Chapter 246-871 WAC

PHARMACEUTICAL—PARENTERAL PRODUCTS FOR NONHOSPITALIZED PATIENTS

WAC

WAC 246-871-001 Scope and purpose. The purpose of this chapter is to provide standards for the preparation, labeling, and distribution of parenteral products by licensed pharmacies, pursuant to an order or prescription. These standards are intended to apply to all parenteral products not administered in a hospital.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-001, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-010, filed 1/17/90, effective 2/17/90.]

WAC 246-871-010 Definitions. (1) Biological safety cabinet - A containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment according to National Sanitation Foundation (NSF) Standard 49.

(2) Class 100 environment - An atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209B.

(3) Antineoplastic - A pharmaceutical that has the capability of killing malignant cells.

(4) Parenteral - Sterile preparations of drugs for injection through one or more layers of skin.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-020, filed 1/17/90, effective 2/17/90.]

WAC 246-871-020 Policy and procedure manual. (1) A policy and procedure manual as it relates to parenteral products shall be available for inspection at the pharmacy. The manual shall be reviewed and revised on an annual basis by the on-site pharmacist-in-charge.

(2) The manual shall include policies and procedures for:

(a) Clinical services;

(b) Parenteral product handling, preparation, dating, storage, and disposal;

(c) Major and minor spills of antineoplastic agents, if applicable;

(d) Disposal of unused supplies and medications;

(e) Drug destruction and returns;

(f) Drug dispensing;

(g) Drug labeling—relabeling;

(h) Duties and qualifications for professional and nonprofessional staff;

(i) Equipment;

(j) Handling of infectious waste pertaining to drug administration;

(k) Infusion devices and drug delivery systems;

(l) Dispensing of investigational medications;

(m) Training and orientation of professional and nonprofessional staff commensurate with the services provided;

(n) Quality assurance;

(o) Recall procedures;

(p) Infection control:

(i) Suspected contamination of parenteral products;

(ii) Orientation of employees to sterile technique;

(q) Sanitation;

(r) Security;

(s) Transportation; and

(t) Absence of a pharmacist.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-030, filed 1/17/90, effective 2/17/90.]

WAC 246-871-030 Physical requirements. (1) Space. The pharmacy shall have a designated area with entry restricted to designated personnel for preparing compounded parenteral products. This area shall be designed to minimize traffic and airflow disturbances. It shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(2) Equipment. The pharmacy preparing parenteral products shall have:

(a) Appropriate environmental control devices capable of maintaining at least a Class 100 environment condition in the workspace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 environment conditions during normal activity;

(b) Clean room and laminar flow hood certification shall be conducted annually by an independent contractor according to Federal Standard 209B or National Sanitation Foundation 49 for operational efficiency. These reports shall be maintained for at least two years;

(c) Prefilters. Prefilters for the clean air source shall be replaced on a regular basis and the replacement date documented;

(d) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;

(e) Appropriate disposal containers for used needles, syringes, etc., and if applicable, antineoplastic agents;

(f) Refrigerator/freezer with thermometer;

(g) Temperature controlled delivery container, if appropriate;

(h) Infusion devices, if appropriate.

(3) Reference library. The pharmacy shall have current reference materials related to parenteral products. These reference materials will contain information on stability, incompatibilities, mixing guidelines, and the handling of antineoplastic products.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-040, filed 1/17/90, effective 2/17/90.]

WAC 246-871-040 Personnel. (1) Pharmacist-in-charge. Each pharmacy shall be managed on site by a pharmacist who is licensed to practice pharmacy in this state and who has been trained in the specialized functions of preparing and dispensing compounded parenteral products, including the principles of aseptic technique and quality assurance. This training may be obtained through residency training programs, continuing education programs, or experience in an IV admixture facility. The pharmacist-in-charge shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all parenteral products. He/she shall also be responsible for the development and continuing review of all policies and procedures, training manuals, and the quality assurance programs. The pharmacist-in-charge may be assisted by additional pharmacists trained in this area of practice.

(2) Supportive personnel. The pharmacist-in-charge may be assisted by a level A pharmacy assistant. The level A pharmacy assistant shall have specialized training in this field and shall work under the immediate supervision of a pharmacist. The training provided to these personnel shall be described in writing in a training manual pursuant to chapter 246-901 WAC and chapter 18.64A RCW. The duties and responsibilities of the level A pharmacy assistant must be consistent with his/her training and experience.

