYSTEMS.

18 VAC 110-20-420. Unit dose dispensing system.

A. A unit dose drug dispensing system may be utilized for the dispensing of drugs to patients in a hospital or long term care facility. The following requirements shall apply regardless of whether licensed or unlicensed persons administer medications:

1. Any equipment outside the pharmacy used to house drugs to be administered in a unit dose system must be fitted with a locking mechanism and be locked at all times when unattended.

2. A signed order by the prescribing practitioner shall accompany the requests for a Schedule II drug, except that a verbal order for a hospital patient for a Schedule II controlled substance may be transmitted to a licensed nurse or pharmacist ~~employed by the hospital~~ at the hospital who ~~will~~ shall promptly reduce the order to writing in the patient's chart. Such an order shall be signed by the prescriber within 72 hours.

3. Properly trained personnel may transcribe the prescriber's drug orders to a patient profile card, fill the medication carts, and perform other such duties related to a unit dose distribution system provided these are done under the personal supervision of a pharmacist.

4. All dosages and drugs shall be labeled with the drug name, strength, lot number and expiration date when indicated.

5. The patient's individual drug drawer or tray shall be labeled with the patient's name and location.

6. All unit dose drugs intended for internal use shall be maintained in the patient's individual drawer or tray unless special storage conditions are necessary.

7. A back-up dose of a drug of not more than one dose unit may be maintained in the patient's drawer, tray, or special storage area provided that the dose is maintained in the patient's drawer, tray, or special storage area with the other drugs for that patient.

8. A record shall be made and maintained within the pharmacy for a period of one year showing:

   a. The date of filling of the drug cart;

   b. The location of the drug cart;

   c. The initials of person who filled the drug cart; and

   d. The initials of the pharmacist checking and certifying the contents of the drug cart in accordance with the provisions in 18 VAC 110-20-270 B.

9. A patient profile record or medication card will be accepted as the dispensing record of the pharmacy for unit dose dispensing systems only, subject to the following conditions:

   a. The record of dispensing must be entered on the patient profile record or medication card at the time the drug drawer or tray is filled.

   b. In the case of Schedule II through V drugs, after the patient profile record or medication card has been completed, the card must be maintained for two years.

   c. In the case of the computer-based distribution system, a uniformly maintained "fill list" or other document containing substantially the same information may be accepted as the dispensing record for Schedule II through VI drugs. Records of disposition/administration for floor stock drugs as provided in 18 VAC 110-20-460 B will be accepted for drugs distributed as floor stock.

B. In providing unit dose systems to hospitals or long term care facilities where only those persons licensed to administer are administering drugs, the pharmacy shall dispense not more than a seven-day supply of a drug in a solid, oral dosage form at any one given time.

C. In addition to the requirements listed in subsection A of this section, the following requirements apply to those long term care facilities in which unlicensed persons administer drugs:

1. The pharmacy providing medications to such facility shall dispense no more than a 72-hour supply of drugs in a solid, oral dosage form at any one given time.

2. The pharmacy shall provide to persons administering medications training specific to the particular unit dose system being used.

3. The pharmacy shall provide a medication administration record to the facility listing each drug to be administered with full dosage directions to include no abbreviations.

4. The drugs in a unit dose system shall be placed in slots within a drawer labeled or coded to indicate time of administration.

PART XII. PHARMACY SERVICES TO HOSPITALS.

18 VAC 110-20-440. Responsibilities of the pharmacist-in-charge.

A. The ~~pharmacist-in-charge~~ PIC in a pharmacy located within a hospital or the ~~pharmacist-in-charge~~ PIC of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for and assuring maintenance of the proper storage, security, and dispensing of all drugs used throughout the hospital.

B. The ~~pharmacist-in-charge~~ PIC of a pharmacy serving a hospital shall be responsible for a ~~monthly review of drug therapy for each patient within the hospital for a length of stay of one month or greater. A record of such review shall be signed and dated by the pharmacist~~ maintaining a policy and procedure for providing reviews of drug therapy ~~and shall~~ to include at a minimum ~~but not limited to~~ any irregularities in drug therapy, drug interactions, drug administration, or transcription errors. All significant irregularities shall be brought to the attention of the attending practitioner or other person having authority to correct the potential problem.

