F. The pharmacy and alternate delivery site shall be exempt from compliance with subsections B through E of this section if (i) the alternate delivery site is a pharmacy, a practitioner of healing arts licensed by the board to practice pharmacy or sell controlled substances, or other entity holding a controlled substances registration for the purpose of delivering controlled substances; (ii) the alternate delivery site does not routinely receive deliveries from the pharmacy; and (iii) compliance with subsections B through E of this section would create a delay in delivery that may result in potential patient harm. However, the pharmacy and alternate delivery site shall comply with following requirements:

1. To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to where the drug was shipped, the name of the patient for whom the drug was dispensed, and any special storage requirements.

2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling.

3. Prescriptions delivered to the alternate delivery 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 prescriber, pharmacist, or either person's designee.

4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient.

G. A pharmacy shall not deliver dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage, reconstitution or compounding prior to administration. An exception to this requirement may be made for patients with inherited bleeding disorders who may require therapy to prevent or treat bleeding episodes.

18VAC110-20-276. Central or remote processing.

A. Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;

2. Entering prescription and patient data into a data processing system;

3. Transferring prescription information;

4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;

5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;

6. Interpreting clinical data for prior authorization for dispensing;

7. Performing therapeutic interventions; or

8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.

B. A pharmacy may outsource certain prescription processing functions as described in subsection A of this section to another pharmacy in Virginia or a registered nonresident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;

2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties that are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;

3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and

4. The pharmacies shall share a common electronic file or have technology that allows sufficient information necessary to process a nondispensing function.

C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of any contract pharmacy providing central or

remote prescription processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

D. A policy and procedure manual that relates to central or remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;

2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;

3. Procedures for protecting the confidentiality and integrity of patient information;

4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;

5. Procedures for maintaining required records;

6. Procedures for complying with all applicable laws and regulations to include counseling;

7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and

8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

E. In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records that show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.

1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.

2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A of this section, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

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

A. Unless otherwise prohibited by federal law, prescription orders for Schedules III through VI drugs may be transmitted to pharmacies by facsimile (fax) device 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:

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

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

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

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

a. The date that the prescription was faxed;

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

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

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

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

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

18VAC110-20-285. Electronic transmission of prescriptions from prescriber to pharmacy.

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

B. A pharmacy receiving an electronic prescription shall maintain such prescription record in accordance with 18VAC110-20-250 A.

C. An electronic prescription shall be transmitted only to the pharmacy of the patient's choice.

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.

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

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

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

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

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

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

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

4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 54.1-3410 of the Drug Control Act, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail postmarked within the seven-day period or transmitted as an electronic prescription in accordance with federal law and regulation to include annotation of the electronic prescription with the original

authorization and date of the oral order. Upon receipt, the dispensing pharmacist shall attach the paper prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to the pharmacist. Failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing practitioner.

D. When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist shall not add or change the prescriber's signature or make changes to the controlled substance prescribed, except for dispensing therapeutically equivalent drugs as permitted by law.

18VAC110-20-300. (Repealed.)

18VAC110-20-310. Partial dispensing of Schedule II prescriptions.

A. The partial filling of a prescription for a drug listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription, and he makes a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be dispensed within 72 hours of the first partial dispensing; however, if the remaining portion is not or cannot be dispensed within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

B. Prescriptions for Schedule II drugs written for patients in long-term care facilities may be dispensed in partial quantities, to include individual dosage units. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II drugs in all partial dispensing shall not exceed the total quantity prescribed. Schedule II prescriptions shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

C. Information pertaining to current Schedule II prescriptions for patients in a long-term care facility may be maintained in a computerized system if this system has the capability to permit:

1. Output (display or printout) of the original prescription number, date of issue, identification of prescribing practitioner, identification of patient, identification of the long-term care facility, identification of drug authorized (to include dosage form, strength, and quantity), listing of partial dispensing under each prescription, and the information required in subsection B of this section.

2. Immediate (real time) updating of the prescription record each time a partial dispensing of the prescription is conducted.

D. A prescription for a Schedule II drug may be filled in partial quantities to include individual dosage units for a patient with a medical diagnosis documenting a terminal illness under the following conditions:

1. The practitioner shall classify the patient as terminally ill, and the pharmacist shall verify and record such notation on the prescription.

2. On each partial filling, the pharmacist shall record the date, quantity dispensed, remaining quantity authorized to be dispensed, and the identity of the dispensing pharmacist.

3. Prior to the subsequent partial filling, the pharmacist shall determine that it is necessary. The total quantity of Schedule II drugs dispensed in all partial fillings shall not exceed the total quantity prescribed.

4. Schedule II prescriptions for terminally ill patients may be partially filled for a period not to exceed 60 days from the issue date unless terminated sooner.

5. Information pertaining to partial filling may be maintained in a computerized system under the conditions set forth in subsection C of this section.

E. A prescription for a Schedule II drug may be filled in partial quantities if the partial fill is requested by the patient or by the practitioner who wrote the prescription provided:

1. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed;

2. The prescription is written and filled in accordance with state and federal law; and

3. The remaining portions are filled not later than 30 days after the date on which the prescription is written.

18VAC110-20-320. Dispensing or refilling of Schedules 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 of the Code of Virginia 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 may be refilled as 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. Except for drugs classified by the American Hospital Formulary Service as psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or for drugs of concern as defined in § 54.1-2519 of the Code of Virginia, a pharmacist, using professional judgment and upon request by the patient, may dispense or refill a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration.

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. 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.

Part VI
Labeling and Packaging Standards for Prescriptions

18VAC110-20-321. Compounding.

A. The compounding of both sterile and nonsterile drug products by a pharmacy that does not share the same physical space with an outsourcing facility shall be performed in accordance with USP-NF compounding standards and § 54.1-3410.2 of the Code of Virginia.

B. The compounding of sterile drug products by an outsourcing facility or by a pharmacy sharing the same physical space with an outsourcing facility shall be performed in accordance with current good manufacturing practices under § 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 USC § 351(a)(2)(B)).

18VAC110-20-322. Placement of chemicals in Schedule I.

A. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid. 1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. Alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agents.

a. Ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA), its salts, isomers, and salts of isomers whenever the

existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until August 16, 2023, unless enacted into law in the Drug Control Act.

B. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid. 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole (other names: N-pyrrolidino etonitazene, etonitazepyne), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 1-(1,3-benzodioxol-5-yl)-2-(propylamino)-1-butanone (other names: 3,4-Methylenedioxy-alpha-propylaminobutiophenone; N-propyl butylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 2-(ethylamino)-1-phenylpentan-1-one (other names: N-ethylpentedrone, alpha-ethylaminopentiophenone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 3,4-methylenedioxy-alpha-cyclohexylaminopropiophenone (other name: Cyputylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. 3,4-methylenedioxy-alpha-cyclohexylmethylaminopropiophenone (other name: 3,4-Methylenedioxy-N,N-cyclohexylmethcathinone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

e. 3,4-methylenedioxy-alpha-isopropylaminobutiophenone (other name: N-isopropyl butylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

f. 4-chloro-N-butylcathinone (other names: 4-chlorobutylcathinone, para-chloro-N-butylcathinone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

g. 4-hydroxy-N-methyl-N-ethyltryptamine (other names: 4-hydroxy MET, Metocin), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Central nervous system stimulant. 4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA), including its salts, isomers, and salts of isomers.

4. Cannabimimetic agent. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indole-3-acetamide (other names: ADB-FUBIATA, AD-18, FUB-ACADB), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until March 14, 2024, unless enacted into law in the Drug Control Act.

C. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid. N,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties. 1-(1,3-benzodioxol-5-yl)-2-(cyclohexylamino)butan-1-one (other names: Cybutylone, N-cyclohexyl Butylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Compounds expected to have depressant properties. 8-bromo-6-(2-chlorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: Clobromazolam, Phenazolam), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Cannabimimetic agents.

a. 5-bromo-N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-5Br-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-5-bromo-1-butylindazole-3-carboxamide (other name: ADB-5'Br-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until July 31, 2024, unless enacted into law in the Drug Control Act.

D. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid. 2-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name: 2-methyl butyryl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 1-(7-methoxy-1,3-benzodioxol-5-yl)propan-2-amine (other names: 5-methoxy-3,4-methylenedioxyamphetamine, 3-methoxy MDA, MMDA), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 1-[1-(3-chlorophenyl)cyclohexyl]-piperidine (other names: 3-Chloro Phencyclidine, 3Cl-PCP, 3-chloro PCP), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Compound expected to have depressant properties. 7-bromo-5-phenyl-1,3-dihydro-1,4-benzodiazepin-2-one (other names: Desalkylgidazepam, Bromonordiazepam), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Compound classified as a cannabimimetic agent. Methyl N-[(5-bromo-1H-indazol-3-yl)carbonyl]-3-methyl-valinate (other name: MDMB-5Br-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until October 12, 2024, unless enacted into law in the Drug Control Act.

18VAC110-20-323. Scheduling for conformity with federal law or rule.

Pursuant to subsection E of § 54.1-3443 of the Code of Virginia and in order to conform the Drug Control Act to recent scheduling changes enacted in federal law or rule, the board:

1. Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;

2. Adds Dronabinol ((-)-delta-9-trans tetrahydrocannabinol) in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II;

3. Deletes naldemedine from Schedule II;

4. Deletes naloxegol and 6β-naltrexol from Schedule II;

5. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP);

6. Adds 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine (4,4'-Dimethylaminorex, 4,4'-DMAR) to Schedule I;

7. Adds 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)pyrrolo[2,3-b]pyridine-3-carboxamide (5F-CUMYL-P7AICA) to Schedule I;

8. Adds ethyl N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]carbamate (fentanyl carbamate) to Schedule I;

9. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide (ortho-fluoroacryl fentanyl) to Schedule I;

10. Adds N-(2-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (ortho-fluoroisobutyryl fentanyl) to Schedule I;

11. Adds N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (para-fluoro furanyl fentanyl) to Schedule I;

12. Adds N-(2-fluorophenyl)-N-[1-[2-(2-fluorophenyl)ethyl]piperidin-4-yl]propanamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl) to Schedule I;

13. Adds N-[1-[2-(4-methylphenyl)ethyl]piperidin-4-yl]-N-phenylacetamide (4'-methyl acetyl fentanyl) to Schedule I;

14. Adds N,3-diphenyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (β'-phenyl fentanyl; beta'-phenyl fentanyl; 3-phenylpropanoyl fentanyl) to Schedule I;

15. Adds N-phenyl-N-[1-(2-phenylpropyl)piperidin-4-yl]propanamide (β-methyl fentanyl) to Schedule I;

16. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (ortho-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl) to Schedule I;

17. Adds N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl acetylfentanyl; 2-methyl acetylfentanyl) to Schedule I;

18. Adds 2-methoxy-N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl) to Schedule I;

19. Adds N-(4-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-methylfentanyl; 4-methylfentanyl) to Schedule I;

20. Adds N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]thiophene-2-carboxamide (thiophene fentanyl) to Schedule I;

21. Adds N-(4-chlorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-chloroisobutyryl fentanyl) to Schedule I;

22. Adds 24. 2-[2-[(4-butoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine (Butonitazene) to Schedule I;

23. Adds N,N-diethyl-2-[2-[(4-fluorophenyl)methyl]-5-nitrobenzimidazol-1-yl] ethanamine (Flunitazene) to Schedule I;

24. Adds Oliceridine to Schedule II;

25. Deletes Samidorphan from Schedule II;

26. Adds Remimazolam to Schedule IV;

27. Adds Serdexmethylphenidate to Schedule IV;

28. Adds Lemborexant to Schedule IV;

29. Adds Daridorexant to Schedule IV; and

30. Adds Ganaxolone to Schedule V.

18VAC110-20-330. Labeling of prescription as to content and quantity.

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

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

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

b. If a generic drug is dispensed when a prescription is written for a brand name drug, the label shall contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed, and the label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed.

c. The requirements of subdivisions 1 a and b of this section shall not apply to drugs dispensed to patients of a hospital or long-term care facility where all drugs are administered by persons licensed to administer.

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

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 recordkeeping. 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. If nonspecial packaging is requested, 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 drugs 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. Repackaging of drugs shall be performed in compliance with USP-NF standards.

