Virginia Department of Health Professions
Board of Medicine
www.dhp.virginia.gov

MIXING, DILUTING or RECONSTITUTING of DRUGS for ADMINISTRATION

Physician's Name: _____ **License Number:** _____
Practice Name: _____ **Phone Number:** _____
Address: _____ **Inspection Date:** _____

C	NC	NA	REQUIREMENTS FOR IMMEDIATE-USE STERILE MIXING, DILUTING OR RECONSITITUING 18VAC85-20-400
☐	☐	☐	Mixing, diluting, or reconstituting of sterile manufactured drug products occurs without direct contact contamination. NOTE: No direct contact contamination means that there is no contamination from touch, gloves, bare skin or secretions from the mouth or nose.
☐	☐	☐	Administration begins within 10 hours of the completion time of the preparation of the drug. If manufacturer's instructions or any other accepted standard specifies or indicates an appropriate time between preparation and administration of less than 10 hours, the mixing, diluting or reconstituting shall be in accordance with the lesser time.
☐	☐	☐	Drugs in fat emulsions are administered within 1 hour of preparation.
			Administration of emergency drugs used in the practice of anesthesiology may exceed 10 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.
			Administration of allergens may exceed 10 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.

C	NC	NA	REQUIREMENTS FOR IMMEDIATE-USE STERILE MIXING, DILUTING OR RECONSITITUING 18VAC85-20-400 Doctors of medicine or osteopathic medicine who engage in immediate-use mixing, diluting or reconstituting shall:
☐	☐	☐	Utilizes the practices and principles of disinfection techniques, aseptic manipulations and solution compatibility in immediate-use mixing, diluting or reconstituting.
☐	☐	☐	Ensure that all personnel under his/her supervision who are involved in immediate-use mixing, diluting or reconstituting are appropriately trained in and utilize the practices and principles of disinfection techniques, aseptic manipulations and solution compatibility.
☐	☐	☐	Established 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 or medicine or osteopathic medicine or a pharmacist, or by a physician assistant or a registered nurse who has been specifically trained pursuant to subdivision 2 of 18VAC85-20-400 in immediate-use mixing, diluting and reconstituting. NOTE: 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 or mixing, diluting or reconstituting of vaccines does not require a second check.
☐	☐	☐	Provide a designated, sanitary work space and equipment appropriate for aseptic manipulations.
☐	☐	☐	Document or ensure that personnel under his/her supervision documents in the patient record or other readily retrievable record the identification of the patient; the name of drugs mixed, diluted or reconstituted; and the date and time of preparation and administration.
☐	☐	☐	Develop and maintain written policies and procedures to be followed in mixing, diluting or reconstituting of sterile products and for the training of personnel.
☐	☐	☐	Any mixing, diluting or reconstituting of drug products that are hazardous to personnel shall be performed consistent with the 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) and USP Chapters 797 and 800.

C	NC	NA	REQUIREMENTS FOR LOW, MEDIUM OR HIGH-RISK STERILE MIXING, DILUTING OR RECONSTITUTING 18VAC85-20-410
☐	☐	☐	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 Chapters 797. NOTE: Any mixing, diluting or reconstituting of sterile products that does not meet the criteria for immediate-use as set forth in 18VAC-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) Subsequent changes to USP Chapter 797 shall apply within one year of the official announcement by USP.
☐	☐	☐	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.

C	NC	NA	RESPONSIBILITIES OF DOCTORS WHO MIX, DILUTE OR RECONSTITUTE DRUGS IN THEIR PRACTICES 18VAC85-20-420
☐	☐	☐	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.
☐	☐	☐	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.

Inspector Signature: _____

Physician Signature: _____