Chapter Phar 6

PHARMACY LICENSES AND EQUIPMENT

Note: Chapter Phar 6 as it existed on January 31, 1983, was repealed and a new chapter Phar 6 was created effective February 1, 1983.

Phar 6.01 Licenses; application. Requirements and procedures for applying for a pharmacy license are specified in s. 450.06, Stats. Approved application forms are available from the board. Appointments for the required pharmacy inspection may be made by contacting the board office. A license application and fee shall be on file with the board at least 30 days prior to the granting of the pharmacy license. A pharmacy may not operate unless a pharmacy license has been granted. Board action shall be taken within 60 business days of receipt of a completed pharmacy application, as provided in s. SPS 4.03.

Note: Applications are available upon request to the board office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; correction made under s. 13.93 (2m) (b) 7., Stats., Register, January, 1989, No. 397; am. Register, August, 1991, No. 428, eff. 9–1–91; am., Register, December, 1998, No. 516, eff. 1–1–99; correction made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.

Phar 6.02 Licenses; change of location or ownership. (1) A pharmacy license authorizes a pharmacy to operate only at the location designated on the license. Licenses may not be transferred to another location.

(1m) A hospital which has a pharmacy area providing outpatient pharmacy services which is physically separate from, and not contiguous to the area from which inpatient pharmacy services are provided, shall have a pharmacy license for the outpatient pharmacy in addition to a license for the inpatient pharmacy.

(2) Any change in pharmacy ownership shall be reported to the board office and the pharmacy license of the former owner returned. A pharmacy license shall be granted to the new pharmacy owner before the pharmacy may operate.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; am. Register, August, 1991, No. 428, eff. 9–1–91; cr. (1m), Register, February, 1996, No. 482, eff. 3–1–96.

Phar 6.025 Licenses; remote dispensing sites. A pharmacy may be subject to rules in this section that apply only to remote dispensing sites, if a pharmacist remotely supervises the location for any period of time. The following conditions shall also be met:

(1) The licensee provides notice to the board of all of the information outlined in s. 450.06, Stats.

(2) The site meets all of the requirements listed in s. Phar 7.43.

(3) The site is any of the location types listed under s. 450.09 (2) (b) 1., Stats.

(4) A managing pharmacist shall report to the board if they are responsible for 5 or more remote dispensing sites. A managing pharmacist may not be responsible for more than 10 remote dispensing sites at any given time without approval from the board.

History: EmR2213: emerg. cr., eff. 11–1–22; CR 23–054: cr. Register August 2024 No. 824, eff. 9–1–24.

Phar 6.03 Changes in managing pharmacist. The pharmacy owner shall report to the board any change of managing pharmacist within 5 days following the change.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83.

Phar 6.04 Floor design. (1) PROFESSIONAL SERVICE AREA. If the building is open at any time while the professional service area is closed, the professional service area shall be secured as specified in sub. (3).

(3) REQUIREMENTS WHEN THE PROFESSIONAL SERVICE AREA IS CLOSED. When the pharmacy professional service area is closed, the pharmacy shall meet all of the following requirements:

(am) A locked, secure physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by unauthorized personnel. A secured barrier may be constructed of other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

(bm) Signs of reasonable size are posted at the professional service area which prominently display the hours the professional services are available.

(cm) The manner in which the telephone is answered does not imply that the professional services are available.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; cr. (4), Register, August, 1991, No. 428, eff. 9–1–91; r. (3) (a) 4., Register, January, 1996, No. 481, eff. 2–1–96; CR 03–096: am. (3) (a) (intro.), cr. (3) (c) Register May 2004 No. 581, eff. 6–1–04; CR 21–074: am. (1), r. (2), r. and recr. (3) (title), renum. (3) (a) (intro.), 1. to (3) (intro.), (am) and am., r. (3) (a) 2., 3., renum. (3) (a) 5., 6. to (3) (bm), (cm), r. (3) (a) 7., (b), (c), (4) Register June 2023 No. 810, eff. 7–1–23; correction in renumbering (3) (intro.) made under s. 13.92 (4) (b) 1., Register June 2023 No. 810.

Phar 6.05 Sanitation. The professional service area of a pharmacy shall have a sink convenient and suitable for cleaning pharmaceutical equipment and supplied with hot and cold running water. Detergent and a waste disposal container also shall be provided in the professional service area.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83.

Phar 6.06 Laws and other references. The professional service area of a pharmacy shall have equipment of appropriate design and size for the intended pharmacy practice and shall have all of the following:

(1j) The latest available or immediately accessible version of federal and state pharmacy laws consisting of:

(a) Drug enforcement administration regulations, 21 CFR 1300 to end.

(b) Wisconsin pharmacy laws, ch. 450, Stats.

(c) Wisconsin controlled substances act, ch. 961, Stats.

(d) Wisconsin administrative code, rules of the pharmacy examining board.

(2k) References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(3L) The telephone number of a poison center. This number shall be conspicuously posted in the prescription department.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; r. and recr. Register, January, 1989, No. 397, eff. 2–1–89; correction in (2) made under s. 13.93 (2m) (b) 6., Stats., Register, January, 1989, No. 397; am. (1) (j) 3., Register, December, 1998, No. 516, eff. 1–1–99; CR 01–023: am. (1) (intro.) and (a) to (c), (j) (intro.) and (k), Register, August 2001 No. 548 eff. 9–1–01; 2017 Wis. Act 18: r. and recr. (title), renum. (1) (intro.) to (intro.) and am., r. (1) (a) to (i), renum. (1) (j), (k), (L) to (1j), (2k), (3L), r. (2) Register June 2017 No. 738, eff. 7–1–17.

Phar 6.07 Storage. (1) The storage of drugs shall be secure, neat, clean and orderly.

(3) All controlled substances shall be stored in a securely locked, substantially–constructed cabinet or dispersed throughout the inventory of non–controlled substances in a manner that obstructs theft or diversion.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; CR 19–165: r. and recr. (1), r. (2), am. (3) Register July 2020 No. 775, eff. 8–1–20.

Phar 6.075 Temperature; Humidity. (1) DEFINITIONS. In this section:

(a) "Business day" means a day the pharmacy is open for business.

(c) "Freezer" means a place in which the temperature is maintained between –13 and +14 degrees Fahrenheit.

(d) "Mean kinetic temperature" means the calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.

(e) "Refrigerator" means a place in which the temperature is maintained between 36 and 46 degrees Fahrenheit.

(2) STORAGE. Drugs shall be stored at appropriate conditions, including temperature and humidity, to prevent drug adulteration.

(3) RECORDING DEVICES. Manual, electromechanical or electronic temperature and humidity recording devices shall be placed within the storage space to accurately determine the area's temperature and humidity.

(4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy and the humidity of the pharmacy shall be continuously monitored. At least once each business day, the minimum and maximum temperature and humidity since the previous documented reading shall be recorded.

(5) RECORDS. Temperature and humidity records shall be maintained for a minimum of 5 years.

(6) DISPENSING OF SAFE DRUGS. The pharmacist shall use professional judgment, including consideration of the mean kinetic temperature, to determine whether a drug is safe to be dispensed.

History: CR 16–073: cr. Register November 2017 No. 743, eff. 12–1–17; corrections in (1) (b) and (c), (6) made under s. 35.17, Stats., Register November 2017 No. 743; CR 19–165: r. (1) (b), am. (2), r. and recr. (4) Register July 2020 No. 775, eff. 8–1–20.

Phar 6.08 Security. A pharmacy shall have a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the board.

History: Cr. Register, December, 1998, No. 516, eff. 1–1–99; CR 05–001: am. Register August 2005 No. 596, eff. 9–1–05; CR 09–098: am. Register May 2010 No. 653, eff. 6–1–10.