Chapter Phar 13

DISTRIBUTOR REQUIREMENTS

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Note: Chapter Phar 13 as it existed on July 31, 1992 was repealed and a new chapter Phar 13 was created effective August 1, 1992.

Phar 13.01 Authority. The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a), 450.02 (3) (a) and 450.07 (4), Stats.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.02 Definitions. In this chapter:

(1) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(2) "Blood component" means that part of blood separated by physical or mechanical means.

(3) "Controlled substance" has the meaning set forth in s. 961.01 (4), Stats.

(4) "Device" has the meaning set forth in s. 450.01 (6), Stats.

(5) "Distribute" has the meaning set forth in s. 450.01 (8), Stats.

(6) "Distributor" means any person engaged in wholesale distribution of prescription drugs or devices, including, but not limited to, manufacturers; repackers; own–label distributors; private–label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and pharmacies that conduct wholesale distributions not coincident to the compounding, packaging, labeling and dispensing of prescription drugs and devices.

(7) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(8) "Facility" means a location at which wholesale distribution operations are conducted.

(9) "Manufacturer" means any person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug or device.

(10) "Prescription drug" has the meaning set forth in s. 450.01 (20), Stats.

(11) "Wholesale distribution" means distribution of prescription drugs or devices to persons other than a consumer or patient. The term does not include:

(a) Intracompany sales, which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under the common ownership and control of a corporate entity.

(b) A pharmacy's coincident distribution of a drug or device, or the sale, purchase, or trade of a drug or device, or an offer to sell, purchase, or trade a drug or device for emergency medical reasons. In this paragraph, "emergency medical reasons" include transfers of prescription drugs or devices by a pharmacy to another pharmacy or other licensed health care entity to alleviate a temporary shortage.

(c) The sale, purchase, or trade of a drug or device, an offer to sell, purchase, or trade a drug or device, or the dispensing of a drug or device pursuant to a prescription order.

(d) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives.

(e) The sale, purchase, or trade of blood and blood components intended for transfusion or further manufacture.

(f) Distributions to a practitioner for the purpose of general dispensing by the practitioner to his or her patients if all of the following apply:

1. The total number of dosage units of all prescription drugs distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of the total number of dosage units of all prescription drugs distributed and dispensed by the pharmacy during the same calendar year.

2. The total number of dosage units of all controlled substances distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of the total number of dosage units of all controlled substances distributed and dispensed by the pharmacy during the same calendar year.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92; cr. (11) (f), Register, February, 1996, No. 482, eff. 3–1–96; am. (3), Register, December, 1998, No. 516, eff. 1–1–99.

Phar 13.03 License required. No person, located within or outside Wisconsin, may sell or distribute at wholesale any prescription drug or device into, out of, or within this state unless a distributor's license is granted to the person by the board under this chapter. A distributor's license may not be transferred from one facility to another or from one person to another. A person must obtain a distributor's license for each facility.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.04 License; application. To obtain a distributor's license a person shall provide the following information to the board:

(1) The name, full business address, and telephone number of the applicant;

(2) All trade or business names to be used by the applicant;

(3) Addresses, telephone numbers, and the names of contact persons for the facility to be used by the applicant for the storage, handling, and distribution of prescription drugs or devices;

(4) Whether the applicant is a partnership, corporation, sole proprietorship or person;

(5) If a partnership, the full name of each partner, and the name of the partnership;

(6) If a corporation, the full name and title of each corporate officer and director, the state of incorporation, and the name of the parent company, if any;

(7) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(8) If a person, the full name of the person;

(9) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(10) Any felony convictions of the applicant under federal, state, or local laws, the circumstances of which are substantially related to the practice of a distributor;

(11) Any suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any devices or drugs, including controlled substances;

(12) The applicant's past experience in the manufacture or distribution of prescription drugs or devices, and any controlled substances;

(13) Compliance with licensing requirements under previously granted licenses, if any; and

(14) Compliance with requirements to maintain or make available to a state licensing authority or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug or device distributors.

Note: An application form may be obtained from the board office, 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.05 License; other requirements. In addition to providing the application information, to obtain a license a person shall:

(1) Pay the fee specified in s. 440.05 (1), Stats.

(2) Pass an inspection of the facility conducted by the board or its representative to determine if the location meets standards specified in Phar 13.08 to 13.11, 21 USC 351 and 352 (1990) and 21 CFR 211.142 (b) (1991).

(3) Register with the drug enforcement administration, if intending to distribute controlled substances.

