

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 6.07 and 6.075

Relating to: Storage

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The objective of the rule is to provide clarity to the storage requirements for a pharmacy.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

Currently the professional service area is required to have a refrigerator, sufficient shelf, drawer or cabinet space for labels and containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment. As health care evolves, there are different types of pharmacies, specifically consulting pharmacies, which may not require all the items listed in the current rule. The proposed rule will update the rule to reflect the requirements for current practices of pharmacy. It will also clarify the manner in which controlled substances must be stored.

In addition, the rule will clarify the provisions relating to temperature and humidity due to stakeholder concerns raised following the implementation of CR 16-073.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

15.08 (5) (b) 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.

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

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

450.02 (3) (e) The Board may promulgate rules establishing minimum standards for the practice of pharmacy.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

100 hours

6. List with description of all entities that may be affected by the proposed rule:

Pharmacies and pharmacists.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

The only portion of the proposed rule which also relates to federal regulations is the storage of controlled substances.

Title 21 CFR 1301

§1301.75 Physical security controls for practitioners.

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) 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.

(c) Sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by §1317.80(d).

(d) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

(e) Thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377



Authorized Signature

June 28, 2018
Date Submitted