C. Prior to the opening of a satellite pharmacy within the hospital, the ~~pharmacist-in-charge~~ PIC shall notify the board as required by 18 VAC 110-20-140 and shall ensure compliance with subsections B through G of 18 VAC 110-20-150, 18 VAC 110-20-160, ~~subdivisions 5 and 6 of~~ 18 VAC 110-20-170, 18 VAC 110-20-180 through 18 VAC 110-20-190. No drugs shall be stocked in a satellite pharmacy until an inspection has been completed and approval given for opening.

D. For the following list of Schedule VI controlled substances, the PIC of a pharmacy serving a hospital may authorize the storage in an area of the hospital outside the pharmacy, and may delegate the ordering and distribution within the hospital to non-pharmacy personnel provided the conditions for proper storage and adequate security and the procedures for distribution are set forth in the pharmacy's policy and procedure manual, and provided that the PIC assures that these storage areas are checked monthly for compliance. The storage areas must be locked when authorized staff is not present in the area. Except for nitrous oxide, medical gases may be stored in an unlocked area.

1. Large volume parenteral solutions that contain no active therapeutic drugs other than electrolytes;

2. Irrigation solutions;

3. Contrast media;

4. Medical gases;

5. Sterile sealed surgical trays that may include a Schedule VI drug; and

6. Blood, blood components and derivatives, and synthetic blood components and products.

18 VAC 110-20-450. After-hours access to the pharmacy.

When authorized by the ~~pharmacist-in-charge~~ PIC, ~~a supervisory~~ an authorized nurse may have access to the pharmacy in the absence of the pharmacist in order to obtain emergency medication, provided that such drug is available in the manufacturer's original package or in units which have been prepared and labeled by a pharmacist and provided further that a separate record shall be made and left within the pharmacy on a form prescribed by the ~~pharmacist-in-charge~~ PIC and such records are maintained within the pharmacy for a period of one year showing:

1. The date of withdrawal;

2. The patient's name;

3. The name of the drug, strength, dosage form and dose prescribed;

4. Number of doses removed; and

5. The signature of the authorized nurse.

18 VAC 110-20-460. Floor stock drugs; proof of delivery; distribution records.

A. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the signatures of the dispensing pharmacist and the receiving nurse. Receipts shall be maintained in the pharmacy for a period of two years or in offsite storage which shall be retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

B. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The ~~pharmacist-in-charge~~ PIC or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record;

4. Initial ~~or sign~~ the returned record, file chronologically by date of issue, and retain for two years from the date of return or in offsite storage which shall be retrievable and made available for inspection or audit within 48 hours of a request by the Board or an authorized agent..

C. The filing requirements of 18 VAC 110-20-240 (A) (1) for separation of schedule II records shall be met for administration records if the schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

18 VAC 110-20-470. Emergency room.

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

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

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

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

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

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

   a. Date and time dispensed;

   b. Patient's name;

   c. Prescriber’s name;

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

18 VAC 110-20-480. ~~Pharmacy services.~~ (Repealed.)

~~A. In addition to service to inpatients, a hospital pharmacy may dispense drugs to the following:~~

~~1. Patients who receive treatments or consultations on the premises;~~

~~2. Outpatients, or emergency patients upon discharge for their personal use away from the hospital; and~~

~~3. The hospital employees, medical staff members, or students for personal use or for the use of their dependents.~~

~~Nothing in this regulation shall prohibit a hospital pharmacy not operated under a separate outpatient pharmacy permit from providing such services or drugs, or both, as are not readily available in the community to patients who may not otherwise be served by the hospital pharmacy.~~

~~B. If a pharmacy located within a hospital dispenses drugs to patients other than those listed in subsection A of this section, the pharmacy shall obtain a separate pharmacy permit and shall operate in a space separated from the hospital pharmacy.~~

18 VAC 110-20-490. Automated devices for dispensing and administration of drugs.

A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in

accordance with 18 VAC 110-20-270, 18 VAC 110-20-420 or 18 VAC 110-20-460 as applicable. The following conditions shall apply:

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

2. At the time of loading, the delivery record for all Schedule II through V drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy and maintained in chronological order for a period of two years from date of delivery. The delivery record and required signatures may be generated and/or maintained electronically provided the system being used has the capability of recording an electronic "signature" which is a unique identifier and restricted to the individual receiving the drugs and provided that this record is maintained in a "read-only" format which cannot be altered after the information is recorded. The electronic record shall be readily retrievable, maintained for a period of two years, and the system used shall be capable of producing a hard copy printout of the record upon request.

