Project 753

BOARD OF PHARMACY

Periodic review

Part I
General Provisions

18VAC110-20-10. 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 this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy 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 50% 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.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"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.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"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.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

"Electronic transmission prescription" means 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 that 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.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

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

"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.

"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.

"NABP" means the National Association of Boards of Pharmacy.

"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.

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

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed, and drugs on hand by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act 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.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"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~~ ongoing 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 nonradioactive 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 noncontiguous 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.

"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" means 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.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-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.

"USP-NF" 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.

18VAC110-20-20. Fees.

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

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

C. Initial application fees.

1. Pharmacist license $180

2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Permitted physician licensed to dispense drugs	$270
6. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Nonresident pharmacy	$270
9. Controlled substances registrations ~~(Between November 2, 2005, and December 31, 2006, the application fee for a controlled substance registration shall be $50)~~	$90
~~10. Robotic pharmacy system approval~~	~~$150~~
~~11.~~ 10. Innovative program approval. 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.	$250
~~12.~~ 11. Approval of a pharmacy technician training program	$150
~~13.~~ 12. 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. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Nonresident pharmacy	$270
9. Controlled substances registrations	$90
10. Innovative program continued approval based on board order not to exceed $200 per approval period.	
11. Approval of a pharmacy technician training program	$75 every two years

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 or within two years in the case of a pharmacy technician training program. 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. Medical equipment supplier permit	$60
7. Humane society permit	$5
8. Nonresident pharmacy	$90
9. Controlled substances registrations	$30
10. Approval of a pharmacy technician training program	$15

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, 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. Medical equipment supplier permit	$210
d. Humane society permit	$30
e. Nonresident pharmacy	$115
f. Controlled substances registration	$180
g. Approval of a pharmacy technician training program	$75

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	$35

~~I. For the annual renewal due on or before December 31, 2006, the following fees shall be imposed for a license, permit or registration:~~

~~1. Pharmacist active license~~	~~$50~~
~~2. Pharmacist inactive license~~	~~$25~~
~~3. Pharmacy technician registration~~	~~$15~~
~~4. Pharmacy permit~~	~~$210~~
~~5. Physician permit to practice pharmacy~~	~~$210~~
~~6. Medical equipment supplier permit~~	~~$140~~
~~7. Humane society permit~~	~~$20~~
~~8. Nonresident pharmacy~~	~~$210~~
~~9. Controlled substances registrations~~	~~$50~~

Part II

Licensure Requirements for Pharmacists

18VAC110-20-30. Requirements for pharmacy practical experience.

A. Each applicant for licensure ~~by examination~~ as a pharmacist 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~~ as set forth in this section and 18VAC110-20-40.

B. An applicant ~~who graduated from an approved school of pharmacy after January 1, 2003 shall accumulate~~ for licensure as a pharmacist shall attain 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 chapter, credit will not be given for more than 50 hours in any one week. 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. Practical experience that is gained within an ACPE-accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1,500 hours of practical experience, shall meet the board's practical experience requirements for licensure as a pharmacist.

~~C.~~ D. All practical experience credit ~~required~~ gained outside of an ACPE-accredited school of pharmacy program shall only be gained after successful completion of the ~~first professional year in an approved school of pharmacy~~ equivalent of at least two semesters in an ACPE-accredited school of pharmacy. Credit shall not be given for more than 50 hours in one week and not less than an average of 20 hours per week averaged

over a month. The board may grant an exception to the minimum number of hours for good cause shown.

~~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.

~~18VAC110-20-40. 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~~ person desiring to gain practical pharmacy experience in Virginia shall first register with the board as a pharmacy intern on a form provided by the board prior to becoming so engaged as a pharmacy intern. This requirement shall ~~also~~ apply to ~~students~~ any person gaining practical experience within the Commonwealth whether for licensure in Virginia or in another state.

B. In order to be eligible to register as a pharmacy intern, an applicant shall meet at least one of the following criteria:

1. The applicant shall be enrolled in and have started course work in a professional degree program of a board-approved school of pharmacy. Such registration is only valid while the student is enrolled in the school of pharmacy and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist. An expiration date shall be assigned to the registration to cover the estimated time period for the student to complete the school program and pass the required examinations. If the student is no longer enrolled in the school program, takes a voluntary break from the program, or is otherwise not actively participating in the school program, except for regularly scheduled school breaks, the registration is no longer valid and shall be returned to the board immediately;

2. The applicant is a graduate of a board-approved school of pharmacy or a graduate of a foreign school of pharmacy, has established educational equivalency and proficiency in English by obtaining the FPGEC certificate, and desires to gain required practical experience required for licensure as a pharmacist. Such applicant shall provide documentation on a board-approved form of current employment or an employment start date within 90 days in a pharmacy in Virginia with approval by the supervising pharmacist. An expiration date shall be assigned to cover the estimated time period needed to obtain the required practical experience hours and take the required examinations to become licensed as a pharmacist;

3. The applicant has already gained the required practical experience, but is an otherwise qualified applicant awaiting examination for licensure. A three-month expiration date shall be assigned to allow the applicant time to take required examinations; or

4. The applicant is an applicant for reactivation or reinstatement of a previously issued pharmacist license and is meeting board requirements for relicensure. An expiration date shall be assigned to reasonably cover the period of time necessary to meet the board requirements.

C. For documented, good cause shown, the executive director of the board may extend the expiration date of the intern registration upon submission of an application form approved by the board and payment of the initial application fee.

~~B. The applicant~~ D. A pharmacy intern shall be supervised by a pharmacist who holds ~~an~~ a current, 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.~~ E. 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.~~ F. Practical experience gained within any other 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.~~ G. All practical experience of the pharmacy intern shall be evidenced by an affidavit approved by the board, which shall be filed prior to or with the application for examination for licensure.

~~F.~~ H. 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 prelicensure intern hours in order to meet the practical experience requirement

I. A pharmacy intern shall notify the board in writing of any change in address of record within 14 days of such change.

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

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

~~1. On and after June 1, 1928, but before June 1, 1936, the applicant for licensure shall have been graduated from a three-year course of study with a pharmacy graduate or pharmacy college degree in pharmacy awarded.~~

~~2.~~ 1. On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy awarded.

~~3.~~ 2. On and after June 1, 1964, the applicant for licensure shall have been graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded.

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

18VAC110-20-60. 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 to include education and practical experience 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.~~ C. 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 1,000 hours of practical experience as a pharmacy intern as set forth in 18VAC110-20-40.

