Final Regulations of the Virginia Board of Pharmacy
18 VAC 110-20-10 et seq.

18 VAC 110-20-10. Definitions.

In addition to words and terms defined in §§54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in 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 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.

"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 nonproprietary 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 nonsealed 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 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.

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

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

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

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

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

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

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

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§1471-1476), i.e., in testing such containers, that 85%6C 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%6C fail in another five minutes after a demonstration of how to open it and that 90%6C 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.

"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 %6820° and %6810°C (%684° 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 Pharmacopeia-National Formulary.

"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.

18 VAC 110-20-20. Fees.

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

B. Fee for initial pharmacist licensure.

1. The application fee for a pharmacist license shall be $50.
2. The fees for taking all required examinations shall be paid directly to the examination service as specified by the board.
3. The application fee for a person whose license has been revoked or suspended indefinitely shall be $300.

C. Renewal of pharmacist license.

1. The annual fee for renewal of a pharmacist license shall be $50.
2. The annual fee for renewal of an inactive pharmacist license shall be $35.
3. If a pharmacist fails to renew his license within the Commonwealth by the renewal date, he must pay the back renewal fee and a $25 late fee within 60 days of expiration.
4. Failure to renew a pharmacist license within 60 days following expiration shall cause the license to lapse and shall require the submission of a reinstatement application, payment of all unpaid renewal fees, and a delinquent fee of $50.

D. Other licenses or permits.

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

a.	Pharmacy permit	$200
b.	Permitted physician to dispense drugs	$200
c.	Nonrestricted manufacturing permit	$200
d.	Restricted manufacturing permit	$150
e.	Wholesale distributor license	$200

f. Warehouser permit $200

g. Medical equipment supplier permit $150

h. Licensed humane society permit $10

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

a. Application for a change of the pharmacist-in-charge $25

b. Application for a change of location or a remodeling which requires an inspection $100

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

a. If a licensee fails to renew a required license or permit prior to the expiration date, a $25 late fee shall be assessed.

b. If a required license or permit is not renewed within 60 days after its expiration, the license or permit shall lapse, and continued practice or operation of business with a lapsed license or permit shall be illegal. Thereafter, reinstatement shall be at the discretion of the board upon submission of an application accompanied by all unpaid renewal fees and a delinquent fee of $50.

E. Controlled substances registration

1. The annual fee for a controlled substances registration as required by § 54.1-3422 of the Code of Virginia shall be $20.

2. If a registration is not renewed within 60 days of the expiration date, the back renewal fee and a $10 late fee shall be paid prior to renewal.

3. If a controlled substance registration has been allowed to lapse for more than 60 days, all back renewal fees and a $25 delinquent fee must be paid before a current registration will be issued. Engaging in activities requiring a controlled substance registration without holding a current

registration is illegal and may subject the registrant to disciplinary action by the board. Reinstatement of a lapsed registration is at the discretion of the board and may be granted by the executive director of the board upon completion of an application and payment of all fees.

F. Other fees.

1. A request for a duplicate wall certificate shall be accompanied by a fee of $25.
2. The fee for a returned check shall be $15.
3. The fee for board approval of an individual CE program is $100.
4. The fee for board approval of a robotic pharmacy system shall be $150.
5. The fee for a board-required inspection of a robotic pharmacy system shall be $150.

18 VAC 110-20-425. Robotic Pharmacy Systems

A. A pharmacy providing services to a hospital or a long-term care facility using a unit dose dispensing system may apply for approval of a robotic pharmacy system and a waiver of 18 VAC 110-20-270 B, provided the accuracy of the final dispensed prescription product is determined by a quality assurance plan. An applicant shall apply using a form provided by the board and shall pay a fee as set forth in 18 VAC 110-20-20.

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

1. Method of ensuring accurate packaging and loading of the robotic pharmacy system.
2. Procedures for conducting quality control checks of final dispensing for accuracy.

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

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

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

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

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

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

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

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

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

Certification

I certify that this regulation is full, true, and correctly dated.

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Elizabeth Scott Russell
Executive Director
Virginia Board of Pharmacy

Date:_____