Chapter Phar 15

STERILE PHARMACEUTICALS

Phar 15.01 Authority. The rules in this chapter are adopted pursuant to the authority in ss. 15.08 (5) (b), 227.11 (2) and 450.02 (3), Stats.

History: Cr. Register, March, 2000, No. 531, eff. 4–1–00.

Phar 15.02 Definitions. In this chapter:

(1) "Aseptic preparation" means preparation using procedures designed to preclude contamination of drugs, packaging equipment or supplies by microorganisms during processing.

(2) "Biological safety cabinet" means a containment unit suitable for preparation of low– to moderate– risk agents where there is a need for protection of the product, personnel and environment, according to national sanitation foundations standard 49.

(3) "Class 100 environment" means an atmospheric environment that contains less than 100 particles 0.5 microns in diameter per cubic foot of air, as described in federal standard 209.

Note: "Federal Standard 209" refers to *Federal standard 209E: airborne particulate cleanliness classes in cleanrooms and clean zones* by the Institute of Environmental Sciences published by the Institute of Environmental Sciences in 1992 and used by the United States General Services Administration as the standard required for use by federal agencies utilizing clean room controlled environments.

(4) "Critical activities" means activities that are different from other activities due to the increased potential opportunity for contamination to occur.

(5) "Critical objects" means objects that are different from other objects due to the increased potential opportunity for contamination to occur.

(6) "Cytotoxic drug" means a pharmaceutical used therapeutically as a toxin to alter biochemical activities of phases of cellular division which uniquely contribute to normal cell growth.

(7) "OSHA" means the federal occupational safety and health administration.

(8) "Parenteral" means a preparation of drugs for injection through one or more layers of skin.

(9) "Practice of pharmacy" has the meaning given in s. 450.01 (16), Stats.

(10) "Sterile pharmaceutical" means any dosage form devoid of viable microorganisms, including but not limited to parenterals, injectables and ophthalmics.

History: Cr. Register, March, 2000, No. 531, eff. 4–1–00.

Phar 15.03 Policy and procedure manual. (1) A pharmacy shall prepare and maintain a policy and procedure manual for compounding, dispensing, delivery, administration, storage and use of sterile pharmaceuticals.

(2) The policy and procedure manual shall include a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, and facilities and include guidelines regarding patient education and the provision of pharmaceutical services. In addition, the manual shall include up–to–date information on the preparation of sterile pharmaceuticals.

(3) The policy and procedure manual shall be available to all personnel and updated annually or as needed to reflect current practice.

(4) The policy and procedure manual shall be current and available for inspection by the board or its designee.

History: Cr. Register, March, 2000, No. 531, eff. 4–1–00.

Phar 15.04 Physical requirements. (1) A pharmacy shall have a designated area for preparing sterile pharmaceuticals. This area shall be a room structurally isolated from other areas, with entry and access restricted to designated personnel and shall be designed to avoid unnecessary traffic and airflow disturbances. The designated area shall only be used for preparation and documentation of sterile pharmaceuticals. The designated area shall be of sufficient size to accommodate a laminar airflow hood and to provide for proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security. Additional drug inventory and bulk supplies shall be stored in an area separate from the designated area for preparing sterile pharmaceuticals.

(2) A pharmacy shall maintain an environment in the designated area suitable for aseptic preparation of sterile pharmaceuticals and shall have all of the following:

(a) Appropriate environment control devices that are capable of maintaining at least a class 100 environment during normal activity in the workplace where critical objects are exposed and critical activities are performed.

(b) Appropriate disposal containers as required by OSHA in 29 CFR PART 1910 for used needles and syringes, and for disposal of other items in compounding and, if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes. This should be disposed of in a timely manner.

(c) Appropriate environmental controls including class II biological safety cabinetry in pharmacies where cytotoxic drug products are prepared.

(d) Temperature–controlled delivery containers as necessary.

(e) For hand washing, a sink with hot and cold running water in close proximity.

(f) Administration devices as necessary.

(3) A pharmacy shall have sufficient reference materials related to sterile pharmaceuticals to meet the needs of the pharmacy staff.

(4) The designated area shall be closed and disinfected at regular intervals with appropriate agents.

History: Cr. Register, March, 2000, No. 531, eff. 4–1–00.

Phar 15.05 Records and reports. (1) Specific records and reports shall be maintained describing the preparation of sterile pharmaceuticals in the pharmacy. These records and reports shall include:

(a) Training and competency evaluations of personnel.

(b) Documentation of refrigerator and freezer temperatures.

(c) Certification of laminar airflow hoods.

(2) The following minimum labeling requirements shall be met for sterile pharmaceuticals prepared for a single patient if the pharmaceuticals are to be completely administered within 28 hours:

(a) The identity of all solutions and ingredients and their corresponding amounts, concentration or volumes on the final preparation container in such a manner as to allow the locating of problematic final products.