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

E. When an applicant fails to pass the law examination, he shall not be allowed to retake it for a period of 30 days.

F. If an applicant requests a testing accommodation for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act, the board may approve a reasonable accommodation that does not compromise the security or integrity of the examination.

1. Supporting documentation shall be provided by the applicant to include the following to be considered for review:

a. A letter of request from the candidate that specifies the testing accommodation requested;

b. A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional that states a diagnosis of the disability, describes the disability, recommends specific accommodations, and provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one that is not subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation; and

c. A written statement from the appropriate person at the applicant's school of pharmacy that describes any testing accommodations made while the student was enrolled, if applicable.

2. The applicant will be notified in writing of the decision. If the request for accommodation is granted, the approval information will be forwarded to the examination contractor and the form of the accommodation will be coordinated with the contractor.

18VAC110-20-70. Requirements for foreign-trained applicants.

A. Applicants for licensure who were trained in foreign schools of pharmacy shall ~~meet the following additional requirements~~ obtain the FPGEC certificate prior to being allowed to ~~take the examinations required by 18VAC110-20-60:~~ register as a pharmacy intern and gain required practical experience in Virginia.

~~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.~~

~~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) or on the TOEFL iBT, the Internet-based tests of listening, reading, speaking and writing.~~

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

~~5. Fulfill~~ B. After obtaining the FPGEC certificate, the applicant may apply for a pharmacy intern registration and shall fulfill ~~the requirements for practical experience as prescribed~~ set forth in 18VAC110-20-30 ~~A, B and E~~ and 18VAC110-20-40 ~~A, B, D, E and F~~ before being admitted to examinations required by 18VAC110-20-60.

~~B.~~ C. Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations ~~as prescribed~~ set forth in 18VAC110-20-60 before being licensed as a pharmacist.

18VAC110-20-80. 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 by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.

D. 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.

E. A pharmacist who has been registered as inactive for more than one year must apply for reinstatement, 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.

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 within 14 days in writing or electronically of any change of an address of record. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law or by these rules and regulations ~~are deemed to be legally given when mailed to the address given~~ of record and shall not relieve the licensee of the obligation to comply.

18VAC110-20-90. Requirements for continuing education.

A. ~~On and after December 31, 1993, a~~ A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs 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 Accreditation Council for Pharmacy 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 18VAC110-20-100.

C. The board may grant an extension pursuant to ~~§ 54.1-3314~~ § 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

D. Pharmacists are required to attest to compliance with CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years' CE documents to verify compliance with requirements. Pharmacists are required to maintain, for ~~two~~ three 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. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

18VAC110-20-100. Approval of continuing education programs.

A. The board will approve without application or further review any program offered by an ACPE-approved provider and will accept for credit certificates bearing the official ACPE logo and program number.

B. The board may approve an individual CE program under the following provisions:

1. An approved individual program is a course, activity, or lecture which includes subject matter related to the competency of the practice of pharmacy and which has been approved for CE credit by the board.

2. In order to receive approval for an individual program, the sponsor or provider must ~~make application~~ apply prior to the program offering on a form provided by the board. The information which must be provided shall include but not be limited to: name of provider, location, date and time of program, charges to participants, description of program content and objectives, credentials of speaker or author, method of delivery, evaluation procedure, evidence of a ~~pre and~~ post ~~test~~ assessment, credits requested, mechanism for recordkeeping, and any such information as the board deems necessary to assure quality and compliance.

3. The sponsor ~~making application~~ applying for board approval of an individual program must pay a fee as required in 18VAC110-20-20 C 18.

4. The board shall notify the provider or sponsor within 60 days following the receipt of a completed application of approval or disapproval of a program and the number of credits which may be awarded. The board shall also assign an expiration date for approval of the program not to exceed two years from the date of approval.

5. The provider of an approved program shall provide to each participant who completes the required hours and passes the post test a certification with the name of the provider, name of the participant, description of course and method of delivery, number of hours credited, date of completion, and program identification number.

6. The provider of an approved program shall maintain all records on that program, its participants, and hours awarded for a period of ~~three~~ five years and shall make those records available to the board upon request.

7. The board shall periodically review and monitor programs. The provider of a CE program shall waive registration fees for a representative of the board for that purpose.

8. Any changes in the information previously provided about an approved program or provider must be submitted or the board may withdraw its approval. If a provider wants to give a live program more than once, all program dates must either be submitted on the original application or provided to the board in subsequent correspondence at least five days prior to giving the program.

Part III

Requirements for Pharmacy Technician Registration

18VAC110-20-101. Application for registration as a pharmacy technician.

A. Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.

B. In order to be registered as a pharmacy technician, an applicant shall provide evidence of the following:

1. Satisfactory completion of an approved training program, and

2. A passing score on a board-approved examination.

C. In lieu of the requirements of subsection B of this section, an applicant may provide evidence of current PTCB certification.

D. A pharmacy technician trainee may perform tasks restricted to pharmacy technicians for no more than nine months without becoming registered as a pharmacy technician.

18VAC110-20-102. Criteria for approval for training programs.

A. Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee and an application on a form approved by the board and meet the criteria established in this section.

B. The curriculum of a training program for pharmacy technicians shall include instruction in applicable, current laws and regulations and in the tasks that may be performed by a pharmacy technician to include the following or any other task restricted to pharmacy technicians in regulation:

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

2. The preparation of prescription labels or patient information;

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

4. The counting, measuring, or compounding of the drug to be dispensed;

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

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process; and

7. The acceptance of refill authorization from a prescriber or his authorized agent provided there is no change to the original prescription.

C. ~~Instructors~~ Each program shall have a program director who shall be either (i) a pharmacist with a current ~~unrestricted~~ license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current ~~unrestricted~~ registration in Virginia or ~~a~~ current PTCB certification and who is not currently suspended or revoked as a pharmacy technician in any jurisdiction; or (iii) other person approved and deemed qualified by the board to be ~~an instructor~~ a program director.

D. Instructors for the core components listed in subsection B of this section shall meet the requirements for the program director listed in subsection C of this section. The program director may serve as an instructor.

~~D.~~ E. The length of the program shall be sufficient to prepare a program participant to sit for the board-approved examination and demonstrate entry-level competency.

~~E.~~ F. The program shall maintain records of program participants either on-site or at another location where the records are readily retrievable upon request for inspection. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by the board. Records shall be maintained for two years from date of completion or termination of program.

G. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, instructors, name of institution or business if applicable, address, program content, length of program, or location of records.

H. A pharmacy technician training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's

approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-20-103. Examination.