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

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

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

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

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

   c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample from each device shall not be less than 24 consecutive hours within the month being audited.

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

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

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit and maintained in the pharmacy for a period of two years. If non-pharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record. These distribution records reviewed in conducting the audit may be maintained electronically provided they can be readily retrieved upon request, provided they are maintained in a "read-only' format which does not allow alteration of the records, and provided a log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, initials of all reviewers.

~~The pharmacist-in-charge or his designee shall conduct at least a monthly audit and review of all distribution and administration of Schedule II through V drugs from each automated dispensing device. The audit shall reconcile the quantities loaded into the device and still on hand with the quantities removed from the device for administration. This audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper record keeping. Random checks shall be made to ensure that a valid order exists for each dose administered. The hard-copy distribution records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit and maintained in the pharmacy for a period of two years. If non-pharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record. These distribution records reviewed in conducting the audit may be maintained electronically provided they can be readily retrieved upon request, provided they are maintained in a "read-only' format which does not allow alteration of the records, and provided a log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, initials of all reviewers.~~

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

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

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

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

18 VAC 110-20-500. Licensed emergency medical service agencies program.

The pharmacy may prepare a drug kit for a licensed emergency medical services agency provided:

1. The ~~pharmacist-in-charge~~ PIC of the hospital pharmacy shall be responsible for all controlled drugs contained in this drug kit.

2. The drug kit is sealed in such a manner that it will preclude any possibility of loss of drugs.

3. Drugs may be administered by a emergency medical technician upon an oral order or written standing order of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the technician and shall be signed by a medical practitioner. Written standing orders shall be signed by the operational medical director for the emergency medical services agency. The emergency medical technician shall make a record of all drugs administered to a patient. This administration record shall be signed by the medical practitioner who assumes responsibility for the patient at the hospital. If the patient is not transported to the hospital or if the attending medical practitioner at the hospital refuses to sign the record, a copy of this record shall be signed and placed in delivery to the hospital pharmacy who was responsible for that kit exchange by the agency's operational medical director within seven days of the administration.

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

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

18 VAC 110-20-510. Identification for intern or resident prescription form in hospitals.

The prescription form for the prescribing of drugs for use by attending physicians, medical interns or residents who prescribe only in a hospital shall bear the prescriber's signature, the legibly printed name, address, and telephone number of the prescriber and an identification number assigned by the hospital. The identification number shall be the Drug Enforcement Administration number assigned to the hospital pharmacy plus a suffix assigned by the institution. The assigned number shall be valid only within the course of duties ~~within the hospital~~ as part of the residency program.

PART XIII. PHARMACY SERVICES TO LONG TERM CARE FACILITIES.

18 VAC 110-20-530. Pharmacy's responsibilities to long term care facilities.

The pharmacy serving a long term care facility shall:

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

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

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

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

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

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

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

   a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for re-dispensing to the indigent if authorized by § 54.1-3411.1 and 18 VAC 110-20-400, or destroyed by appropriate means in compliance with any applicable local, state, and federal laws and regulations.

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

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

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

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

9. Ensure that a monthly review of a drug therapy by a pharmacist is conducted for each patient in long term care facilities except those licensed under Title 63-1 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

18 VAC 110-20-540. Emergency drug kit.

The pharmacist providing services may prepare an emergency kit for a facility in which only those persons licensed to administer are administering drugs under the following conditions:

1. The contents of the emergency kit shall be of such a nature that the absence of the drugs would threaten the survival of the patients.

2. The contents of the kit shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL may be included.

3. The kit is sealed in such a manner that it will preclude any possible loss of the drug.

   a. The dispensing pharmacy must have a method of sealing such kits so that once the seal is broken; it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced.

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

4. The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time and name and quantity of item(s) removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.

5. Any drug used from the kit shall be covered by a prescription, signed by the prescriber, when legally required, within 72 hours.

18 VAC 110-20-550. Stat-drug box.

An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. A stat-drug box shall be provided to those facilities in which only those persons licensed to administer are administering drugs and shall be subject to the following conditions:

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

a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken; it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

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

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

3. Any drug used from the box shall be covered by a drug order signed by the prescriber, when legally required, within 72 hours.

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

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

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

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

b. The stat-drug box shall contain no Schedule II drugs.

c. The stat-drug box shall contain no more than one Schedule III through V drug in each therapeutic class and no more than five doses of each.