D. 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 numbers and expiration date for all lots placed into the bin at the time of filling;

d. Any assigned lot number;

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

f. The date of filling; and

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

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

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

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

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

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

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

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

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

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

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

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

Part VII
Standards for Prescription Transactions

18VAC110-20-360. Issuing a copy of a prescription that can be filed or refilled.

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

B. The transfer of original prescription information for a drug listed in Schedules III through VI for the purpose of dispensing is permissible between pharmacies if the transfer is communicated directly between the two pharmacies either orally by direct communication

between the transferring pharmacist and the receiving pharmacist, or by facsimile machine or by electronic transmission, provided:

1. The transferring pharmacy:

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

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

c. Records the date of the transfer and, in the case of an oral transfer, the name of the pharmacist transferring the information; and

2. The receiving pharmacy:

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

b. Provides all information required to be on a prescription to include:

(1) Date of issuance of original prescription;

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

(3) Date of original dispensing, if applicable;

(4) Number of valid refills remaining and date of last dispensing;

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

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

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

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

D. In lieu of recording the required information in subsection B of this section on a hard copy prescription, a pharmacy may record all required information in an automated data processing system used for storage and retrieval of dispensing information in accordance with 18VAC110-20-250.

E. For prescriptions transferred between pharmacies using a common database, the pharmacy receiving the prescription shall not be required to maintain a hard copy pursuant to 18VAC110-20-240 B provided that the system used is capable of generating a hard copy of the transferred prescription upon request or except as required by federal law.

18VAC110-20-370 to 18VAC110-20-380. (Repealed.)

18VAC110-20-390. Kickbacks, fee-splitting, interference with supplier.

A. A pharmacy shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, kickbacks, fee-splitting, or special charges in exchange for prescription orders.

B. A pharmacy shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person in denying a patient the opportunity to select his supplier of prescribed medications.

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.

18VAC110-20-400. Returning of drugs and devices.

Drugs may be accepted for return or exchange by any pharmacist or pharmacy for resale in accordance with the provisions of § 54.1-3411.1 of the Code of Virginia. Devices may be accepted for return or exchange provided the device is in the manufacturer's original sealed packaging.

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.

18VAC110-20-411. to 18VAC110-20-416. (Repealed.)

18VAC110-20-417. (Reserved.)

18VAC110-20-418. Continuous quality improvement programs.

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with § 54.1-3434.03 of the Code of Virginia and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

B. Pharmacies not actively reporting to patient safety organizations, consistent with § 54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on duty of the dispensing error.

b. A pharmacist on duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.

c. A pharmacist on duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error, that may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization, and analysis of the event.

b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18VAC110-20-10, of dispensing errors. An analysis of each dispensing error shall be performed within 30 days of identifying the error.

c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.

d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.

e. A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information:

(1) Dates the analysis was initiated and completed;

(2) Names of the participants in the analysis;

(3) General description of remedial action taken to prevent or reduce future errors; and

(4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days.

18VAC110-20-419. (Reserved.)

Part VIII
Unit Dose Dispensing Systems

18VAC110-20-420. Unit dose dispensing system.

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

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

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

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

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

5. The patient's individual drug drawer or tray shall be labeled in a manner to identify the patient and his location without violating health privacy laws.

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

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

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

a. The date of filling of the drug cart;

b. The location of the drug cart;

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

d. The initials of the pharmacist checking and certifying the contents of the drug cart in accordance with the provisions in 18VAC110-20-270 C.

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

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

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

c. In the case of the computer-based distribution system, a uniformly maintained "fill list" or other document containing substantially the same information may be accepted as the dispensing record for Schedule II through VI drugs. Records of disposition/administration for floor stock drugs as provided in 18VAC110-20-460 B will be accepted for drugs distributed as floor stock.

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

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

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

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

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

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

18VAC110-20-425. Robotic pharmacy systems.

A. Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in barcoded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply:

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

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

3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial 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 complied with and shall include at a minimum procedures for ensuring:

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

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. Accurate recording of any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution;

h. Appropriately performing an analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

i. Maintaining quality assurance reports.

5. All manual picks shall be checked by pharmacists.

6. If it is identified that the robot selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot. An investigation of the cause of the event shall be completed, and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format.

7. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include a summary indicating the date and description of all discrepancies that include 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. Intravenous admixture robotics may be utilized to compound drugs in compliance with § 54.1-3410.2 of the Code of Virginia and 18VAC110-20-321; however, a pharmacist shall verify the accuracy of all compounded drugs pursuant to 18VAC110-20-270 B.

C. Medication carousels functioning with or without a robotic pharmacy system in a hospital may be utilized to store and guide the selection of drugs to be dispensed or removed from the pharmacy under the following conditions:

1. The entry of drug information into the barcode database for assignment of a barcode to an individual drug shall be performed by a pharmacist who shall verify the accuracy of the barcode assignment.

2. A pharmacist is not required to verify the accuracy of a patient-specific drug removed from a medication carousel if:

a. The entry of the order for a patient-specific drug into the pharmacy's dispensing software is verified by a pharmacist for accuracy and is electronically transmitted to the medication carousel; and

b. The patient-specific drug removed from the medication carousel by a pharmacy technician is verified for accuracy by the pharmacy technician who shall scan each drug unit removed from the medication carousel prior to dispensing, and a nurse or other person authorized to administer the drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient. The requirement for scanning by a nurse or other person authorized to administer is waived in an emergent event when a delay would cause imminent harm to the patient; or

c. The patient-specific drug is checked by two pharmacy technicians if a hospital does not have the capability for the drug to be verified for accuracy by scanning each drug unit. The first pharmacy technician removing the patient-specific drug from the medication carousel shall perform a visual inspection of each drug unit for accuracy and then double check the accuracy by scanning an individual unit of each drug. A second, different pharmacy technician shall perform a separate visual inspection of each drug unit and scan an individual unit of each drug for final verification. A nurse or other person authorized to administer the drug shall scan each drug unit prior to administration, unless the drug is being administered to treat an emergent event when a delay would cause imminent harm to the patient.

