Commonwealth of Virginia

REGULATIONS

GOVERNING THE PRACTICE OF MEDICINE, OSTEOPATHIC MEDICINE, PODIATRY AND CHIROPRACTIC

VIRGINIA BOARD OF MEDICINE

Title of Regulations: 18 VAC 85-20-10 et seq.

Statutory Authority: § 54.1-2400 and Chapter 29 of Title 54.1 of the *Code of Virginia*

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Part IX.

Mixing, Diluting or Reconstituting of Drugs for Administration

18VAC85-20-400. Requirements for immediate-use sterile mixing, diluting or reconstituting.

A. For the purposes of this chapter, the mixing, diluting, or reconstituting of sterile manufactured drug products, when there is no direct contact contamination and administration begins within eight hours of the completion time of preparation shall be considered immediate-use. If manufacturers' instructions or any other accepted standard specifies or indicates an appropriate time between preparation and administration of less than eight hours, the mixing, diluting or reconstituting shall be in accordance with the lesser time. No direct contact contamination means that there is no contamination from touch, gloves, bare skin or secretions from the mouth or nose. Emergency drugs used in the practice of anesthesiology and administration of allergens may exceed eight hours after completion of the preparation, provided there is compliance with all other requirements of this section.

B. Doctors of medicine or osteopathic medicine who engage in immediate-use mixing, diluting or reconstituting shall:

1. Ensure that all personnel under their supervision who are involved in immediate-use mixing, diluting or reconstituting are appropriately and properly trained in and utilize the practices and principles of sanitization techniques, aseptic manipulations and solution compatibility. Evidence of such training by a doctor of medicine or osteopathic medicine shall be documented and maintained in personnel files. For the purposes of this chapter, aseptic manipulations shall mean to:

a. Design a specific site, such as a countertop, in an area of the practice facility where personnel traffic is restricted and activities that may contribute to microbial contamination (eg., eating, food preparation, placement of used diagnostic devices and materials and soiled linens) are prohibited.

b. Sanitize the preparation area with 70% isopropanol in water that does not contain added ingredients, such as dyes and glycerin.

c. Thoroughly wash hands to wrists with detergent or soap and potable water. Substitution of hand washing by treatment with sanitizing agents containing alcohol and/or 70% isopropanol in water is acceptable.

d. Don clean gloves that do not contain powdered lubricants, without touching non-sterile materials.

e. Sanitize necks of ampuls to be opened and stoppers of vials to be needle-punctured with isopropanol.

f. Avoid direct contact contamination of sterile needles, syringes, and other drug administration devices and sites on containers of manufactured sterile drug products from which drugs are administered. Sources of direct contact contamination include, but are not limited to, touch by personnel and non-sterile objects, human secretions, blood, and exposure to other non-sterile materials.

2. Establish procedures for verification of the accuracy of the product that has been mixed, diluted, or reconstituted to include a second check performed by a doctor of medicine or osteopathic medicine or a pharmacist or by a physician assistant or a licensed nurse who has been specifically trained pursuant to subdivision B 1 of this subsection in immediate-use mixing, diluting or reconstituting, unless such mixing, diluting or reconstituting is performed by a doctor of medicine or osteopathic medicine, a pharmacist or a certified registered nurse anesthetist.

3. Provide a designated, sanitary work space and equipment appropriate for aseptic manipulations.

4. Document or ensure that personnel under his supervision documents in the patient record or other readily-retrievable record that identifies the patient and the following: the names of drugs mixed, diluted or reconstituted, the date of preparation, and the date of administration as evidence that the mixing, diluting or reconstituting was immediate-use.

5. Develop and maintain a policy and procedure manual for the procedures to be followed in mixing, diluting or reconstituting of sterile products and for the training of personnel pursuant to subdivision B 1 of this subsection.

C. Any mixing, diluting or reconstituting of drug products that are hazardous to personnel shall be performed consistent with requirements of all applicable federal and state laws and regulations for safety and air quality, to include but not be limited to those of the Occupational Safety and Health Administration (OSHA). For the purposes of this chapter, Appendix A of the National Institute for Occupational Safety and Health publication, *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* will serve as the reference list of hazardous drug products.

18VAC85-20-410. Requirements for low, medium- or high-risk sterile mixing, diluting or reconstituting.

A. Any mixing, diluting or reconstituting of sterile products that does not meet the criteria for immediate-use as set forth in 18VAC85-20-400 A shall be defined as low-, medium-, or high-risk compounding under the definitions of Chapter 797 of the U. S. Pharmacopeia (USP).

B. Until July 1, 2007, all low-, medium-, or high-risk mixing, diluting or reconstituting of sterile products shall comply with the standards for immediate-use mixing, diluting or reconstituting as specified in 18VAC85-20-400. Beginning July 1, 2007, doctors of medicine or osteopathic medicine who engage in low-, medium-, or high-risk mixing, diluting or reconstituting of sterile products shall comply with all applicable requirements of USP Chapter 797. Subsequent changes to the USP Chapter 797 shall apply within one year of the official announcement by USP.

C. A current copy, in any published format, of USP Chapter 797 shall be maintained at the location where low-, medium- or high-risk mixing, diluting or reconstituting of sterile products is performed.

Emergency Regulations

18VAC85-20-420. Responsibilities of doctors who mix, dilute or reconstitute drugs in their practices.

A. Doctors of medicine or osteopathic medicine who delegate the mixing, diluting or reconstituting of sterile drug products for administration retain responsibility for patient care and shall monitor and document any adverse responses to the drugs.

B. Doctors who engage in the mixing, diluting or reconstituting of sterile drug products in their practices shall disclose this information to the board in a manner prescribed by the board, and are subject to unannounced inspections by the board or its agents.