Commonwealth of Virginia

PROPOSED 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 ten 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 ten 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 ten hours after completion of the preparation, provided administration does not exceed the specified expiration date of a multiple use vial and 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. Utilize the practices and principles of disinfection techniques, aseptic manipulations and solution compatibility in immediate-use mixing, diluting or reconstituting; and

2. 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 disinfection techniques, aseptic manipulations and solution compatibility.

3. Establish and implement 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 registered nurse who has been specifically trained pursuant to subdivision B 2 of this subsection in immediate-use mixing, diluting or reconstituting. Mixing, diluting or reconstituting that is performed by a doctor of medicine or osteopathic medicine, a pharmacist, or by a specifically trained physician assistant or registered nurse does not require a second check.

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

5. Document or ensure that personnel under his supervision documents in the patient record or other readily-retrievable record that identifies the patient, the names of drugs mixed, diluted or reconstituted and the date of administration.

6. Develop and maintain written policies and procedures to be followed in mixing, diluting or reconstituting of sterile products and for the training of personnel.

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 (NIOSH Publication No. 2004-165), *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* is incorporated by reference for the list of hazardous drug products and can be found at www.cdc.gov/niosh/docs/2004-165.

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.

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.