A. The board shall approve one or more examinations to test entry-level competency for pharmacy technicians. In order to be approved, a competency examination shall be developed in accordance with and meet the recognized acceptable test measurement standards of the Joint Technical Standards for Education and Psychological Testing (American Psychological Association, current edition), and shall be administered by an independent third party.

B. The board may contract with an examination service for the development and administration of a competency examination.

C. The board shall determine the minimum passing standard on the competency examination.

D. Any requests for testing accommodations under the Americans with Disabilities Act shall be in accordance with the provisions of 18VAC110-20-60 F.

18VAC110-20-104. Address of record; maintenance of certificate.

A. It shall be the duty and responsibility of each pharmacy technician to inform the board of his current address. A pharmacy technician shall notify the board in writing or electronically of any change of an address of record within ~~30~~ 14 days. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law or by these rules and regulations are deemed to be legally given when mailed to the address ~~given~~ of record and shall not relieve the registrant of the obligation to comply.

B. A pharmacy technician shall maintain his current registration certificate at his principal place of practice available for inspection upon request. A pharmacy technician who does not have a principal place of practice may maintain it at any pharmacy in which he practices or his address of record.

18VAC110-20-106. Requirements for continued competency.

A. A pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved continuing education for each annual renewal of registration. Hours in excess of the number required for renewal may not be transferred or credited to another year.

B. An approved continuing education program shall meet the requirements as set forth in subsection B of ~~18VAC110-20-90~~ 18VAC110-20-100.

C. Upon written request of a pharmacy technician, the board may grant an extension of up to one year in order for the pharmacy technician to fulfill the continuing education requirements for the period of time in question. The granting of an extension shall not relieve the pharmacy technician from complying with current year requirements. Any subsequent extension shall be granted for good cause shown.

D. Original certificates showing successful completion of continuing education programs shall be maintained by the pharmacy technician for a period of ~~two~~ three years following the renewal of his registration. The pharmacy technician shall provide such original certificates to the board upon request in a manner to be determined by the board.

Part IV
Pharmacies

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than 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 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 PIC ceases practice at a pharmacy or no longer wishes to be designated as 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 indicating the effective date on which he ceased to be the PIC.

D. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedule II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

E. 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[~~,~~ and]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.~~ F. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. 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 executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

G. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

H. Before any permit is issued, the applicant shall attest to compliance with all federal, state and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after (effective date of this subsection).

18VAC110-20-111. Pharmacy technicians.

A. Every pharmacy that employs or uses pharmacy technicians shall maintain a site-specific training program and manual for training pharmacy technicians to work at that pharmacy. The program shall include training consistent with that specific pharmacy practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used at the pharmacy in performing technician duties, and pharmacy calculations consistent with the duties at that pharmacy.

B. Every pharmacy shall maintain documentation of successful completion of the site specific training program for each pharmacy technician for the duration of the

employment and for a period of two years from date of termination of employment. Documentation for currently employed pharmacy technicians shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

C. Every pharmacy that employs or uses a person enrolled in an approved pharmacy technician training program pursuant to § 54.1-3321 D of the Code of Virginia shall allow such person to conduct tasks restricted to pharmacy technicians for no more than nine months without that person becoming registered as a pharmacy technician with the board as set forth in 18VAC110-20-101. Every pharmacy using such a person shall have documentation on site and available for inspection showing that the person is currently enrolled in an approved training program and the start date for each pharmacy technician in training.

18VAC110-20-120. Special or limited-use pharmacy permits.

A. 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.

B. For a special-use pharmacy located in or providing services to a free clinic that uses volunteer pharmacists on a part-time basis with pharmacy business hours less than 20 hours a week, the board may grant a waiver to the restricted access provisions of 18VAC110-20-190 under the following conditions:

1. The access is only for the purpose of repairing or upgrading essential equipment or for the purpose of securing a delivered drug order in the pharmacy.

2. The PIC shall be notified prior to each entry and give permission for the designated, specific individuals to enter.

3. If entry is by a nonpharmacist, two persons must enter together, one of whom must be an employee or volunteer of the free clinic who holds a license as a nurse, physician, or a physician assistant. Both persons must remain in the pharmacy the entire time that access is required.

4. The key or other means of unlocking the pharmacy and the alarm access code shall be maintained in a secure location within the facility in a sealed envelope or other container with the name of the "sealing" pharmacist written across the seal. If a nonpharmacist accesses the pharmacy, this means of access may be used, and the licensed health professional, as set forth in subdivision 3 of this subsection, is responsible for resealing the means of access and writing his name across the seal. The PIC shall ensure that the alarm access code is

changed within 48 hours. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.

5. A log must be maintained of each nonpharmacist entry showing date and time of entry, names of the two persons entering, purpose for entry, and notation that permission was granted by the pharmacist-in-charge and the date it was granted. Such log shall be maintained on premises for one year.

18VAC110-20-130. Pharmacy closings; going out of business; 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. Prescription records for prescriptions with active refills shall be transferred to another pharmacy where a patient may obtain access for the purpose of obtaining refills either at that location or in accordance with the transfer provisions of 18VAC110-20-360.

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 in subsection A of this section, the 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 chapter 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.

18VAC110-20-140. 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, 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 accessible to anyone for purposes other than for continuity of pharmacy services at substantially the same level offered by the previous owner or for the necessary transfer of prescription records, the owner of the pharmacy acquiring the records shall disclose such information in writing to each patient 14 days prior to the acquisition. Such release of prescription records shall be allowed only to the extent authorized by § 32.1-127.1:03 of the Code of Virginia.

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 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180, and 18VAC110-20-190.

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 18VAC110-20-20 prior to a reinspection being conducted.

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

E. Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, the pharmacy shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

18VAC110-20-180. Security system.

A. 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 monitored in accordance with accepted industry standards, maintained in operating order ~~and shall~~ , have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.

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 18VAC110-20-190 B 2, and the system shall be activated whenever the prescription department is closed for business.

B. Exceptions to provisions in this section:

~~5. This regulation shall not apply to pharmacies which have been granted a permit~~ 1. Alarm systems approved prior to November 4, 1993, will be deemed to meet the requirements of subdivisions A 1, 2, and 3, 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. If a breaking with a loss of drugs occurs, the pharmacy shall immediately upgrade the alarm to meet the current standards and shall file an application with the board in accordance with 18VAC110-20-140 A.

~~6.~~ 2. 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.~~ 3. 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 PIC or owner must immediately notify the board, file an application in accordance with 18VAC110-20-140 A, and have installed ~~within 72 hours~~ prior to closing, a security system ~~which~~ that meets the requirements of subdivisions A 1 through 4 of this section.