3. A pharmacist is not required to verify the accuracy of the drug removed from the medication carousel by a pharmacy technician if that drug is intended to be placed into an automated drug dispensing system as defined in § 54.1-3401 of the Code of Virginia or distributed to another entity legally authorized to possess the drug if:

a. The list of drugs to be removed from the medication carousel for loading or replenishing an individual automated dispensing system is electronically transmitted to the medication carousel; and

b. The drug removed from the medication carousel is verified for accuracy by the pharmacy technician by scanning each drug unit removed from the medication carousel prior to leaving the pharmacy and delivering the drug to the automated drug dispensing system or distributed to another entity, and a nurse or other person authorized to administer the drug scans each drug unit using barcode technology to verify the accuracy

of the drug prior to administration of the drug to the patient. If the drug is placed into an automated drug dispensing system located within a hospital, or the entity receiving the distributed drug, wherein a nurse or other person authorized to administer the drug will not be able to scan each drug unit using barcode technology to verify the accuracy of the drug prior to patient administration, then a second verification for accuracy shall be performed by a pharmacy technician by scanning each drug unit at the time of placing the drugs into the automated dispensing system; or

c. The drug intended for restocking an automated dispensing device is checked by two pharmacy technicians if the hospital does not have the capability for scanning each drug unit. The first pharmacy technician removing the drug for restocking from the medication carousel shall perform a visual inspection of each drug unit for accuracy and then double check the accuracy by scanning an individual unit of each drug of the automated dispensing device restock order prior to leaving the pharmacy. A second, different pharmacy technician shall perform a separate visual inspection of each drug unit and scan an individual unit for each drug of the restock order for final verification at the time of placing the drug into the automated dispensing device. A nurse or other person authorized to administer the drug shall scan each drug unit prior to administration, unless the drug is being administered to treat an emergent event where a delay would cause imminent harm to the patient.

4. A pharmacist shall verify the accuracy of all drugs that are manually removed from the medication carousel by a pharmacy technician without the use of barcode scanning technology to verify the accuracy of the selection of the drug product prior to dispensing those drugs or those drugs leaving the pharmacy.

5. A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of drugs prepared that day utilizing the medication carousel technology. A manual or electronic record, from which information can be readily retrieved, shall be maintained and shall include:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of the pharmacist verifying the accuracy of the process.

D. 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 of the board.

18VAC110-20-430. (Repealed.)

Part IX
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 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 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 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.

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.

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.

18VAC110-20-470. Emergency room.

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

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

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

3. A medical practitioner may dispense drugs to his patients if in a bona fide medical emergency or when pharmaceutical services are not readily available and if permitted to do so by the

hospital; the drug container and the labeling shall comply with the requirements of this chapter and the Drug Control Act.

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

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

a. Date and time dispensed;

b. Patient's name;

c. Prescriber's name; and

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

18VAC110-20-480. (Repealed.)

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

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

B. Policy and procedure manual; access codes.

1. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual, which shall include provisions for granting and terminating user access.

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

C. Distribution of drugs from the pharmacy.

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

2. At the time of loading any Schedules 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 ensuring reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution of drugs from the device.

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

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

E. Discrepancy reports. A discrepancy report for all Schedules II through V drugs and any drugs of concern, as defined in § 54.1-3456.1 of the Code of Virginia, shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

F. Reviews and audits.

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

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

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

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

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

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

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

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

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

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity, which includes usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

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

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

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

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

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

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

H. Records.

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

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

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

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

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

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

4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided

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

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

A. The pharmacy may prepare a kit for a licensed EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this kit. Except as authorized in 18VAC110-20-505, a pharmacist shall check each kit after filling and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The kit is sealed, secured, and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection of theft or loss.

a. The hospital pharmacy shall have a method of sealing the kits such 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. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.

c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.

3. Drugs and devices may be administered by an EMS provider upon an oral or written order or standing protocol 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 EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The EMS provider shall make a record of all drugs and devices administered to a patient.

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. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the

pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

5. Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year:

a. The record of filling and verifying the kit to include the drug contents of the kit, the initials of the pharmacist verifying the contents, the date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit, which shall be no later than the expiration date associated with the first drug or device scheduled to expire.

b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.

6. Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation shall be maintained in the pharmacy for a period of two years from the date of destruction.

7. The record of the drugs and devices 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.

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

9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.

B. A licensed EMS agency may obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.

1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.

2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.

3. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.

4. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge, which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

5. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs or devices, Schedule II, III, IV, or V drugs shall remain in a separate, sealed container and shall only be exchanged in accordance with provisions of subsection A of this section.

18VAC110-20-505. Use of radio-frequency identification.

A hospital pharmacy may use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for licensed emergency medical services pursuant to 18VAC110-20-500 or other kits used as floor stock throughout the hospital under the following conditions:

1. A pharmacist shall be responsible for performing and verifying the accuracy of the following tasks:

a. The addition, modification, or deletion of drug information into the RFID database for assignment of a RFID tag to an individual drug; and

b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags.

2. A pharmacy technician may place the RFID tag on the drugs, and a pharmacist shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.

3. A pharmacy technician may remove RFID-tagged drugs from the pharmacy's inventory whose RFID tags have been previously verified for accuracy by a pharmacist and place the drugs into the kit's container. A pharmacy technician may then place the container into the pharmacy's device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.

4. A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of all kits prepared that day utilizing the RFID technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of pharmacist verifying the accuracy of the process.

5. Pharmacies engaged in RFID tagging of drugs shall be exempt from the requirements in subsection C of 18VAC110-20-490, subsection A of 18VAC110-20-460, and subsection A of 18VAC110-20-355.

6. All records required by this subsection shall be maintained for a period of one year from the date of verification by the pharmacist.

18VAC110-20-510. Identification for medical intern or resident prescription form in hospitals.

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

18VAC110-20-515. Remote prescription order processing for hospitals and long-term care facilities.

A. Remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;

2. Entering prescription and patient data into a data processing system;

3. Transferring prescription information;

4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication;

5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order;

6. Interpreting or acting on clinical data;

7. Performing therapeutic interventions;

8. Providing drug information to the medical or nursing staff of the hospital or long-term care facility; or

9. Authorizing the administration of the drug to the patient by appropriate hospital or long-term care facility staff.

B. The primary pharmacy providing pharmacy services to a hospital or long-term care facility may outsource certain order processing functions as described in subsection A of this section to another pharmacy in Virginia or a registered nonresident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;

2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties that are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;

3. Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist; and

4. The pharmacies shall share a common electronic file or have technology that allows sufficient information necessary to process a prescription order.