(3) Staffing. A pharmacist shall be accessible twenty-four hours per day for each pharmacy to respond to patient's and other health professionals' questions and needs.

[Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-871-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-060, filed 1/17/90, effective 2/17/90.]

WAC 246-871-050 Drug distribution and control. (1) Prescription. The pharmacist, or pharmacy intern acting under the immediate supervision of a pharmacist, must receive a written or verbal prescription from an authorized prescriber before dispensing any parenteral product. Prescriptions may be filed within the pharmacy by patient-assigned consecutive numbers. A new prescription is required every twelve months or upon any prescription change. These prescriptions shall, at a minimum, contain the following:

(a) Patient name;

(b) Patient address;

(c) Drug name, strength, and dispensing quantity;

(d) Patient directions for use;

(e) Date written;

(f) Authorizing prescriber's name;

(g) Physician's address and Drug Enforcement Administration identification code, if applicable;

(h) Refill instructions, if applicable; and

(i) Provision for generic substitution.

(2) Profile or medication record system. A pharmacy-generated profile or medication record system must be separated from the oral prescription file. The patient profile or medication record system shall be maintained under the control of the pharmacist-in-charge for a period of two years after the last dispensing activity. The patient profile or medication record system shall contain, at a minimum:

(a) Patient's full name;

(b) Date of birth or age;

(c) Weight, if applicable;

(d) Sex, if applicable;

(e) Parenteral products dispensed;

(f) Date dispensed;

(g) Drug content and quantity;

(h) Patient directions;

(i) Prescription identifying number;

(j) Identification of dispensing pharmacist and preparing level A pharmacy assistant, if applicable;

(k) Other drugs patient is receiving;

(l) Known drug sensitivities and allergies to drugs and foods;

(m) Primary diagnosis, chronic conditions; and

(n) Name of manufacturer and lot numbers of components or a policy for return of recalled product if lot numbers are not recorded.

(3) Labeling. Parenteral products dispensed to patients shall be labeled with the following information with a permanent label:

(a) Name, address, and telephone number of the pharmacy;

(b) Date and prescription identifying number;

(c) Patient's full name;

(d) Name of each component, strength, and amount;

(e) Directions for use including infusion rate;

(f) Prescriber's name;

(g) Required transfer warnings;

(h) Date of compounding;

(i) Expiration date and expiration time, if applicable;

(j) Identity of pharmacist compounding and dispensing or other authorized individual;

(k) Storage requirements;

(l) Auxiliary labels, where applicable;

(m) Antineoplastic drug auxiliary labels, where applicable; and

(n) On all parenteral products, a twenty-four hour phone number where a pharmacist can be contacted.

(4) Records and reports. The pharmacist-in-charge shall maintain access to and submit, as appropriate, such records and reports as are required to ensure patient's health, safety, and welfare. Such records shall be readily available, maintained for two years, and subject to inspections by the board

of pharmacy. These shall include, as a minimum, the following:

(a) Patient profile/medication record system;

(b) Policy and procedure manual;

(c) Training manuals; and

(d) Such other records and reports as may be required by law and rules of the board of pharmacy.

Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's record. Release of this information shall be in accordance with federal and/or state laws or rules.

(5) Delivery service. There will be a provision for the timely delivery of parenteral products from a pharmacy so a practitioner's order for drug therapy can be implemented without undue delay. The pharmacist-in-charge shall assure the environmental control of all parenteral products shipped. Therefore, any parenteral products must be shipped or delivered to a patient in appropriate temperature controlled delivery containers (as defined by USP Standards) and stored appropriately in the patient's home. Chain of possession for the delivery of controlled substances via contracted courier must be documented, and a receipt required. The pharmacy, on request, will provide instruction for the destruction of unused parenteral products and supplies in the event a parenteral product is being discontinued or a patient dies.

(6) Disposal of infectious wastes. The pharmacist-in-charge is responsible for assuring that there is a system for the disposal of infectious waste pertaining to drug administration in a manner so as not to endanger the public health.