18VAC110-20-190. Prescription department enclosures; access to prescription department.

A. The prescription ~~departments~~ department 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~~ prescription drugs 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 a person from reaching over to gain access to the drugs~~ locked and alarmed at all times when a pharmacist is not on duty.

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.~~ The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department.

~~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 into a locked prescription department and the alarm access code ~~to the dispensing areas~~ shall be ~~subject to the following requirements: 1. Only~~ restricted to pharmacists practicing at the pharmacy and authorized by the 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.~~ with the following exceptions:

~~2.~~ 1. The PIC or a pharmacist on duty, for emergency access, may place a key or other means of ~~opening the locking device~~ unlocking the prescription department 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 or other secured place within the pharmacy ~~or other secured place~~. This ~~key or code~~ means of emergency access shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with subsection 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.

2. Pharmacy interns, pharmacy technicians, and other persons authorized by the PIC or pharmacist on duty may possess a key or other means of entry into a locked prescription department only when a pharmacist is on duty. Such key or other means of entry shall not allow entry when a pharmacist is not on duty.

C. The prescription department is restricted to pharmacists who are practicing at the pharmacy. ~~Interns~~ Pharmacy interns, pharmacy technicians, and other persons designated by the pharmacist on duty may be allowed access by the pharmacist but only ~~during the hours~~ when the pharmacist is on duty. Each pharmacist while on duty shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of prescription drugs and devices.

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 18VAC110-20-200 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.

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

A. Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a ~~secure place~~ secured area outside of the prescription department ~~and~~, not accessible to the public, where access to the prescriptions is restricted to individuals designated 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 and Schedule VI medical devices. Controlled paraphernalia and Schedule VI medical devices shall not be placed 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, or otherwise adulterated or misbranded drugs; security. Any drug which has exceeded the expiration date, or is otherwise adulterated or misbranded, 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.

18VAC110-20-210. Disposal of drugs by pharmacies.

If a 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, or other board-approved method, 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 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 section.

c. The actual destruction shall be witnessed by the 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 VI

Drug Inventory and Records

18VAC110-20-240. 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. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least every 30 days. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

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

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

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

5. Invoices or other records showing receipts of Schedule VI drugs shall be maintained, but may be stored in an electronic database or record as an

electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

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

B. Prescriptions.

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

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

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

C. Chart orders.

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

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

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

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

3. Requirements for filing of chart orders.

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

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

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

Part VII

Prescription Order and Dispensing Standards

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

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

B. ~~A pharmacist directly monitoring the activities of a person enrolled in an approved pharmacy technician training program who is performing the tasks restricted to a pharmacy technician prior to registration in accordance with § 54.1-3321 D of the Code of Virginia shall not monitor more than two such trainees at the same time, and at no time shall a pharmacist supervise more than four persons performing technician functions to include technicians and trainees.~~ A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time.

C. After the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained on a pharmacy record for the required time period of two years, unless otherwise specified in regulation.

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

E. If a pharmacist determines from a prescriber or other means that a prescription presented for dispensing is a forgery, the pharmacist shall not return the forged prescription to the person presenting it. The forged prescription may be given to a law-enforcement official investigating the forgery; or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigative or other legitimate purpose.

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

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver prescriptions to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law.

B. Delivery to another pharmacy.

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

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

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

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

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

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

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

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

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

h. The procedure for informing the patient and obtaining consent ~~if required by law~~ for using such a dispensing and delivery process.

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

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

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

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

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

b. Procedure for providing counseling;

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

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

e. The procedure for informing the patient and obtaining consent ~~if required by law~~ for using such a delivery process.

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

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

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

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

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

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

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

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

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

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

b. Faxing an oral prescription by authorized agent under the conditions set forth in subdivision 2 of this subsection; or

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

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

a. The date that the prescription was faxed;

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

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

B. Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for orders to be administered to ~~nursing home~~ long-term care facility and home infusion patients in accordance with § 54.1-3408.01 B of the Code of Virginia and except for prescriptions written for a Schedule II narcotic substance for patients residing in a

hospice certified by Medicare under Title XVIII or licensed by the state, which may include home hospice. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's 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.

18VAC110-20-286. Chart orders for outpatients.

A chart order may be filled by an outpatient (community/retail) pharmacy for outpatient use provided the following conditions are met:

1. The chart order was written for a patient while in a hospital or long-term care facility.

2. The pharmacist has all information necessary to constitute a valid outpatient prescription.

3. The pharmacist in an outpatient setting has direction, either written or obtained verbally, that the chart order is actually intended to be outpatient or discharge prescription orders, and not merely a listing drugs the patient was taking while an inpatient.

4. The orders include some direction related to quantity to be dispensed or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration.

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

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

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

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

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

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

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

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

A prescription for a Schedule VI drug or device shall not be dispensed or refilled more than one year after the date on which it was issued unless the prescriber

specifically authorizes dispensing or refilling for a longer period of time not to exceed two years.

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

D. ~~Authorized refills of all prescription drugs may only be dispensed in~~ The timing of dispensing an authorized refill of a prescription shall be within reasonable conformity with the directions for use as indicated by the practitioner; if directions have not been provided, then any authorized refills may only be dispensed in reasonable conformity with the recommended dosage and with the exercise of sound professional judgment. An authorized refill may be dispensed early provided the pharmacist documents a valid reason for the necessity of the early refill.

18VAC110-20-340. Packaging standards for dispensed prescriptions.

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

B. Drugs may be dispensed in compliance packaging for self-administration when requested by the patient or for use in hospitals or long-term care facilities provided that such packaging meets all current U.S.P.-N.F. standards for packaging, labeling and record keeping. Compliance packaging that is comprised of a series of individual containers or pockets labeled with the specific date and time when the contents of that container are to be taken, and which may contain more than one different drug, shall comply with USP-NF standards for customized patient medication packages to include:

1. If the packaging allows for the separation of the individual containers, the labels for each individual container shall be labeled with the identity of each of the drug products contained within; and

2. The main packaging label shall contain all the required elements for any outpatient prescription label and shall contain a physical description identifying each solid dosage form contained within the individual containers.

18VAC110-20-350. 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.~~ B. If nonspecial packaging is requested, ~~a release of such request shall be obtained from the patient or the patient's authorized agent and maintained for two years from the date of dispensing~~ a notation shall be made on the dispensing record or other retrievable record.