C. A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;

2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in remote processing;

3. Procedures for protecting the confidentiality and integrity of patient information;

4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;

5. Procedures for maintaining required records;

6. Procedures for complying with all applicable laws and regulations;

7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and

8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

D. A pharmacy involved in remote prescription order processing shall maintain a record that identifies each person who performed a processing function for every order.

1. The record shall be available by prescription order or by patient name.

2. The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout that identifies every person who performed a task involved in processing a prescription order and the location where the task was processed.

3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

E. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A of this section provided the pharmacy establishes controls to protect the privacy and security of confidential records.

Part X
Pharmacy Services to Long-Term Care Facilities

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

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.

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

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

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

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

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

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

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

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

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

a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by § 54.1-3411.1 of the Code of Virginia and 18VAC110-20-400, or 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 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 drug therapy, drug interactions, drug administration, or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

B. A pharmacist employed by or contracted with a pharmacy providing services to a long-term care facility may share a copy of a Schedule VI prescription or order with a pharmacist at another pharmacy for the purpose of dispensing an immediate supply of drugs, not to exceed a seven-day supply, without transferring the prescription pursuant to 18VAC110-20-360.

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.

A. The pharmacist providing services may prepare an emergency kit for a long-term care facility in which 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 or an automated drug dispensing system, as provided in subsection B of this section, 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, diazepam rectal gel, and the intranasal spray formulation of naloxone 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, resealing, or both. 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 items 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.

B. Drugs that would be stocked in an emergency kit, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555.

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

A. An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box shall be subject to the following conditions:

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

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

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication 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, the time, and the name and quantity of items removed. When the stat-drug box has been opened, it is returned to the pharmacy.

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

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

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

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

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

B. Drugs that would be stocked in a stat-drug box, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555, except that the quantity of drugs in Schedules II through V stocked in the system shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the nursing home.

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

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

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

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have online 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, unless the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.

3. For facilities not required to obtain a controlled substance registration, access to the automated dispensing device shall be restricted to a licensed nurse, pharmacist, or prescriber, or a registered pharmacy technician for the purpose of stocking or reloading.

4. 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, including a drug that would be stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550, 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 online 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.

5. 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.

6. 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.

7. 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.

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

9. At the time of loading any Schedules 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.

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

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

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

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

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

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

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

11. 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.

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

13. 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.

14. 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. Schedules II through V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 14 a and 14 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 offsite 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.

18VAC110-20-560. Floor stock.

In addition to an emergency box or stat-drug box, a long-term care facility in which only those persons licensed to administer are administering drugs may maintain a stock of intravenous fluids, irrigation fluids, heparin flush kits, medicinal gases, sterile water and saline, and prescription devices. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.

Part XI
Other Institutions and Facilities

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

A. 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 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 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.

18VAC110-20-580. Animal shelters.

An animal shelter, after having obtained the proper registrations pursuant to state and federal laws, may purchase, possess and administer 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 public or private animal shelter, as defined in § 3.2-6500 of the Code of Virginia, shall only be stored and administered at the address of the shelter.

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 persons 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.

3. The person in charge of administration of drugs 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 registration to the board and shall take a complete and accurate inventory of all drugs in stock.

b. An application for a new registration 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.

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

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

6. 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 facilities.

A. All prescription drugs at any correctional facility shall be subject to the following conditions:

1. Notwithstanding the allowances in subsections B, C, and D of this section, prescription drugs shall be obtained only on an individual prescription basis.

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

3. 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.

4. 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. Schedule VI 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.

5. After performing the audit required by subdivision 4 a of this subsection and ensuring the proper maintenance of the administration records, drugs in Schedules II through V shall be destroyed at the site of the correctional facility using a method of destruction that renders the drug unrecoverable.

a. The destruction shall be performed by a nurse, pharmacist, or physician and witnessed by the nurse supervisor, a pharmacist, or a physician.

b. Destruction of drugs shall occur within 30 days of discontinuance.

c. A complete and accurate record of the drugs destroyed shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the correctional 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.

B. Emergency and stat-drug box. An emergency box and a stat-drug box may be prepared for 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.

C. A correctional facility may maintain a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline to be accessed only by those persons licensed to administer drugs and shall be administered only by such persons pursuant to a valid prescription or lawful order of a prescriber. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.

D. Except for drugs in an emergency box, stat-drug box, or a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline, prescription drugs, including vaccines, may be 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 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.

Part XII
Exempted Stimulant or Depressant Drugs and Chemical Preparations

18VAC110-20-600. Excluded substances.

The list of excluded substances, which may be lawfully sold over the counter without a prescription under the federal Food, Drug and Cosmetic Control Act (21 USC § 301), as set forth in 21 CFR 1308.22, is adopted pursuant to the authority set forth in §§ 54.1-3443, 54.1-3450 and 54.1-3452 of the Drug Control Act.

18VAC110-20-610. Exempted chemical preparations.

The list of exempt chemical preparations 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 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 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 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.

Part XIII
Medical Equipment Suppliers

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

A. Any person or entity desiring to obtain a permit as a medical equipment supplier shall file an application with the board on a form approved by the board. An application shall be filed for a new permit or for acquisition of an existing medical equipment supplier. The application shall designate the hours of operation the location will be open to service the public and shall be signed by a person who works at the location address on the application and will act as a responsible party for that location.

B. Any change in the hours of operation expected to last for more than one week shall be reported to the board in writing and a notice posted, at least 14 days prior to the anticipated change, in a conspicuous place to the public.

1. Such notification of a change in hours of operation is not required when the change is necessitated by emergency circumstances beyond the control of the owner or responsible party or when the change will result in an expansion of the current hours of operation.

2. If the medical equipment supplier is unable to post the change in hours 14 days in advance, the responsible party or owner shall ensure the board is notified as soon as he knows of the change and disclose the emergency circumstances preventing the required notification.

C. Within 14 days of a change in the responsible party assigned to the permit, the outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name of the new responsible party.

D. A permit holder proposing to change the location of an existing license or permit or make structural changes to an existing location shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.

E. A permit shall not be issued to any medical equipment supplier to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license or permit is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.

18VAC110-20-640. to 18VAC110-20-670. (Repealed.)

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.