18 VAC 110-20-555. Use of automated dispensing devices.

~~A. An automated dispensing device may be used in place of stat drug boxes or emergency drug kits provided the conditions of subdivisions 1, 2, and 5 of 18 VAC 110-20-540 and subdivisions 3 and 6 of 18 VAC 110-20-550 have been met. In addition to these provisions, the drugs placed in these devices shall be limited to the drugs which would have been stocked in the stat drug boxes and emergency kits, and the quantity of any one drug shall not exceed the total quantity which would have been stored at one facility in all stat boxes and emergency kits combined. No more than a 48-hour supply per each 50 residents per drug may be stocked in the device.~~ Nursing homes licensed pursuant to Section 32.1, Chapter 5 (§123-162.15) may use automated drug dispensing systems, as defined in § 54.1-3401, upon meeting the following conditions:

~~B. The use of such devices is limited to those long-term care facilities where only persons holding a license to administer drugs are actually administering. Use of automated dispensing devices in long-term care facilities shall be in compliance with the following:~~

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

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

3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber. A drug may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order. The PIC of the provider pharmacy shall ensure that a pharmacist who has on-line access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

~~1~~ 4. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original packaging or in repackaged containers in compliance with the requirements of 18 VAC 110-20-355 relating to repackaging, labeling, and records.

~~2~~ 5. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; nursing home; and a unique identifier for the specific device receiving drugs; and initials of pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution.

3 6. ~~Drugs may be loaded in the device by a pharmacist or by a person licensed to administer drugs working at the long term care facility.~~ At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

4 7. At the time of loading, the delivery record for all Schedule II through V drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy and maintained in chronological order for a period of two years from date of delivery. The delivery record and required signatures may be generated or maintained electronically provided the system being used has the capability of recording an electronic "signature" which is a unique identifier and restricted to the individual receiving the drugs and provided that this record is maintained in a "read-only" format which cannot be altered after the information is recorded. The electronic record shall be readily retrievable, maintained for a period of two years, and the system used shall be capable of producing a hard copy printout of the record upon request.

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

~~6. The provider pharmacy shall have the capability of on-line communication with any automated dispensing devices in a long-term care facility. The pharmacy shall be capable of producing a hard copy record of distribution from the device which shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug. Except for emergency or urgent administration during times when a pharmacist is not available, the pharmacist shall review and approve a new order prior to a dose being removed for administration to a patient.~~

~~7~~9. The PIC of the provider pharmacy or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

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

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

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample from each device shall not be less than 24 consecutive hours within the month being audited.

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

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

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit and maintained in the pharmacy for a period of two years. If non-pharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record. These distribution records reviewed in conducting the audit may be maintained electronically provided they can be readily retrieved upon request, provided they are maintained in a "read-only' format which does not allow alteration of the records, and provided a log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, initials of all reviewers.

~~The pharmacist-in-charge of the provider pharmacy or his designee shall conduct at least a monthly audit and review of all distribution and administration of Schedule II through V drugs from each automated dispensing device. The audit shall reconcile the quantities loaded into the device and still on hand with the quantities removed from the device for administration. This audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper record keeping. A check by the pharmacy shall be made to ensure that a valid order exists for each dose administered from the automated dispensing device. The hard copy distribution records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit and maintained in the pharmacy for a period of two years. If the person designated by the pharmacist-in-charge to conduct the audit is not a pharmacist, a pharmacist shall review the audit and shall initial and date the record of the audit. These distribution records reviewed in conducting the audit may be maintained electronically provided they can be readily retrieved upon request, provided they are maintained in a "read-only' format which does not allow alteration of the records, and provided a log is maintained for a period of two years showing the dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.~~

~~8~~10. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

~~9~~11. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

~~10~~12.~~Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.~~ The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this regulation.

PART XIV. OTHER INSTITUTIONS AND FACILITIES

18 VAC 110-20-590. Drugs in correctional institutions.

A. All prescription drugs at any correctional unit shall be obtained only on an individual prescription basis from a pharmacy and subject to the following conditions:

1. All prepared drugs shall be maintained in a suitable locked storage area with only the person responsible for administering the drugs having access.

2. Complete and accurate records shall be maintained of all drugs received, administered and discontinued. The administration record shall show the:

a. ~~Prescription number~~ Patient name;

b. Drug name and strength;

c. Number of dosage units received;

d. Prescriber's name; and

e. Date, time and signature of person administering the individual dose of drug.

