

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Board of Pharmacy

855

Agency and Division

Administrative Rules Chapter Number

Amend registration rules for drug manufacturers and wholesalers, and amend fee schedules.

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of: **Rules for Drug Manufacturers and Wholesale Drug Outlets**

Statutory Authority: ORS 689.205

Other Authority:

Stats. Implemented: ORS 689.155, Chapter 799, Oregon Laws 2009

Need for the Rule(s): Since the Board last revised the administrative rules for the registration of manufacturers and wholesalers, the industry has evolved and a number of new business models have developed that do not fit easily or cleanly into any existing definitions. The FDA now regulates manufacturers much more stringently and state rules can reflect that oversight without adverse effect on public safety. In addition, there has been a significant increase in the number of entities that, while intrinsically involved in the drug distribution process, do not ever actually possess or take title to any drug products. A new category is necessary to enable them to register with the Board without having to undergo the more stringent procedures that are required of companies that actually make, store and distribute drugs. The amendments to the fee schedules are necessary to include the new category of Drug Distribution Agent, and to add the Electronic Prescription Monitoring Fund fee imposed on all pharmacists by statute. In addition, Division 110 is further amended to make all applications non-refundable, and updates miscellaneous administrative fees.

Documents Relied Upon, and where they are available: **None**

Fiscal and Economic Impact:

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)): **None**
2. Cost of compliance effect on small business (ORS 183.336): **None**
 - a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule: **None**
 - b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services: **None**
 - c. Equipment, supplies, labor and increased administration required for compliance: **None**

How were small businesses involved in the development of this rule? **Industry organizations were fully consulted during the development of these rules. Major companies were also involved; however, there are very few small businesses (none known in Oregon) in this industry.**

Administrative Rule Advisory Committee consulted?: **NO**

If not, why?: **This amendment was developed in discussion with industry organizations and representatives of major companies. Additional fee on pharmacists is mandated by statute.**



Gary A. Schnabel

October 14, 2009

Signature

Printed name

Date