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BOARD OF PHARMACY
Drug donation program

Part I
General Provisions

18VAC110-20-10. Definitions.

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

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

"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.

"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.

"DEA" means the United States Drug Enforcement Administration.

<u>"Drug donation site" means a permitted pharmacy that specifically registers with the Virginia Board of Pharmacy for the purpose of receiving or re-dispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.</u>

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

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

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

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

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

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

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

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

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

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

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that resul ts 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 experi enced 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 (1 04°F).

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

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

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

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

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

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

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

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

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

~~A.~~ 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.

~~B. Any pharmacy accepting drugs returned from nursing homes for the purpose of redispensing to the indigent free of charge shall maintain a copy of a written agreement with the nursing home in accordance with §54.1-3411.1 B of the Code of Virginia and a current policy and procedure manual describing the following:~~

~~1. Method of delivery from the nursing home to the pharmacy and of tracking of all prescription medications;~~

~~2. Procedure for determining the suitability and integrity of drugs for redispensing to include assurance that the drugs have been stored according to official compendial standards; and~~

~~3. Procedure for assigning a beyond-use date on redispensed drugs.~~

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 re-dispense 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, subdivision A2;

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 the pharmacist's professional judgment, experience, knowledge, or 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 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 re-dispensing;

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 of 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 re-dispensing 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.

E. 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 re-dispensing.

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 re-dispensing donated prescription drugs shall comply with applicable federal and state laws and regulations for dispensing prescription drugs.

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

C. Recipients of a re-dispensed 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 re-dispensing pursuant to §54.1-3411.1. 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 re-dispensing shall dispose of such drugs in compliance with 18 VAC110-20-210.

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 which provides an exact, clearly legible, image of the document; or

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.