

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Note: Chapter Phar 13 as it existed on July 31, 1992 was repealed and a new chapter Phar 13 was created effective August 1, 1992.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

(3m) “Department” means the department of regulation and licensing.

(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.

(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 where a wholesale distributor stores, handles, repackages, or offers for sale prescription drugs.

(9) “Manufacturer” means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of “manufacturer” under the federal food and drug administration’s regulations and interpreted guidance implementing the federal prescription drug marketing act.

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

(11) “Wholesale distribution” means distribution of a prescription drug to a person other than a consumer or patient, but does not include any of the following:

(a) Intracompany sales of prescription drugs which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under common ownership or control of a corporate entity or any transaction between co-licensees or a co-licensed product.

(b) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(c) The distribution of prescription drug samples, if the distribution is permitted under 21 CFR 353 (d).

(d) Drug returns, when conducted by a hospital, health care entity, or charitable institution as provided in 21 CFR 203.23.

(e) 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.

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

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

(h) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record, if the manufacturer states in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the drug and the supplying authorized distributor of record states in writing that the drug has previously been exclusively in the normal distribution channel.

(i) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier’s usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the drug.

(j) A transaction excluded from the definition of “wholesale distribution” under 21 CFR 203.3 (cc).

(k) The donation or distribution of a prescription drug under s. 255.056, Stats.

(L) The transfer from a retail pharmacy or pharmacy warehouse of an expired, damaged, returned, or recalled prescription drug to the original manufacturer or original wholesale distributor or to a 3rd-party returns processor or reverse distributor.

(m) The return of a prescription drug, if the return is authorized by the law of this state.

(12) “Wholesale distributor” means a person engaged in the wholesale distribution of prescription drugs, including manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses; manufacturers’ exclusive distributors; manufacturers’ authorized distributors of record; prescription drug wholesalers and distributors; independent wholesale prescription drug traders; 3rd-party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

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; **EmR0815: emerg. cr. (3m), (11) (b) to (d) and (f) to (m), renum. (6) and**

(11) (f) to be (12) and (11) (e) and am. (12), am. (8), (9), (11) (intro.) and (a), r. (11) (b) to (e), eff. 6-1-08; CR 08-051: cr. (3m), (11) (b) to (d) and (f) to (m), renum. (6) and (11) (f) to be (12) and (11) (e) and am. (12), am. (8), (9), (11) (intro.) and (a), r. (11) (b) to (e) Register November 2008 No. 635, eff. 12-1-08.

Phar 13.03 License required. History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. r. eff. 6-1-08; CR 08-051: r. Register November 2008 No. 635, eff. 12-1-08.

Phar 13.04 License; application. History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. r. eff. 6-1-08; CR 08-051: r. Register November 2008 No. 635, eff. 12-1-08.

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 in the 3-year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each inspection to determine if the location meets standards specified in ss. Phar 13.08 to 13.11.

(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; CR 00-157: am. (2) Register May 2002 No. 557, eff. 6-1-02; EmR0815: emerg. am. (2), eff. 6-1-08; CR 08-051: am. (2) Register November 2008 No. 635, eff. 12-1-08.

Phar 13.055 Surety bond, irrevocable letter of credit. The applicant shall supply a surety bond or irrevocable letter of credit in the amount of \$5,000.00, which is issued by a company authorized to do business in Wisconsin. The form of the bond or letter of credit shall be approved by the department and conditioned so that the state shall be fully compensated or reimbursed for, and shall be used to, secure payment of fees or costs that relate to the issuance of a wholesale distributor's license that have not been paid within 30 days after the fees or costs have become final. The bond or letter shall be valid for the entire period of an unexpired license issued to the applicant. No claim may be made against a bond or other security under this section more than one year after the date on which the applicant's wholesale distributor's license expires.

History: EmR0815: emerg. cr. eff. 6-1-08; CR 08-051: cr. Register November 2008 No. 635, eff. 12-1-08.

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;

(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; EmR0815: emerg. r. (3), eff. 6-1-08; CR 08-051: r. (3) Register November 2008 No. 635, eff. 12-1-08.

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.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. eff. 6-1-08; CR 08-051: am. Register November 2008 No. 635, eff. 12-1-08.

Phar 13.09 Facility requirements. All facilities at which prescription drugs 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 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; EmR0815: emerg. am. (intro.) and (3), eff. 6-1-08; CR 08-051: am. (intro.) and (3) Register November 2008 No. 635, eff. 12-1-08.

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 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; EmR0815: emerg. am. (3), eff. 6-1-08; CR 08-051: am. (3) Register November 2008 No. 635, eff. 12-1-08.

Phar 13.11 Storage requirements. (1) All prescription drugs 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, 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, or logs shall be utilized to document proper storage of prescription drugs.

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

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. eff. 6-1-08; CR 08-051: am. Register November 2008 No. 635, eff. 12-1-08.

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 prescription drugs 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 and to ensure that there is no delivery of prescription drugs 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 at a facility.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. eff. 6-1-08; CR 08-051: am. Register November 2008 No. 635, eff. 12-1-08.

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

(2) Any prescription drugs 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 until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug 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.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. eff. 6-1-08; CR 08-051: am. Register November 2008 No. 635, eff. 12-1-08.

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. These records shall include the following information:

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

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

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

(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 3 years following distribution or other disposition of the drugs.

(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; EmR0815: emerg. am. (1) and (2), eff. 6-1-08; CR 08-051: am. (1) and (2) Register November 2008 No. 635, eff. 12-1-08.

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, 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 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. 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 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 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. This documentation shall be maintained for 3 years after disposition of the outdated drugs.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. (intro.), (1), (2) (intro.), (b) and (4), eff. 6-1-08; CR 08-051: am. (intro.), (1), (2) (intro.), (b) and (4) Register November 2008 No. 635, eff. 12-1-08.

Phar 13.16 Responsible persons.

A distributor shall establish and maintain lists of officers, directors, managers, and the designated representative in charge of wholesale drug 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; EmR0815: emerg. am. eff. 6-1-08; CR 08-051: am. Register November 2008 No. 635, eff. 12-1-08.

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 shall operate in compliance with any applicable federal electronic track and trace pedigree system implemented after July 1, 2011, unless an earlier implementation date is mandated by federal law which explicitly preempts state law. 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; **EmR0815: emerg. am. (1), eff. 6-1-08; CR 08-051: am. (1) Register November 2008 No. 635, eff. 12-1-08.**