PROPOSED REGULATIONS

PART I. GENERAL PROVISIONS

18 VAC 110-20-10. Definitions.

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

"*ACPE*" means the American Council on Pharmaceutical Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of fifty percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly-owned subsidiary owning the entity, with another business or corporation.

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

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

"*Board*" means the Virginia Board of Pharmacy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"*Light resistant container*" means a container that protects the contents from the effects of light by virtue of the specific properties of the material of which it is composed, including any coating

applied to it. Alternatively, a clear and colorless or a translucent container may be made light-resistant by means of an opaque covering, in which case the label of the container bears a statement that the opaque covering is needed until the contents have been used. Where a monograph directs protection from light, storage in a light-resistant container is intended.

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

"*Nuclear pharmacy*" means a pharmacy providing radiopharmaceutical services.

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

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

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

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

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

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

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

"*Radiopharmaceutical*" means any article that exhibits spontaneous decay or disintegration of any unstable atomic nucleus, usually accompanied by the emission of ionizing radiation and any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such article.

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

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

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

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

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

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

"*Storage temperature*" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that

storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

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

2. "Room temperature" means the temperature prevailing in a working area.

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

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

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

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its

characteristics, the container label bears an appropriate instruction to protect the product from freezing.

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

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

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

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

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

"*Unit dose system*" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and

location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a physician's order or medication administration record.

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

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

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

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

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

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

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

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

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

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

3. At the time of the inspection, the dispensing area shall comply with 18 VAC 110-20-150, 18 VAC 110-20-160, 18 VAC 110-20-170, 18 VAC 110-20-180 and 18 VAC 110-20-190 of this chapter.

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

XVI. CONTROLLED SUBSTANCES REGISTRATION FOR OTHER PERSONS OR ENTITIES.

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

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

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, ambulatory surgery centers, out-patient clinics, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

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

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

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

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

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

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

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

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

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

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

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

B. The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall

be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

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

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

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

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

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

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

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

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

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

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

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

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

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

18 VAC 110-20-720. Requirements for record-keeping.

The person named as the responsible party on the controlled substances registration shall be responsible for record-keeping 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).