E. A valid order authorizing the dispensing of drugs or devices may be transferred from one medical equipment supplier to another medical equipment supplier provided the order can be filled or refilled. The transfer shall be communicated either orally by direct communication between an individual at the transferring medical equipment supplier and the receiving medical equipment supplier, by facsimile machine, or by electronic transmission.

1. The transferring medical equipment supplier shall:

a. Record the word "VOID" on the face of the invalidated order;

b. Record on the reverse side of the invalidated order the name and address of the medical equipment supplier to which it was transferred, the date of the transfer, and for an oral transfer, the name of the individual receiving the prescription information and the name of the individual transferring the information.

2. The receiving medical equipment supplier shall:

a. Write the word "TRANSFER" on the face of the transferred prescription;

b. Provide all information required to be on a valid order to include:

(1) Date of issuance of original order;

(2) Original number of refills authorized on the original order;

(3) Date of original dispensing if applicable;

(4) Number of valid refills remaining and date of last dispensing;

(5) Medical equipment supplier name and address from which the order information was transferred; and

(6) Name of transferring individual if transferred orally.

3. Both the original and transferred order shall be maintained for a period of two years from the date of last refill. In lieu of recording the required information on the hard copy of a valid order, a medical equipment supplier may record all required information in an automated data processing system used for the storage and retrieval of dispensing information.

F. A nonresident medical equipment supplier shall register and practice in accordance with § 54.1-3435.3:1 of the Code of Virginia.

Part XVI
Controlled Substances Registration for Other Persons or Entities

18VAC110-20-685. Definitions for controlled substances registration.

For purposes of this part, the following definitions shall apply:

"BHA" means a behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

"CSB" means a community services board facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

"PACE" means a program of all-inclusive care for the elderly overseen by the Department of Medical Assistance Services in accordance with § 32.1-330.3 of the Code of Virginia.

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity that maintains or intends to maintain a supply of Schedules II through Schedule VI controlled substances, other than manufacturers' samples, 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 that may be registered by the board shall include 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, crisis stabilization units, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, 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.

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, pharmacy technician for alternate delivery sites, a person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, or other person approved by the board who is authorized to administer the controlled substances.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedules 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.

F. The board may issue a controlled substance registration to an entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images

and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedules II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration provided:

1. There is a documented need for such registration, and issuance of the registration of the entity is consistent with the public interest;

2. The entity is under the general supervision of a licensed pharmacist or a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine; and

3. The application is signed by a person who will act as the responsible party for the entity for the purpose of compliance with provisions of this subsection. The responsible party shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer 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 type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs that 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 (i) 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; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation;

or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. 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, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including 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 that meet USP-NF specifications or manufacturers' suggested storage for each drug.

B. Any drug that 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 Schedules 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 that 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 that has a security device for the detection of breaking that 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 and device shall be based on accepted alarm industry standards.

3. The device shall be maintained in operating order, 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, alternate delivery sites as provided in 18VAC110-20-275, emergency medical services agencies stocking only intravenous fluids with no added drug, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and teaching institutions possessing only Schedule VI drugs.

18VAC110-20-720. Requirements for recordkeeping.

The person named as the responsible party on the controlled substances registration shall be responsible for recordkeeping for Schedule II through VI drugs in accordance with provisions of § 54.1-3404 of the Code of Virginia and the following:

1. Inventories and administration records of Schedule II drugs shall be maintained separately from all other records and shall be kept in chronological order by date of administration.

2. All records shall be maintained at the same location as listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. In the event that an inventory is taken as the result of a theft of drugs, 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. 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 or after the close of business on that date. An entity which is open 24 hours a day shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

4. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining under the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia).

5. The Department of Forensic Science may exclude from any inventory quantities of controlled substances used to conduct chemical analyses and controlled substances received for analyses as evidentiary material as provided in § 54.1-3404 G of the Code of Virginia.

18VAC110-20-725. Repackaging by a CSB, BHA, or PACE site.

A. Definition. For purposes of this section, "repackaging" shall mean removing a drug from a container already dispensed and labeled by a pharmacy or medical practitioner authorized to dispense, for a particular client of a CSB, BHA, or PACE site, and placing it in a container designed for a person to be able to repackage his own dispensed prescription medications to assist with self-administration and compliance with dosage instructions. Such repackaging shall not include the preparation of a patient-specific label that includes drug name, strength, or directions for use or any other process restricted to a pharmacist or pharmacy technician under the direct supervision of a pharmacist.

B. Persons authorized to repackage. Repackaging shall be performed by a pharmacist, pharmacy technician, nurse, or such other person who has successfully completed a board-approved training program for repackaging of prescription drug orders as authorized in § 54.1-3420.2 of the Code of Virginia. A CSB, BHA, or PACE site using such other person shall maintain documentation of completion of an approved training program for at least one year from date of termination of employment or cessation of repackaging activities.

C. Requirements for repackaging.

1. The repackaging of a dispensed prescription drug order pursuant to § 54.1-3420.2 of the Code of Virginia shall only be done at a CSB, BHA, or PACE site.

2. The repackaging of dispensed prescription drugs shall be restricted to solid oral dosage forms and a maximum of a 14-day supply of drugs.

3. The drug container used for repackaging pursuant to this section shall bear a label containing the client's first and last name and name and 24-hour contact information for the CSB, BHA, or PACE site.

4. A clean, well-closed container that assists the client with self-administration shall be used when multiple doses of a repackaged drug are provided to the client at one time.

5. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier.

D. Written information for client. At the time a repackaged drug is initially given to a client, and upon any subsequent change in the medication order, the client shall be provided written information about the name and strength of the drug and the directions for use. Such written information shall have been prepared by a pharmacy or by a nurse at the CSB, BHA, or PACE site.

E. Retention, storage, and destruction of repackaged drugs.

1. Any portion of a client's prescription drug order not placed into a container intended to assist with self-administration may be either given to the client or retained by the CSB, BHA, or PACE site for subsequent repackaging. If retained by the CSB, BHA, or PACE site, the remaining portion shall be stored within the board-approved drug storage location in the original labeled container and shall only be used for the client for whom the drug was originally dispensed.

2. Any portion of a prescription drug order remaining at the CSB, BHA, or PACE site that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the CSB, BHA, or PACE site shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client.