(b) The identity of personnel involved in preparation.

(c) The date and time of pharmacy preparation where applicable.

(d) The final sterile pharmaceuticals expiration date and storage requirements, where applicable.

History: Cr. Register, March, 2000, No. 531, eff. 4−1−00.

Phar 15.06 Delivery service. The pharmacist shall assure the appropriate environmental control of all products shipped.

History: Cr. Register, March, 2000, No. 531, eff. 4−1−00.

Phar 15.07 Emergency kits. (1) When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy shall supply the patient or the patient's agent with emergency drugs, when authorized by the physician under protocol, if an emergency situation has been anticipated by either the physician, nurse or pharmacist.

(2) The dispensing pharmacy shall be responsible for providing written instructions on the storage and recordkeeping requirements for the emergency kit.

History: Cr. Register, March, 2000, No. 531, eff. 4−1−00.

Phar 15.08 Cytotoxic drugs. In addition to the minimum requirements for a pharmacy established by rule of the board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs:

(1) All cytotoxic drugs shall be compounded in a vertical flow, class II, biological safety cabinet. If non−exposed surfaces become contaminated with cytotoxic agents, no products other than cytotoxic drugs may be compounded in this cabinet until such time as the cabinet is decontaminated utilizing appropriate techniques to eradicate the contaminant.

(2) Personnel shall be protected by a protective barrier or apparel which shall include gloves, gowns and other applicable protective apparel as described in 29 CFR PART 1910 of OSHA regulations.

(3) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile pharmaceuticals.

(4) Pharmacy disposal and patient and caregiver education regarding disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements.

(5) Written procedures for the handling of both major and minor spills of cytotoxic agents shall be developed and shall be included in the pharmacy policy and procedure manual.

(6) Prepared doses of cytotoxic drugs shall be dispensed, labeled with proper precautions on the primary and shipping container and should be shipped in a manner to minimize the risk of accidental rupture of the primary container.

History: Cr. Register, March, 2000, No. 531, eff. 4−1−00.

Phar 15.09 Labeling. In addition to the labeling requirements of s. 450.11 (4), Stats., the following shall also be included on the labels of sterile pharmaceuticals:

(1) Control or lot number.

(2) Expiration date and time, when applicable.

(3) Appropriate auxiliary labeling, including precautions.

(4) Storage requirements.

(5) Identification of the responsible pharmacist.

History: Cr. Register, March, 2000, No. 531, eff. 4−1−00.

Phar 15.10 Patient training. A pharmacist is responsible for documenting the patient's training and competency in managing the type of therapy provided by the pharmacist to the patient if administered by the patient or a caregiver. A pharmacist is responsible for the provision of or supervision of the patient training process in any area that relates to drug compounding, administration, labeling, storage, stability or incompatibility. A pharmacist shall be responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

History: Cr. Register, March, 2000, No. 531, eff. 4−1−00.

Phar 15.11 Quality assurance. (1) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting specifications.

(2) The area designated for preparing sterile pharmaceuticals and all horizontal and vertical laminar flow hoods shall be certified to be operationally efficient and meet the standards of a class 100 environment by an independent contractor. All biological safety cabinets shall be certified according to national sanitation foundations standard 49 or manufacturer's specifications. Certification shall take place before initial use or after relocation and at least annually. Certification records shall be maintained.

Note: "National Sanitation Foundations Standard 49" refers to *National Sanitation Foundation standard no 49 for class II (laminar flow) biohazard cabinetry / as prepared by the NSF Advisory Committee on Biohazard Cabinetry; and recommended for adoption by the NSF Council of Public Health Consultants* by the National Sanitation Foundation (U.S.) published in 1983 by the National Sanitation Foundation of Ann Arbor, Michigan.

(3) A pharmacy shall have written procedures requiring sampling for microbial contamination through a validation procedure, simulation of actual aseptic preparation, and by using bacterial growth medium to culture environmental samples.

(4) If compounding of parenteral solutions is performed using non−sterile chemicals, extensive end−product sterility testing shall be documented. If any parenteral solution fails the testing, procedures shall be in place to quarantine future products for sterility testing to assure end−product sterility prior to release of the products from quarantine. The compounding process shall utilize components and techniques that assure a sterile and particulate−free product.

(5) A pharmacy shall have written justification of the assigned expiration date for pharmacy prepared sterile pharmaceuticals.

(6) A pharmacy shall have documentation of quality assurance audits, including infection control and sterile technique audits at least annually.

(7) A pharmacy shall have procedures to assure consistent preparation of sterile pharmaceuticals.

History: Cr. Register, March, 2000, No. 531, eff. 4−1−00.