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

A. Pharmacies in which bulk reconstitution of injectable, bulk compounding or the repackaging or prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the drug(s) used; strength, if any; date repackaged; quantity

prepared; initials of the pharmacist verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

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

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

a. The drug name and strength, if any;

b. The name of the manufacturer or distributor;

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

d. Any assigned lot number; ~~and~~

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

f. The date of filling; and

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

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

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

4. If only one lot is added to a bin at one time, but a ~~second~~ subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed, 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.

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

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

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

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

18VAC110-20-391. Prescription blanks.

If a pharmacy provides prescription blanks to prescribers, no advertising or other information shall be on the face of the prescription blank other than prompts for essential information required by law to be on a written prescription. Any nonessential information such as coupons or pharmacy name may be placed on the back of the prescription blank or on a separate sheet of paper, but shall not be on or attached to the face of the blank.

~~18VAC110-20-395. Purchase of drugs.~~

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

18VAC110-20-410. Permitted physician licensed by the board.

A. Pursuant to § 54.1-3304 of the Code of Virginia, 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," "pharmacy," and "PIC" in the following shall be deemed to mean the physician permitted by the board:

1. 18VAC110-20-110 C and D;
2. 18VAC110-20-130 A;
3. 18VAC110-20-140 A and C;
4. 18VAC110-20-150 except that these requirements shall not apply to physicians licensed prior to August 25, 2004, unless the dispensing area is relocated or remodeled;
5. 18VAC110-20-160;
6. 18VAC110-20-180;
7. 18VAC110-20-190 A, B and C;
8. 18VAC110-20-200;
9. 18VAC110-20-210; and
10. 18VAC110-20-240 through 18VAC110-20-410.

B. A physician may apply for a special or limited use permit in accordance with 18VAC110-20-120.

18VAC110-20-425. Robotic ~~Pharmacy Systems~~ pharmacy systems.

~~A.~~ A pharmacy providing services to a hospital or a long-term care facility using a unit dose dispensing system may ~~apply for approval of~~ operate a robotic pharmacy system ~~and a waiver of 18VAC110-20-270 B~~ dispensing unit dose, bar-coded drugs, and is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product ~~is determined by~~ complies with a written quality assurance plan and requirements of this chapter. ~~An applicant shall apply using a form provided by the board and shall pay a fee as set forth in 18VAC110-20-20.~~ The following requirements for operation of a robotic pharmacy system shall apply:

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

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

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

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

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

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

c. Removing expired drugs;

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

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

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

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

h. Maintaining quality assurance reports.

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

6. All manual picks shall be checked by pharmacists.

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

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

a. A summary indicating the date and description of all discrepancies that include but are not limited to discrepancies involving the packaging, repackaging and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

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

c. The total number of doses picked by the robot that were checked in conducting the 5.0% patient bin check, 5.0% cart updates check, and 5.0% first dose check.

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

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

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

~~B. A copy of the quality assurance plan shall be submitted as a part of the application and shall include at a minimum the following:~~

~~1. Method of ensuring accurate packaging and loading of the robotic pharmacy system.~~

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

~~3. Manufacturer's schedules and recommendations for maintenance of the device.~~

~~4. Plan for maintenance of all related documentation for a minimum of two years.~~

~~C. The application shall be reviewed by an informal conference committee of the board, consisting of no less than two members of the board.~~

~~1. The informal conference committee may approve or deny the application, or may approve the application upon terms and conditions.~~

~~2. The committee may require an inspection of a new or modified robotic pharmacy system prior to approval.~~

~~3. The committee may require that periodic reports be submitted detailing frequency and types of errors determined by the continuous quality assurance checks.~~

~~4. The board may withdraw the approval of a waiver for failure to comply with the quality assurance plan or with other terms and conditions which have been established by the board.~~

~~D. The board shall be notified prior to implementing any modification to the approved application and no modification may be implemented until approved by the board.~~

~~E. If a robotic pharmacy system is used, a pharmacist shall review all data entry of prescription orders into the computer operating the system for accuracy and appropriateness of therapy and shall check all repackaged medication prior to use in loading the system.~~

Part XI
Pharmacy Services to Hospitals

18VAC110-20-440. Responsibilities of the pharmacist-in-charge.

A. The PIC in a pharmacy located within a hospital or the 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 PIC of a pharmacy serving a hospital shall be responsible for maintaining a policy and procedure for providing reviews of drug therapy to include at a minimum 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~~ consistent with § 54.1-3319 A of the Code of Virginia.

C. Prior to the opening of a satellite pharmacy within the hospital, the PIC shall notify the board as required by 18VAC110-20-140 and shall ensure compliance with subsections B through G of 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180 and 18VAC110-20-190. 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 nonpharmacy 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 components and derivatives, and synthetic blood components and products that are classified as prescription drugs.

18VAC110-20-450. After-hours access to the pharmacy.

A. When authorized by the PIC, an authorized nurse may have access to ~~the pharmacy in the absence of the pharmacist~~ a supply of drugs maintained by the pharmacy at a location outside the pharmacy in order to obtain emergency medication during hours the pharmacy is closed, 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~~ at the location of the stock of drugs on a form prescribed by the 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.

B. If the after-hours supply of drugs is in an area that is continuously open and staffed, such as a patient floor or emergency room, then the area does not need to be alarmed. If the after-hours supply is maintained in an area of the hospital that is not open and continuously staffed, such as a floor that primarily houses departments that are closed daily, then an alarm that meets the requirements of 18VAC110-20-180 shall be installed and activated at all times.

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.

A. A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. 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 manual or electronic signatures of the dispensing pharmacist and the receiving nurse. ~~Receipts shall be maintained in the pharmacy for a period of two years or in off-site 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.~~ C. 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 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; and

4. Initial the returned record~~, file chronologically by date of issue, and retain for two years from the date of return or in off-site 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.~~ D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 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.

18VAC110-20-490. 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 §§ 54.3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420 or 18VAC110-20-460 as applicable. 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 the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist ~~reviewing the transaction~~ checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

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

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

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

~~the month being audited~~ shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

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

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

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit ~~and maintained in the pharmacy for a period of two years~~. If nonpharmacist 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, and the 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.

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

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

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

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

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

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 10 a and b of this section if authorized by DEA or in federal law or regulation.

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

18VAC110-20-500. Licensed emergency medical services agencies program.

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

1. The PIC of the hospital pharmacy shall be responsible for all ~~controlled~~ prescription drugs contained in this drug kit. A pharmacist shall check each drug kit after filling the kit, and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The drug kit is sealed in such a manner that it will ~~preclude any possibility of~~ deter theft or loss of drugs and aid in detection of such.