F. Recordkeeping.

1. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following:

a. Date of repackaging;

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Pharmacy name;

e. Drug name and strength;

f. Quantity of drug repackaged; and

g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container.

2. A record of destruction shall be made and maintained for one year for any prescription drug orders destroyed by the CSB, BHA, or PACE site and shall include the following:

a. Date of destruction;

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Drug name and strength;

e. Quantity of drug destroyed; and

f. Initials of the person performing the destruction.

18VAC110-20-726. Criteria for approval of repackaging training programs.

A. Application. Any person wishing to apply for approval of a repackaging training program shall submit the application fee prescribed in 18VAC110-20-20 and an application on a form approved by the board and shall meet the criteria established in this section. The application shall name a program director who is responsible for compliance with this section.

B. Curriculum. The curriculum for a repackaging training program shall include instruction in current laws and regulations applicable to a CSB, BHA, or PACE site for the purpose of assisting a client with self-administration pursuant to § 54.1-3420.2 of the Code of Virginia and in the following repackaging tasks:

1. Selection of an appropriate container;

2. Proper preparation of a container in accordance with instructions for administration;

3. Selection of the drug;

4. Counting of the drug;

5. Repackaging of the drug within the selected container;

6. Maintenance of records;

7. Proper storage of drugs;

8. Translation of medical abbreviations;

9. Review of administration records and prescriber's orders for the purpose of identifying any changes in dosage administration;

10. Reporting and recording the client's failure to take medication;

11. Identification, separation, and removal of expired or discontinued drugs; and

12. Prevention and reporting of repackaging errors.

C. Instructors and program director. Instructors for the program shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States or (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked in any jurisdiction in the United States. The program director shall maintain a list of instructors for the program.

D. Program requirements.

1. The length of the program shall be sufficient to prepare a program participant to competently perform repackaging consistent with § 54.1-3420.2 of the Code of Virginia and 18VAC110-20-725.

2. The program shall include a post-training assessment to demonstrate the knowledge and skills necessary for repackaging with safety and accuracy.

3. 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 a CSB, BHA, PACE site, or the board.

4. The program shall maintain records of training completion by persons authorized to repackage in accordance with § 54.1-3420.2 of the Code of Virginia. Records shall be retained for two years from date of completion of training or termination of the program.

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

E. Expiration and renewal of program approval. A repackaging 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.

18VAC110-20-727. Pharmacists repackaging for clients of a CSB, BHA, or PACE.

A. As an alternative to repackaging as defined in 18VAC110-20-725, a pharmacist at a CSB, BHA, or PACE site may repackage a client's prescription drugs that have been dispensed by another pharmacy into compliance packaging under the following conditions:

1. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier.

2. The compliance packaging shall comply with the requirements of 18VAC110-20-340 B.

3. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following:

a. Date of repackaging;

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Pharmacy name;

e. Drug name and strength;

f. Quantity of drug repackaged; and

g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container.

4. Any portion of a prescription drug order remaining at the CSB, BHA, or PACE site that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the CSB, BHA, or PACE site shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client.

B. A primary provider pharmacy may also provide this service in compliance with the provisions of 18VAC110-20-535.

18VAC110-20-728. Drugs for immediate treatment in crisis stabilization units.

A. In accordance with § 54.1-3423 of the Code of Virginia, a crisis stabilization unit shall apply for and obtain a controlled substances registration in order to maintain a stock of Schedule VI controlled substances for immediate treatment of patients in crisis. Schedule II through V controlled substances shall not be stocked. The responsible party listed on the application shall be a nurse who regularly administers controlled substances at the crisis stabilization unit and the supervising practitioner shall be either the medical director for the unit or a pharmacist from a provider pharmacy.

B. In consultation with a provider pharmacist, the medical director for the unit shall determine the list of controlled substances to be stocked at the crisis stabilization unit. The list shall be limited to Schedule VI controlled substances and only those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked.

C. A nurse administering a drug from this stock pursuant to an oral order of a prescriber in accordance with § 54.1-3423 of the Code of Virginia shall record such order in the patient's medical record.

D. Records.

1. A record shall be maintained of all drugs received as stock by the crisis stabilization unit.

2. A record shall be made documenting administration or other authorized disposition of stocked drugs that includes the following:

a. Name of patient;

b. Date and time of administration;

c. Drug name, strength, and quantity administered;

d. Name or initials of person administering; and

e. Prescriber name.

3. Records shall be maintained at the same location listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It

shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining.

4. Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible.

18VAC110-20-730. Requirements for practitioner of medicine or osteopathy in free clinics.

A. Any practitioner of medicine or osteopathy who provides controlled substances that have been donated pursuant to subdivision 11 of § 54.1-3301 of the Code of Virginia shall apply for a controlled substances registration.

B. A practitioner in a free clinic may only accept donated drugs pursuant to this registration if they are donated by an entity or practitioner who holds a current active license, permit, or registration issued by the board authorizing the dispensing or distribution of drugs.

C. A practitioner shall store such donated drugs for dispensing in compliance with the storage and security requirements set forth in 18VAC110-20-710, and a drug that has exceeded its expiration date shall not be dispensed. A practitioner shall be responsible for maintaining and complying with a written procedure for reviewing inventory for the purpose of removing expired drugs.

D. A practitioner shall package any dispensed drugs in accordance with the provisions of §§ 54.1-3426 and 54.1-3427 of the Code of Virginia and 18VAC110-20-340 and 18VAC110-20-350.

E. A practitioner shall label any dispensed drugs in accordance with the provisions of §§ 54.1-3410 and 54.1-3463 of the Code of Virginia and 18VAC110-20-330 to include the free clinic name and address; name of the prescriber; patient name; date of dispensing; drug name to include the generic name if the drug has a single active ingredient; drug strength, if applicable; quantity; and directions for use.

F. A practitioner shall comply with all recordkeeping requirements of § 54.1-3404 of the Code of Virginia and shall also maintain a chronological record of all Schedule II through VI drugs dispensed showing patient name and address; date of dispensing; drug name, strength, and quantity dispensed; and name or initials of the dispensing practitioner.

G. A practitioner under this section may enter into a contract or written agreement with a pharmacy whereby the pharmacy maintains all or part of the donated stock, dispenses the prescription pursuant to a written prescription by a prescriber at the free clinic, and delivers the dispensed prescription to the free clinic for pick up by the patient in accordance with subsection C of 18VAC110-20-275.

