

Secretary of State
NOTICE OF PROPOSED RULEMAKING HEARING*

A Statement of Need and Fiscal Impact accompanies this form.

Board of Pharmacy

855

Agency and Division

Administrative Rules Chapter Number

Karen MacLean

800 NE Oregon St #150, Portland, OR 97232

971-673-0001

Rules Coordinator

Address

Telephone

RULE CAPTION

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

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

November 23, 2009

9.00 a.m.

800 NE Oregon St, Room 1B, Portland, OR

Tony Burt

Hearing Date

Time

Location

Hearings Officer

Hearing Date

Time

Location

Hearings Officer

Hearing Date

Time

Location

Hearings Officer

Auxiliary aids for persons with disabilities are available upon advance request.

RULEMAKING ACTION

ADOPT: 855-060-0003, 855-062-0003, 855-062-0005, 855-062-0020, 855-062-0030, 855-062-0040, 855-062-0050, 855-110-0003.

AMEND: 855-065-0001, 855-065-0005, 855-065-0006, 855-110-0005, 855-110-0007, 855-110-0010.

REPEAL: 855-060-0003T, 855-062-0003T, 855-062-0005T, 855-062-0020T, 855-062-0030T, 855-062-0040T, 855-062-0050T, 855-110-0003T.

RENUMBER: Secure approval of rule numbers with the Administrative Rules Unit prior to filing.

AMEND & RENUMBER: Secure approval of rule numbers with the Administrative Rules Unit prior to filing.

ORS 689.205

Stat. Auth.

Other Authority

ORS 689.155, Chapter 799, Oregon Laws 2009

Stats. Implemented

RULE SUMMARY

The new rules in Division 60 and 62, and the amended rules in Division 65 define more clearly which entities must register as drug manufacturers and as drug wholesalers. A new category of Drug Distribution Agent is created in Division 62 to accommodate entities that are involved in the drug manufacturing and distribution industry but that do not ever take ownership or possession of actual product and are not licensed with the FDA as manufacturers. Division 65 is further amended to eliminate confusion over the status of repackagers and brokers, and to eliminate the requirement for a surety bond for a wholesale drug outlet that is accredited by the National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program. The fee schedule in Division 110 is amended to include the new category of Drug Distribution Agent. Division 110 is also amended to add the \$25 Electronic Prescription Monitoring Fund Fee mandated by SB 355 (Oregon Laws 2009, Chapter 799), to the pharmacist license fee. Finally, Division 110 is further amended to make all applications non-refundable, and updates miscellaneous administrative fees.

Complete text of the proposed rule can be found on the Board's website at www.pharmacy.state.or.us.

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing the negative economic impact of the rule on business.



Signature

November 30, 2009

Last Day for Public Comment

Last day to submit written comments to the Rules Coordinator

Gary A. Schnabel

Printed name

October 14, 2009

Date

*The *Oregon Bulletin* is published on the 1st of each month and updates the rule text found in the Oregon Administrative Rules Compilation. Notice forms must be submitted to the Administrative Rules Unit, Oregon State Archives, 800 Summer Street NE, Salem, Oregon 97310 by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a Saturday, Sunday or legal holiday when Notice forms are accepted until 5:00pm on the preceding workday.

ARC 920-2005