3. Drugs may be administered by an 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.

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

18VAC110-20-520. Drugs in long-term care facilities.

~~Drugs~~ Prescription drugs, as defined in the Drug Control Act, shall not be floor stocked by a long-term care facility, except those in the stat drug box or emergency drug box or as provided for in 18VAC110-20-560 within this chapter.

Part XII

Pharmacy Services to Long-Term Care Facilities

18VAC110-20-530. 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 redispensing to the indigent if authorized by § 54.1-3411.1 and 18VAC110-20-400, or ~~destroyed~~ disposed of by appropriate means in compliance with 18VAC110-20-210 and with any applicable local, state, and federal laws and regulations.

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

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

d. Long-term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy [~~without~~ within] 30 days of the date the drug was discontinued.

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

9. Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title 63.2 of

the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

18VAC110-20-535. Repackaging of already dispensed prescriptions.

The primary provider pharmacy for a long-term care facility may, but shall not be required to, repackage a resident's prescription drugs dispensed by another pharmacy into the unit-dose or compliance packaging system used by the long-term care facility to assist in maintaining a uniform or more accurate system of administration.

1. Such repackaging shall only be done at the provider pharmacy.

2. Unit dose repackaging shall comply with requirements of 18VAC110-20-420 and compliance packaging shall comply with 18VAC110-20-340 B.

3. Records shall be maintained of all such repackaging of previously dispensed medications to include date; repackaging pharmacist's initials (or those of the checking pharmacist); and the pharmacy name, address, and prescription number of the original dispensing.

4. Any portion of a resident's medication not placed into unit dose or compliance packaging may be returned to the resident or kept for subsequent repackaging at the provider pharmacy in the original labeled container. If kept at the pharmacy, the medication shall be stored within the prescription department but separate from any working stock of drugs used for dispensing by the pharmacy, and shall only be used for the patient to whom the medication was originally dispensed.

18VAC110-20-536. Prescription drugs sent outside the facility.

A. The provider pharmacy shall assure that residents who leave a long-term care facility for short periods of time or are discharged and who are allowed to take dispensed prescription medications with them, do so only in appropriate packaging, properly labeled for outpatient use.

B. Pharmacies that provide medication to residents in compliance packaging that meets the requirements of 18VAC110-20-340 B, shall assure that if the facility separates and sends only the individual containers needed during the time the resident is away without the main package label, that the resident is also given a copy of the main package label or other appropriate documentation that contains the complete labeling information on the main package label.

18VAC110-20-540. Emergency drug kit.

The pharmacist providing services may prepare an emergency kit for a long-term care facility in which ~~only those persons licensed to administer are administering drugs~~ access to the kit is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the kit and only 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.

18VAC110-20-550. 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. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box ~~shall be 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 or resealing, or both. 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.~~ 3. There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.

~~5.~~ 4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.

~~6.~~ 5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.

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

b. The stat-drug box shall contain no 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.

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

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

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

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

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

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

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

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

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

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

5. Prior to the 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; a unique identifier for the specific device receiving drugs; and initials of the

pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

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

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

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

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

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

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

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

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

f. The hard copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit ~~and maintained in the pharmacy for a period of two years~~. If nonpharmacist 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 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.~~

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

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

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

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

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

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

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

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

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

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained off site or electronically provided they can be readily retrieved upon request; provided

they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

Part XIII
Other Institutions and Facilities

18VAC110-20-570. Drugs in infirmaries/first aid rooms.

A. ~~Controlled~~ Prescription drugs purchased by an institution, agency, or business within the Commonwealth, having been purchased in the name of a practitioner licensed by the Commonwealth of Virginia and who is employed by an institution, agency, or business which does not hold a pharmacy permit, shall be used only for administering to those persons at that institution, agency, or business.

B. All ~~controlled~~ prescription drugs shall be maintained and secured in a suitable locked storage area, the key to which will be in the possession of the practitioner or nurse who is under the direction and supervision of the practitioner.

C. Such institution, agency, or business shall adopt a specific protocol for the administration of prescription drugs, listing the inventory of such drugs maintained, and authorizing the administering of such drugs in the absence of a practitioner in an emergency situation when the timely prior verbal or written order of a prescriber is not possible. Administering of such drugs shall be followed by written orders.

1. For the purpose of this chapter, "emergency" means a circumstance requiring administration of ~~controlled~~ prescription drugs necessary to preserve life or to prevent significant or permanent injury or disability.

2. The protocol shall be maintained for inspection and documentation purposes.

~~D. A nurse may, in the absence of a practitioner, administer and provide nonprescription drugs in unit dose containers in quantities which in the professional judgment of the nurse will maintain the person at an optimal comfort level until the person's personal practitioner can be consulted. The administering and providing of such medication must be in accordance with explicit instructions of a specific protocol promulgated by the practitioner in charge of the institution, agency, or business.~~

18VAC110-20-580. Humane societies and animal shelters.

A humane society or animal shelter, after having obtained the proper permits pursuant to state and federal laws, may purchase, possess and administer [~~any drug approved by the State Veterinarian to euthanize injured, sick, homeless and unwanted domestic pets and animals~~ controlled substances in accordance with provisions of § 54.1-3423 of the Code of Virginia provided that these procedures are followed:

1. Drugs ordered by a humane society [~~for euthanasia~~ or animal shelter] shall only be stored and administered at the address of the humane society [or shelter~~. Humane societies shall not order or possess a stock of drugs for any purpose other than euthanasia~~].

~~1.~~ 2. A veterinarian shall provide general supervision for the facility and shall provide and certify training in accordance with guidelines set forth by the State Veterinarian to the person(s) responsible for administration of the drugs. Certification of training signed by the veterinarian providing the training shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering.

~~2.~~ 3. The person in charge of administration of drugs for euthanasia for the facility shall obtain the required permit and controlled substances registration from the board and shall be responsible for maintaining proper security and required records of all controlled substances obtained and administered.

a. If that person ceases employment with the facility or relinquishes his position, he shall immediately return the permit to the board and shall take a complete and accurate inventory of all drugs in stock.

b. An application for a new permit shall be filed with the required fee within 14 days on a form provided by the board. At that time, the new responsible person shall take a complete and accurate inventory of all drugs in stock.

~~3.~~ 4. Drugs shall be stored in a secure, locked place and only the person(s) ~~responsible for administering may have access to the drugs.~~

~~4.~~ 5. Any drug used shall be obtained and administered in the injectable form only.