18VAC110-20-735. Requirements for dispensing of naloxone by trained individuals.

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal pursuant to subsection Y of § 54.1-3408 of the Code of Virginia shall maintain the following records:

1. The prescriber's standing order issued in accordance with subsection Y of § 54.1-3408 of the Code of Virginia authorizing the trained individual to dispense naloxone.

2. Invoices or other records showing receipts of naloxone 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 site 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.

3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services.

4. Record of dispensing indicating the name of the person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

B. The naloxone shall be labeled with directions for use in accordance with the prescriber's standing order, date of dispensing, name of person receiving the drug, drug name and strength, and the name and the telephone number for the entity associated with the controlled substances registration.

C. The naloxone shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect it from adulteration.

D. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate shall ensure compliance with recall procedures as issued by the manufacturer, U.S. Food and Drug Administration, or board to ensure an affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

E. Except for a prescriber's standing order, which shall be maintained on site for a period of not less than two years from the date of the last dispensing, records shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

18VAC110-20-740. Drug donation sites.

Any pharmacy with a current active pharmacy permit may apply on a form provided by the board for registration as a drug donation site. A registered drug donation site may receive eligible donated drugs, transfer such donated drugs to another registered drug donation site, or redispense the donated drugs in accordance with § 54.1-3411.1 of the Code of Virginia to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. Drugs collected under the drug donation program may not be dispensed to any other patient, sold, or otherwise distributed except as authorized in 18VAC110-20-770 or 18VAC110-20-790.

18VAC110-20-750. Eligible drugs.

A. Drugs may be accepted by a registered drug donation site only if the following criteria are met:

1. Official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium Class A or B container requirements, or better, as set forth in § 54.1-3411.1 A 2 of the Code of Virginia;

2. The drugs bear an expiration date that is not less than 90 days from the date the drug is donated; and

3. The drugs have not been adulterated or misbranded.

B. The following drugs shall not be accepted by a drug donation site:

1. Schedule II-V controlled substances or any other drug if such return is inconsistent with federal law;

2. Drugs determined to be hazardous for donation based on (i) the pharmacist's professional judgment, experience or knowledge, or (ii) available reference materials;

3. Drugs that may only be dispensed to a patient registered with the drug manufacturer under a restricted distribution system; and

4. Drugs that have been previously compounded.

18VAC110-20-760. Procedures for collecting eligible donated drugs.

A. A pharmacist or a pharmacy technician under the personal supervision of a pharmacist shall receive and conduct the initial screening for eligibility of donated drugs.

B. At the time of accepting donated drugs, the drug donation site shall ensure that a donor form is completed. The drug donation site shall give a copy of the donor form to the person donating the drug at the time of the donation and shall maintain the original donor form. A donor form is not required for drugs donated by a patient residing in a long-term care facility or other facility where drugs are administered to that patient if the drugs are donated directly to the provider pharmacy for that facility and such provider pharmacy is registered as a drug donation site.

C. A donor form shall include the following information:

1. A statement that the donor is the patient or patient's agent for whom the prescription drug was dispensed;

2. A statement that the donor intends to voluntarily donate the prescription drug for redispensing;

3. A statement attesting that the drugs have been properly stored at all times while in the possession of the patient according to official compendium storage requirements;

4. Contact information for the patient or patient's agent;

5. The date of donation;

6. A listing of the donated drugs to include name, strength, and quantity;

7. A statement that private health information will be protected;

8. The signature of the patient or patient's agent; and

9. The initials of the receiving pharmacist, or the initials of the receiving pharmacy technician and supervising pharmacist.

D. Donated prescription drugs shall be stored within the prescription department, separate from other drug inventory.

E. Prior to transferring any donated drugs or redispensing donated drugs, a pharmacist shall perform a final review of any donated drug for eligibility and shall ensure that all the donor's patient specific information has been removed from previous labeling or rendered unreadable.

F. A drug donation site may not charge a fee for collecting donated drugs.

18VAC110-20-770. Procedure for transferring donated prescription drugs.

A. A drug donation site may transfer eligible donated prescription drugs to another drug donation site for the purpose of redispensing.

B. The transferring drug donation site shall provide a transfer record to the receiving drug donation site that includes the following:

1. The names and addresses of the transferring site and the receiving site;

2. The name, strength, and quantity of each donated drug being transferred; and

3. The date of transfer.

C. The original transfer record shall be maintained by the transferring drug donation site.

D. A copy of the transfer record shall be provided to the receiving drug donation site, the date of receipt shall be recorded on the copy, and it shall be maintained by the receiving drug donation site.

18VAC110-20-780. Procedure for dispensing donated prescription drugs.

A. A drug donation site redispensing donated prescription drugs shall comply with applicable federal and state laws and regulations for dispensing prescription drugs.

B. The pharmacy redispensing donated drugs shall not charge for cost of donated drugs, but may charge a dispensing or administrative fee for each such drug redispensed, consistent with the provisions of subdivision 10 of § 54.1-3301 of the Code of Virginia.

C. Recipients of a redispensed donated drug shall sign a form prior to receiving the drug that includes a statement that the recipient understands that the drug received has been donated for the purpose of redispensing pursuant to § 54.1-3411.1 of the Code of Virginia. The drug donation site shall maintain this form.

D. A drug donation site is under no obligation to obtain a prescription drug that is not in inventory at the time of a request for such drug.

18VAC110-20-790. Procedures for disposing of donated prescription drugs.

A. A drug donation site in possession of donated prescription drugs ineligible for redispensing shall dispose of such drugs in compliance with 18VAC110-20-210.

B. A drug donation site shall maintain records of disposal or transfer for disposal of donated prescription drugs separately from other pharmacy disposal records.

18VAC110-20-800. Records.

A. All records required for drug donation programs shall be maintained chronologically for two years.

B. Records and prescriptions related to donated drugs shall be maintained separately from other pharmacy records.

C. Storage of records.

1. Transfer, dispensing, and disposal records may be stored in an electronic database or record.

2. Prescriptions and signed forms, as well as any other records, may be stored as an electronic image that provides an exact, clearly legible image of the document.

3. Records may be stored in secured storage, either on or offsite.

D. All records in offsite 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.