Repeal of Part X. Compounding Sterile Pharmaceutical Products

Conforming Regulations to the Code of Virginia

Chapter 200 of the 2005 Acts of the Assembly

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.

~~"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.~~

"DEA" means the United States Drug Enforcement Administration.

"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.

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

"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.

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

~~"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.

“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.

~~"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 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.

18VAC110-20-321. Compounding.

The compounding of both sterile and non-sterile drug products shall be performed in accordance with USP-NF compounding standards and §54.1-3410.2 of the Code of Virginia.

~~Part X. Compounding Sterile Pharmaceutical Products~~ (Repealed)

18VAC110-20-411. ~~General requirements.~~ (Repealed)

~~Products intended for parenteral administration or ophthalmic instillation shall be compounded using aseptic processing and in accordance with §54.1-3410.2 of the Code of Virginia.~~

18VAC110-20-412. ~~Policy and procedure manual.~~ (Repealed)

~~A policy and procedure manual shall be prepared and maintained for the compounding, dispensing and delivery of sterile products that is consistent with USP-NF standards and guidance and shall include at least the following elements:~~

~~1. Personnel qualifications including initial and follow-up training and method of periodic reevaluation of qualifications and performance;~~

~~2. Scope of compounding performed at the pharmacy and proper procedures for compounding to include maintaining suitable environmental conditions in the compounding area, wearing appropriate garb to reduce particulate matter and contamination of work area, performing aseptic procedures.~~

~~3. Procedures for maintaining and monitoring proper operating conditions for all equipment used in sterile compounding;~~

~~4. Guidelines for patient or caretaker education if products are dispensed for home use to include instructions concerning proper storage, aseptic manipulation of the product, proper administration and use of devices if applicable, recognizing signs of instability or incompatibility, and procedures in case of an emergency with the product;~~

~~5. Guidelines for assignment of beyond-use dates for all compounded sterile products and justification for any date chosen which exceeds the standard set forth in this chapter;~~

~~6. Separate procedures for handling cytotoxic drugs, if applicable, to include protective apparel; disposal procedures consistent with applicable local, state, and federal requirements; procedures for handling spills; special packaging and labeling requirements, and delivery procedures to minimize risks of accidental spills;~~

~~7. If applicable, separate procedures for compounding sterile products using nonsterile components or open system transfer techniques and for end-product sterilization of these products.~~

18VAC110-20-413. ~~Physical and equipment requirements for pharmacies preparing sterile products.~~ (Repealed)

~~A. The sterile compounding area shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies used in aseptic processing.~~

~~B. The sterile compounding area where parenteral products are routinely prepared shall be isolated from other areas and other pharmacy functions.~~

~~C. Sterile compounding shall be performed within a laminar flow hood or other appropriate environmental control device capable of maintaining, during normal activity, at least Class 100 conditions in the work area where sterile compounding is performed. Compounding of cytotoxic preparations shall be performed in a vertical flow Class II biological safety cabinet.~~

~~D. A pharmacy preparing sterile products shall maintain supplies adequate for the aseptic preparation of sterile products including, but not limited to, the following:~~

~~1. Antimicrobial soap;~~

~~2. Hot and cold water supply easily accessible to the sterile compounding area for hand washing prior to aseptic compounding;~~

~~3. Appropriate apparel for personnel performing sterile compounding;~~

~~4. Suitable disposal containers for used needles, syringes, etc. and, if applicable, containers for cytotoxic waste and infectious wastes.~~

~~E. A pharmacy preparing sterile products shall have sufficient current reference materials related to sterile products consistent with the policy and procedure manual and with the types of products prepared.~~

~~F. The pharmacy preparing sterile products shall have equipment necessary for maintaining and monitoring required temperature storage conditions both in the pharmacy and during delivery to the patient, if applicable.~~

18VAC110-20-414. ~~Labeling requirements.~~ (Repealed)

~~A. In addition to other applicable labeling requirements for prescriptions as set forth in §54.1-3410 of the Code of Virginia and 18VAC110-20-260 B and 18VAC110-20-330, the label of a compounded sterile product shall include all active ingredient names, strengths, amounts, and concentrations, when applicable, and for IV infusion shall include the name of all solutions.~~

~~B. The label of a compounded parenteral sterile product shall include an appropriate beyond-use date and time, if applicable, and the required storage conditions to assure product integrity for that time period. Unless otherwise specified and justification provided in the policy and procedure manual, the expiration date for unpreserved sterile products prepared aseptically in a closed system for a single patient shall bear a maximum beyond-use date, including administration, as follows:~~

~~1. Twenty-eight hours if stored at controlled room temperature;~~

~~2. Seven days if stored under refrigeration; and~~

~~3. Thirty days if stored under freezing conditions.~~

~~C. The label of other compounded sterile products shall bear an appropriate beyond-use date, not to exceed 30 days from the date of preparation.~~

~~D. If the product is for home or other outpatient use, the label shall bear the prescribed administration regimen including rate and route of administration and any device specific instructions.~~

~~E. The label shall bear any appropriate auxiliary labeling, including precautions for cytotoxic drugs.~~

18VAC110-20-415. ~~Quality assurance.~~ (Repealed)

~~A. The PIC in a pharmacy compounding sterile products shall be responsible for maintaining and updating the policy and procedure manual as set forth in 18VAC110-20-411 in accordance with current acceptable standards, and for ensuring compliance with the policy and procedure manual.~~

~~B. All laminar flow hoods or other environmental control devices shall be certified according to accepted standards for operational efficiency by a qualified independent contractor initially, at least every six months and after relocation.~~

18VAC110-20-416. ~~Records for sterile compounding.~~ (Repealed)

~~In addition to other required records, the following additional records shall be maintained for sterile compounding:~~

~~1. Compounding records maintained on or with the original prescription, or in a log format which can be cross-referenced with the prescription, or in an automated data processing system which contains the same information required in a manual system and is capable of producing a hard copy printout of a two-year history of prescription compounding and dispensing upon request within 72 hours. In addition to prescription information, the record must include the following information:~~

~~a. Date of sterile compounding;~~

~~b. Beyond-use date assigned to the sterile product; and~~

~~c. Signature, initials, or electronic identification of pharmacist compounding, or of both the nonpharmacist compounding and pharmacist checking the compounding of the sterile product.~~

~~2. Record documenting certification of clean room or laminar flow hoods.~~

~~3. If sterile products are provided to a patient's residence, a record documenting training of the patient or caregiver, or both, in the proper storage and use of the product and any devices used to administer the devices.~~

Part ~~XI~~. X. Unit Dose Dispensing Systems

Part ~~XII~~. XI. Pharmacy Services to Hospitals

Part ~~XIII~~. XII. Pharmacy Services to Long-Term Care Facilities

Part ~~XIV~~. XIII. Other Institutions and Facilities

Part ~~XV.~~ XIV. Exempted Stimulant or Depressant Drugs and Chemical Preparations

Part ~~XVI~~. XV. Manufacturers, Wholesale Distributors, Warehousers, and Medical Equipment Suppliers

Part ~~XVII.~~ XVI. Controlled Substances Registration for Other Persons or Entities

Certification

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

_____

Elizabeth Scott Russell

Executive Director
Virginia Board of Pharmacy

Date: _____