~~5.~~ 6. All invoices and order forms shall be maintained for a period of two years.

~~6.~~ 7. Complete and accurate records shall be maintained for two years on the administration of the drug. The record shall show the name and strength of the drug, date of administration, the species of the animal, the weight of animal, the amount of drug administered and the signature of the person administering the drug.

18VAC110-20-590. Drugs in correctional ~~institutions~~ facilities.

A. All prescription drugs at any correctional ~~unit~~ facility 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. Patient name;

b. Drug name and strength;

c. Number of dosage units received;

d. Prescriber's name; and

e. Date, time and signature of the 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, a copy of the drug administration record, or other form showing substantially the same information, within 30 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 pharmacy to the facility.

c. Drugs may be returned to pharmacy stock in compliance with the provisions of 18VAC110-20-400.

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

4. 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 3 a of this subsection and ensuring the proper maintenance of the administration records.

B. Emergency and stat-drug box. An emergency box and a stat-drug box may be prepared for ~~the~~ a correctional facility served by the pharmacy pursuant to 18VAC110-20-540 and 18VAC110-20-550 provided that the facility employs one or more full-time ~~physicians, registered nurses, licensed practical nurses,~~ or ~~physician assistants or correctional health assistants~~.

C. Prescription drugs, including but not limited to vaccines, may be ~~stocked~~ floor-stocked only at a medical clinic or surgery center that is part of a correctional facility and that is staffed by one or more ~~physicians~~ prescribers during the hours of operation, provided the clinic first obtains a controlled substances registration and complies with the requirements of 18VAC110-20-690, 18VAC110-20-700, 18VAC110-20-710, and 18VAC110-20-720.

18VAC110-20-610. Exempted chemical preparations.

The list of exempt chemical preparations ~~set forth in~~ pursuant to 21 CFR §1308.24 and maintained by the administrator of DEA is adopted pursuant to the authority set forth in §§ 54.1-3443, 54.1-3450 and 54.1-3452 of the Drug Control Act.

18VAC110-20-620. Exempted prescription products.

The list of exempt prescription products ~~set forth in~~ pursuant to 21 CFR 1308.32 and maintained by the administrator of DEA is adopted pursuant to the authority set forth in §§ 54.1-3443, 54.1-3450 and 54.1-3452 of the Drug Control Act; the exempted prescription products are drugs which are subject to the provisions of § 54.1-3455 of the Drug Control Act.

18VAC110-20-621. Exempted anabolic steroid products.

The list of exempt anabolic steroid products ~~set forth in~~ pursuant to 21 CFR 1308.34 and maintained by the administrator of DEA is adopted pursuant to the authority set forth in §§ 54.1-3443, 54.1-3450 and 54.1-3452 of the Drug Control Act; the exempted anabolic steroid products are drugs which are subject to the provisions of § 54.1-3455 of the Drug Control Act.

18VAC110-20-622. Excluded veterinary anabolic steroid implant products.

The list of excluded veterinary anabolic steroid implant products ~~set forth in~~ pursuant to 21 CFR 1308.26 and maintained by the administrator of DEA is adopted only for legitimate veterinary use pursuant to the authority set forth in §§ 54.1-3443, 54.1-3450 and 54.1-3452 of the Drug Control Act; the exempted anabolic steroid products are drugs which are subject to the provisions of § 54.1-3455 of the Drug Control Act when used for implant to cattle or other nonhuman species. These products are not excluded from Schedule III if prescribed, administered, dispensed, or otherwise distributed for human use.

18VAC110-20-680. 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 shall 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. In lieu of a hard copy, an electronic image of an order may be maintained in an electronic database provided it preserves and provides an exact image of the order that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.

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 XVI

Controlled Substances Registration for Other Persons or Entities

18VAC110-20-690. 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 manufacturers' samples, ~~in order to administer such drugs~~ in accordance with provisions of the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) 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, outpatient clinics, alternate delivery sites, 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.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date, or requests that are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates that 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.

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected consistent with subsection B of this section.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, or pharmacy technician for alternate delivery sites or other person approved by the board who is authorized to administer or otherwise possess the controlled substances for that type entity.

~~D.~~ E. ~~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 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.

18VAC110-20-700. 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~~ type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the ~~person or entity~~ applicant or registrant and who is approved by the board ~~shall~~ may 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

by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, and overseeing delivery of dispensed prescriptions at an alternate delivery site.

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 recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-710. 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 18VAC110-20-700 C.

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 which meets the following conditions:

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

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

3. The device shall be maintained in operating order ~~and shall~~, have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.

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, animal control officers, humane societies, or alternate delivery sites as provided in 18VAC110-20-275.

Changes to a Schedule II Prescription

Background:
See attached FAQ from DEA's website related to changes a pharmacist may make to a written Schedule II prescription upon oral consultation with the prescriber. DEA had previous guidance about changes, but retracted that guidance recently in a Federal Register publication.

Until such time as DEA can promulgate regulations addressing this issue, it is deferring to state regulations or policy as to what changes may be made. Because the Board has no regulations related to this, and because DEA will defer to "policy", it may be useful to pharmacists for the Board to adopt a guidance document establishing "policy" as to what changes a pharmacist may make. Staff has drafted a guidance document that reflects DEA's previous guidance.

Action: The Board should review the draft guidance document and consider a motion to adopt the guidance document as written or amended.

http://www.deadiversion.usdoj.gov/faq/general.htm#rx-7

Question: What changes may a pharmacist make to a prescription written for a controlled substance in schedule II?

Answer: On November 19, 2007, the DEA published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed)...may not be modified orally."

The instructions contained in the Rule's preamble are in opposition to DEA's previous policy which permitted the same changes a pharmacist may make to schedules III-V controlled substance prescriptions after oral consultation with the prescriber. DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. **Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber.**

Question: What changes may a pharmacist make to a prescription written for a controlled substance in schedules III-V?

Answer: The pharmacist may add or change the patient's address upon verification. The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to controlled substance prescriptions.

The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature.

Virginia Board of Pharmacy

Changes a Pharmacist May Make to a Prescription Written for a Schedule II Controlled Substance

On November 19, 2007, the DEA published in the Federal Register the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed)...may not be modified orally." This, however, is in opposition to DEA's previous policy which permitted the pharmacist to make limited changes to a prescription written for a Schedule II controlled substance after oral consultation with the prescriber. DEA plans to resolve this confusion through future rulemaking and instructs pharmacists to adhere to state regulations or policy regarding changes that a pharmacist may make to a schedule II prescription. Therefore, through policy, the Board will allow a pharmacist to make limited changes to a schedule II prescription as stated below.