3. All unused or discontinued drugs shall be sealed and the amount in the container at the time of the sealing shall be recorded on the drug administration record. Such drugs shall be returned to the provider pharmacy or to a secondary pharmacy along with the drug administration record within ~~seven~~ thirty days of discontinuance.

a. The provider or secondary pharmacy shall conduct random audits of returned drug administration records for accountability.

b. The drug administration records shall be filed in chronological order by the provider or secondary pharmacy and maintained for a period of one year or, at the option of the facility, the records may be returned by the ~~provider~~ pharmacy to the facility.

c. Drugs may be returned to ~~the provider~~ pharmacy stock in compliance with the provisions of 18 VAC 110-20-400.

d. Other drugs shall be disposed of or destroyed by the provider pharmacy in accordance with local, state, and federal regulations.

Alternatively, drugs for destruction may be forwarded by a pharmacist directly from the correctional facility to a returns company after performing the audit required by subdivision a of this section and ensuring the proper maintenance of the administration records.

B. ~~4.~~ Emergency and stat-drug box. An emergency box and a stat-drug box may be prepared for the facility served by the pharmacy pursuant to 18 VAC 110-20-540 and 18 VAC 110-20-550 provided that the facility employs one or more full-time physicians, registered nurses, licensed practical nurses, physician assistants or correctional health assistants.

C. Prescription drugs may be stocked at a medical clinic or surgery center which is part of a correctional facility and which is staffed by one or more physicians during the hours of operation provided the clinic first obtains a controlled substances registration and complies with the requirements of 18 VAC 110-20-690, 18 VAC 110-20-700, 18 VAC 110-20-710, and 18 VAC 110-20-720.

PART XV. EXEMPTED STIMULANT OR DEPRESSANT DRUGS AND CHEMICAL PREPARATIONS

PART XVI. MANUFACTURERS, WHOLESALE DISTRIBUTORS, WAREHOUSERS, AND MEDICAL EQUIPMENT SUPPLIERS

18 VAC 110-20-680. Medical equipment suppliers

A. A medical equipment supplier's location shall be inspected by the board prior to engaging in business. The location shall be clean and sanitary, and shall have a system of temperature control to provide for specified storage conditions for any Schedule VI drug or device.

B. Hypodermic needles and syringes and Schedule VI drugs shall not be placed on open display or in an open area where patrons will have access to such items. No Schedule VI devices shall be placed in an area where responsible parties cannot exercise reasonable supervision and control.

C. A medical equipment supplier must receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier.

D. Medical equipment suppliers shall make a record at the time of dispensing. This record shall be maintained on the premises for two years from date of dispensing and shall include:

1. Name and address of patient;

2. Item dispensed and quantity, if applicable; and

3. Date of dispensing.

PART XVII. CONTROLLED SUBSTANCES REGISTRATION FOR OTHER PERSONS OR ENTITIES.

18 VAC 110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity which maintains or intends to maintain a supply of Schedule II through Schedule VI controlled substances, other than manufacturer's samples, in order to administer such drugs in accordance with provisions of the Drug Control Act may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, out-patient clinics, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and

hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant the board shall consider factors listed in subsections A and D of § 54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

D. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedule II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion , theft, or other unusual loss of controlled substances which requires reporting pursuant to §54.1-3404 of the Code of Virginia, Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

18 VAC 110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other person or entity approved by the board, a practitioner of pharmacy, medicine, osteopathy, podiatry, dentistry, or veterinary medicine whose scope of practice is consistent with the practice of the person or entity and who is approved by the board shall provide the required supervision.

B. The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia or to other such persons as designated to have access in an emergency situation.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and record-keeping.

18 VAC 110-20-710. Requirements for storage and security for controlled substances registrants.

A. Drugs shall be stored under conditions which meet USP-NF specifications or manufacturers' suggested storage for each drug.

B. Any drug which has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.

C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedule II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.

D. Drugs shall be maintained in a lockable cabinet, cart, device or other area which shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with subsection C of 18 VAC 110-20-700.

E. In a facility not staffed 24-hours a day, the drugs shall be stored in a fixed and secured room, cabinet or area which has a security device for the detection of breaking meeting the following conditions:

1. The device shall be 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.

6. An alarm system is not required for researchers or animal control officers.