

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 19-165)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 6.07 (2) and 6.075 (1) (b); to amend Phar 6.07 (3), and 6.075 (2); and to repeal and recreate Phar 6.075 (4) and 6.07 (1) relating to storage.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.09 (4), Stats.

Statutory authority: ss. 15.08 (5) (b), and 450.02 (3) (a), (d) and (e), Stats.

Explanation of agency authority:

The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession. [s. 15.08 (5) (b), Stats.]

The Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs. [s. 450.02 (3) (a), Stats.]

The Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961. [s. 450.02 (3) (d), Stats.]

The Board may promulgate rules establishing minimum standards for the practice of pharmacy. [s. 450.02 (3) (e), Stats.]

Related statute or rule: N/A

Plain language analysis:

Section 1 and 2 repeals the specific requirement that a pharmacy have a refrigerator, sufficient shelf, drawer or cabinet space for prescription labels, prescription containers and adequate stock

of prescription drugs, chemicals and pharmacy equipment. This is replaced with the storage of drugs shall be secure, neat, clean and orderly.

Section 3 clarifies that all controlled substances are to be stored securely or dispersed in a way which obstructs theft or diversion.

Section 4 repeals the definition of “dry place” as it is no longer being used.

Section 5 amends the manner in which drugs are to be stored. Drugs are to be stored at appropriate conditions including, temperature and humidity, to prevent drug adulteration. It also clarifies that the pharmacy will record each business day the maximum and minimum temperature and humidity since the last documented readings.

Summary of, and comparison with, existing or proposed federal regulation:

Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. [21 C.F.R. §13.01.75 (b)]

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:

Illinois: Illinois requires all pharmacies and equipment in the pharmacy to be maintained in a clean condition and in good repair. Illinois does require a sink to be required in all pharmacies that maintain drug inventory. Refrigeration shall be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

Iowa: Iowa requires effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program.

Michigan: Michigan requires all prescription drugs to be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings. Michigan requires a pharmacy to have necessary drawers, shelves, storage cabinets, prescription files, a sink with hot and cold running water and a refrigerator of reasonable capacity. In Michigan, controlled substances are required to be stored in a securely locked, substantially constructed cabinet, room, or cart or they may be dispersed throughout the stock of noncontrolled substances in a manner to obstruct the theft or diversion of controlled substances.

Minnesota: Minnesota requires a refrigerator and a sink with hot and cold running water. The refrigerator designated for drug storage shall have a manual, electromechanical, or electronic temperature recording equipment, devices, or logs to document proper storage of legend drugs every business day.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board reviewed the storage requirements in light of health care evolving and recognizing that there are different types of pharmacies which may not require the specific items required in the current rule.

In addition, stakeholders raised concerns regarding the implementation of CR 16-073 and the Pharmacy Examining Board made clarifications to the temperature and humidity provisions as a result of the concerns raised.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule was posted for economic comments and none were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on January 30, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 6.07 (1) is repealed and recreated to read:

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

SECTION 2. Phar 6.07 (2) is repealed.

SECTION 3. Phar 6.07 (3) is amended to read:

Phar 6.07 (3) ~~Controlled~~ 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.

SECTION 4. Repeal Phar 6.075 (1) (b) is repealed.

SECTION 5. Phar 6.075 (2) is amended to read:

Phar 6.075 (2) STORAGE. Drugs shall be stored at appropriate ~~temperature and under~~ appropriate conditions, including ~~in a dry place~~ temperature and humidity, according to ~~the manufacturer recommendation or an official pharmaceutical compendium~~ prevent drug adulteration.

SECTION 6. Phar 6.075 (4) is repealed and recreated to read:

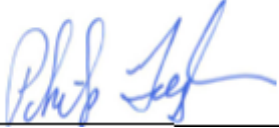
Phar 6.075 (4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy and the humidity of the pharmacy shall be continuously monitored. At least once each business day, the minimum and maximum temperature and humidity since the previous documented reading shall be recorded.

SECTION 7. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Dated February 12, 2020

Agency 
Chair of the Pharmacy Examining Board