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

SMARxT DISPOSAL

A Prescription for a Healthy Planet

January 12, 2009

En Espanol Con babelfish de traducción automática.

SHARE

Home

Resources

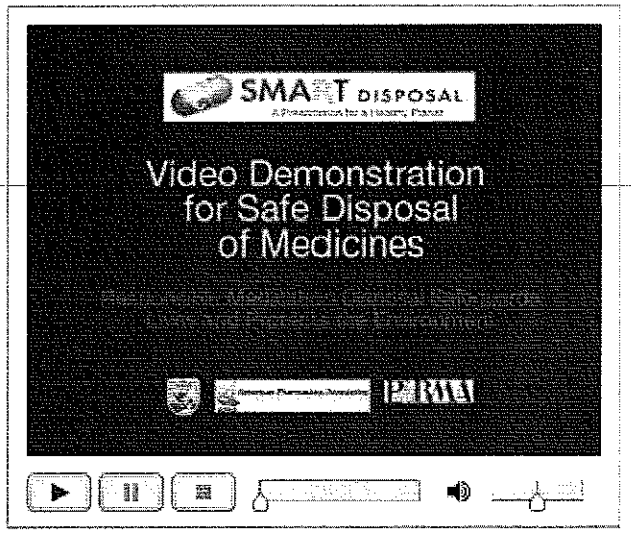
About the Partnership

Become a Supporter

Common Questions

Choose a language to translate this page!

Select to language



Responsible Medication Disposal Safeguards Lives and Protects the Environment.

Many of us enjoy an unparalleled quality of life. We have diverse hobbies, numerous economic opportunities, tremendous cultural and outdoor resources and the best health care in the world. In fact, we often combine our hobbies with our passion for the natural environment. And protecting these resources is an important part of our overall enjoyment.

A concern we must all address is the disposal of medications and their effect on human life, wildlife, lakes, rivers and streams throughout our country. This issue is relevant to everyone's personal health safety and the protection of our environment.

The SMAR$_X$T DISPOSAL ™ campaign is designed to raise awareness about the

A few small steps can make an important difference in safeguarding lives and protecting the environment.

Follow your medication prescriber's instructions and use all medications as instructed. If you do not use all of your prescribed or over-the-counter medication, you can take a few small steps to make a huge impact in safeguarding lives and protecting the environment by disposing of unused medicines properly:

- **DO NOT FLUSH unused medications and DO NOT POUR them down a sink or drain*.**
- **Be Proactive and Dispose of Unused Medication In Household Trash. When discarding unused medications, ensure you protect children and pets from potentially negative effects:**
  a. **Pour medication into a sealable plastic bag. If medication is a solid (pill, liquid capsule, etc.), crush it or add water to dissolve it.**
  b. **Add kitty litter, sawdust, coffee grounds (or any material that mixes with the medication and makes it less appealing for pets and children to eat) to the plastic bag.**
  c. **Seal the plastic bag and put it in the trash.**
  d. **Remove and destroy ALL**

potential environmental impact from improperly disposed of medications and to provide proactive guidance through proper disposal alternatives.

***Note:** The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:

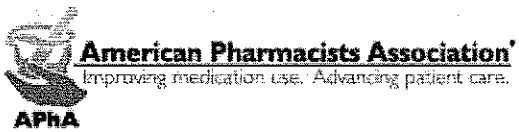
Actiq (fentanyl citrate)
Daytrana Transdermal Patch (methylphenidate)
Duragesic Transdermal System (fentanyl)
OxyContin Tablets (oxycodone)
Avinza Capsules (morphine sulfate)
Baraclude Tablets (entecavir)
Reyataz Capsules (atazanavir sulfate)
Tequin Tablets (gatifloxacin)
Zerit for Oral Solution (stavudine)
Meperidine HCl Tablets
Percocet (Oxycodone and Acetaminophen)
Xyrem (Sodium Oxybate)
Fentora (fentanyl buccal tablet)

Additional Note: Patients should always refer to printed material accompanying their medication for specific instructions.

identifying personal information (prescription label) from all medication containers before recycling them or throwing them away.

- Check for Approved State and Local Collection Programs. Another option is to check for approved state and local collection alternatives such as community based household hazardous waste collection programs. In certain states, you may be able to take your unused medications to your community pharmacy or other location for disposal.
- **Consult your pharmacist with any questions.**

SMARxT DISPOSAL ™ public awareness campaign is a unique public-private partnership between the U.S. Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America.



167

May Medical Equipment Suppliers accept an oral order for those products they can lawfully dispense?

Background: Staff had received several questions from MESs asking whether they may accept a verbal order for devices, oxygen, etc. Most believe that they have to have a written prescription/order in order to dispense, but have recently been challenged by some prescribers who want to call in orders. The statute does not specify the format of these prescriptions or orders. The provisions for MES to dispense certain things, i.e. devices, oxygen, etc, is a "carve-out" of the practice of pharmacy, that the General Assembly believed could be done outside a permitted pharmacy and by persons other than pharmacists.

Relevant statutes:
§ 54.1-3300. Definitions.
...
"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging and dispensing of drugs, medicines and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.
...

§ 54.1-3320. Acts restricted to pharmacists.
A. Within the practice of pharmacy as defined in § 54.1-3300, the following acts shall be performed by pharmacists, except as provided in subsection B:
...
2. The receipt of an oral prescription from a practitioner or his authorized agent;
...

§ 54.1-3401. Definitions.
...
"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.
...

§ 54.1-3435.2. Permit to act as medical equipment supplier; storage; limitation; regulations.
A. Unless otherwise authorized by this chapter or Chapter 33 (§ 54.1-3300 et seq.) of this title, it shall be unlawful for any person to act as a medical equipment supplier, as defined in § 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit to act as a medical equipment supplier in this Commonwealth shall apply to the Board for a permit, using such form as the Board may furnish; renew such permit, if granted, annually on a date determined by the Board in regulation; and remit a fee as determined by the Board.
B. Prescription drugs received, stored, and distributed by authority of this section shall be limited to those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.
C. Distribution of any Schedule VI drug or device or of any hypodermic needle or syringe, or medicinal oxygen by authority of this section is limited to delivery to the ultimate user upon lawful order by a prescriber authorized to prescribe such drugs and devices.
D. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs, devices and controlled paraphernalia by medical equipment suppliers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices and controlled paraphernalia, and to protect the public.
§ 54.1-3435.3. Inspection and audit.
Medical equipment suppliers shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures.