

Notice of Hearing

The Pharmacy Examining Board announces that it will hold a public hearing on a permanent rule repeal and recreate ch. Phar 15 relating to compounding pharmaceuticals, at the time and place shown below.

Hearing Information

Date: January 17, 2016
Time: 8:30 a.m.
Location: 1400 East Washington Avenue, Room 121A
Madison, Wisconsin

Appearances at the Hearing and Submittal of Written Comments

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, 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 17, 2017 to be included in the record of rule-making proceedings. The rule may be reviewed and comments made at <http://docs.legis.wisconsin.gov/code/chr/hearings>.

Initial Regulatory Flexibility Analysis

The Board does not know how many or which pharmacies are compounding sterile pharmaceuticals and UPS 795 and 797 are the recognized pharmacopeial standards. The Board did not receive any economic comments. Therefore the Board was unable to determine whether there will be an effect on small businesses.

The proposed rule may have an effect on small businesses, as defined under s. 227.114 (1).

1. Description of the types of small businesses that will be affected by the rule:
Pharmacies which compound unsterile or sterile pharmaceuticals
2. Description of the proposed reporting, bookkeeping and other procedures required for compliance with the rule:
There are no reporting or bookkeeping procedures. The pharmacy would be required to maintain documentation necessary to trace, evaluate and replicate the compounding steps throughout the process of the preparation and records of personnel training. Pharmacies compounding sterile pharmaceuticals would have to meet certain equipment and sterility requirements.
3. Description of the types of professional skills necessary for compliance with the rule:
Education, training and experience to compound nonsterile and/or sterile pharmaceuticals.

Agency Small Business Regulatory Coordinator

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