STATEMENT OF SCOPE

Pharmacy Examining Board

Rule No.: Phar 6

Relating to: Temperature and Humidity Controls

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 proposed rule is to create rules relating to temperature and humidity requirements to ensure the integrity of the pharmaceuticals prior to dispensing.

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 there are not rules relating to the temperature and humidity requirements for a pharmacy. Pharmaceuticals need to be stored, compounded or maintained in the correct environment in order to ensure the product quality, safety and efficiency.

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) 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:

80 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:

None

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

Minimal economic impact. It is not likely to have a significant economic impact on small business.

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Department Head or Authorized Signature

2/11/15

Date Submitted