Note: Copies of federal applications may be obtained from the Drug Enforcement Administration, Suite 500, Dirksen Federal Building, 219 South Dearborn Street, Chicago, Illinois 60604. Copies of federal statutes and rules may be obtained from the Superintendent of Documents, Government Printing Office, Washington DC 20402–9325.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.06 License; factors considered. In determining eligibility for a distributor's license, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under federal, state, or local laws, the circumstances of which are substantially related to the practice of a distributor;

(3) The applicant's past experience in the manufacture or distribution of prescription drugs or devices, and any controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any devices or drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with the requirements to maintain or make available to a state licensing authority or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug or device distributors; and

(8) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.07 Application review. The board shall act upon an application for a license within 60 business days after receiving the completed application, as provided in s. RL 4.03. If the license is denied, the applicant may request a hearing pursuant to ch. RL 1.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92; am., Register, December, 1998, No. 516, eff. 1–1–99.

Phar 13.08 Personnel. A distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs and devices.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.09 Facility requirements. All facilities at which prescription drugs or devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.10 Security requirements. All facilities shall require that:

(1) Access from outside the premises is kept to a minimum and be well controlled;

(2) The outside perimeter of the premises is well lighted;

(3) Entry into areas where prescription drugs or devices are held is limited to authorized personnel;

(4) An alarm system is maintained to detect entry after hours; and

(5) A security system is maintained that will provide suitable protection against theft and diversion, including, when appropriate, a system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.11 Storage requirements. (1) All prescription drugs and devices stored in a facility shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such products, or with requirements in the current edition of an official compendium.

(2) If no storage requirements are established for a prescription drug or device, the product may be held at a controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs and devices.

(4) The recordkeeping requirements in s. Phar 13.14 shall be followed for all stored drugs and devices.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.12 Examination of materials requirements. (1) Upon receipt by a facility, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or devices, or prescription drugs or devices that are otherwise unfit for distribution. This

examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment from a facility shall be carefully inspected for identity of the prescription drug or device and to ensure that there is no delivery of prescription drugs or devices that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in s. Phar 13.14 shall be followed for all incoming and outgoing prescription drugs and devices at a facility.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.13 Returned, damaged and outdated prescription drug and device requirements. (1) Prescription drugs and devices in a facility that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs and devices until they are destroyed or returned to their supplier.

(2) Any prescription drugs or devices in a facility whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs and devices until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug or device has been returned to a facility cast doubt on the product's safety, identity, strength, quality, or purity, then the product shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the product meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a product has been returned cast doubt on its safety, identity, strength, quality, or purity, the distributor shall consider, among other things, the conditions under which the product has been held, stored, or shipped before or during its return and the condition of the product and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in s. Phar 13.14 shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and devices.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.14 Recordkeeping requirements. (1) A distributor shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and devices. These records shall include the following information:

(a) The source of the drugs or devices, including the name and principal address of the seller or transferor, and the address of the location from which the drugs or devices were shipped;

(b) The identity and quantity of the drugs or devices received and distributed or disposed of; and

(c) The dates of receipt and distribution or other disposition of the drugs or devices.

(2) Inventories and records shall be made available for inspection and copying by the board, its authorized representatives, and authorized representatives of federal, state and local law enforcement agencies for a period of 2 years following distribution or other disposition of the drugs or devices.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by the board or its authorized representative.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.15 Written policies and procedures. A distributor shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs and devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. A distributor shall include in their written policies and procedures the following:

(1) A procedure to ensure that the oldest approved stock of a prescription drug or device is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs and devices. The procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other governmental agency, including the board;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs or devices from the market; or

(c) Any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that a distributor prepares for, protects against, and handles any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs or devices are segregated from other products and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs or devices. This documentation shall be maintained for 2 years after disposition of the outdated drugs or devices.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.16 Responsible persons. A distributor shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug and device distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.

Phar 13.17 Compliance with federal, state and local laws. (1) A distributor shall operate in compliance with applicable federal, state, and local laws and regulations. A distributor that deals in controlled substances shall register with the drug enforcement administration.

(2) Failure to comply with applicable federal, state, and local laws and regulations constitutes unprofessional conduct for purposes of s. 450.10, Stats.

(3) A distributor shall permit the board or its authorized representatives and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to a distributor's premises and delivery vehicles.

History: Cr. Register, July, 1992, No. 439, eff. 8–1–92.