(7) Emergency kit. When parenteral products are provided to home care patients, the dispensing pharmacy may supply the registered nurse with emergency drugs if the physician has authorized the use of these drugs by a protocol for use in an emergency situation, e.g., anaphylactic shock. A protocol for the emergency kit must be submitted to and approved by the board of pharmacy.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-070, filed 1/17/90, effective 2/17/90.]

WAC 246-871-060 Antineoplastic medications. The following additional requirements are necessary for those pharmacies that prepare antineoplatic medications to assure the protection of the personnel involved.

(1) All antineoplastic medications shall be compounded within a certified Class II type A or Class II type B vertical laminar airflow hood.

Policy and procedures shall be developed for the cleaning of the laminar airflow hood between compounding antineoplastic medications and other parenteral products, if applicable.

(2) Protective apparel shall be worn by personnel compounding antineoplastic medications. This shall include disposable gloves, gowns with tight cuffs, masks, and protective eye shields if the safety cabinet is not equipped with splash guards.

(3) Appropriate safety containment techniques for compounding antineoplastic medications shall be used in conjunction with the aseptic techniques required for preparing parenteral products.

(4) Disposal of antineoplastic waste shall comply with all applicable local, state, and federal requirements, i.e., Occupational Safety and Health Administration (OSHA) and Washington Industrial Safety and Health Administration (WISHA).

(5) Written procedures for handling both major and minor spills of antineoplastic medications must be developed and must be included in the policy and procedure manual. These procedures will include providing spill kits along with directions for use to those persons receiving therapy.

(6) Prepared doses of antineoplastic medications must be dispensed and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(7) Documentation that personnel have been trained in compounding, handling, and destruction of antineoplastic medications.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-080, filed 1/17/90, effective 2/17/90.]

WAC 246-871-070 Clinical services. (1) Primary provider. There shall be an authorizing practitioner primarily responsible for the patient's medical care. There shall be a clear understanding between the authorizing practitioner, the patient, the home health care agency, and the pharmacy of the responsibilities of each in the areas of the delivery of care and the monitoring of the patient. This shall be documented in the patient's medication record system.

(2) A systematic process of medication use review must be designed, followed, and documented on an ongoing basis.

(3) Pharmacist-patient relationship. The pharmacist is responsible for seeing that the patient's compliance and adherence to a medication regimen is followed.

(4) Patient monitoring. The pharmacist will have access to clinical and laboratory data concerning each patient. Any abnormal values will be reported to the authorizing practitioner in a timely manner.

(5) Documentation. There must be documentation of ongoing drug therapy monitoring and assessment shall include but not be limited to:

(a) Therapeutic duplication in the patient's drug regimen;

(b) The appropriateness of the dose, frequency, and route of administration;

(c) Clinical laboratory or clinical monitoring methods to detect side effects, toxicity, or adverse effects and whether the findings have been reported to the authorizing practitioner.

(6) Patient training. The patient, the patient's agent, the authorizing practitioner, the home health care agency, or the pharmacy must demonstrate or document the patient's training and competency in managing this type of therapy in the home environment. A pharmacist is responsible for the patient training process in any area that relates to medication compounding, labeling, storage, stability, or incompatibility. The pharmacist must be responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

(7) A pharmacist will verify that any parenteral product a patient has not received before will be administered under

the supervision of a person authorized to manage anaphylaxis.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-090, filed 1/17/90, effective 2/17/90.]

WAC 246-871-080 Quality assurance. There shall be a documented, ongoing quality assurance program that is reviewed at least annually.

(1) The quality assurance program shall include but not be limited to methods to document:

(a) Medication errors;

(b) Adverse drug reactions;

(c) Patient satisfaction;

(d) Product sterility.

There shall be written documentation that the end product has been tested on a sampling basis for microbial contamination by the employee responsible for compounding parenteral products. Documentation shall be on a quarterly basis at a minimum.

(2) Nonsterile compounding. If bulk compounding of parenteral solutions is performed utilizing nonsterile chemicals, extensive end product testing, as referenced in *Remington*, must be documented prior to the release of the product from quarantine. This process must include appropriate testing for particulate matter and testing for pyrogens.

(3) Expiration dates. There shall be written justification of the chosen expiration dates for compounded parenteral products.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-100, filed 1/17/90, effective 2/17/90.]