

Secretary of State
NOTICE OF PROPOSED RULEMAKING HEARING*

A Statement of Need and Fiscal Impact accompanies this form.

Oregon Board of Pharmacy	Chapter 855
Agency and Division	Administrative Rules Chapter Number
Karen MacLean	971-673-0001
Rules Coordinator	Telephone

800 NE Oregon St., Suite 150, Portland, OR 97232

RULE CAPTION

Amend or adopt new Collaborative Therapy, Immunization, Intern, Pharmacy Depots, Manufacturer, Controlled Substance and Fee Rules

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

November 22, 2011	9:00AM **	800 NE Oregon St., Conf. Rm 1-A, Portland, OR 97232	Courtney Frank
Hearing Date	Time	Location	Hearings Officer

(**If no parties appear to testify by 9:30, the hearing will end)

Hearing Date	Time	Location	Hearings Officer
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Auxiliary aids for persons with disabilities are available upon advance request.

RULEMAKING ACTION

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing.

ADOPT:

855-060-0004, 855-080-0103

AMEND:

855-019, 855-031, 855-041, 855-080, 855-110

REPEAL:

RENUMBER:

AMEND & RENUMBER:

Stat. Auth. : ORS 689.205

Other Auth.: 2009 OL Ch. 536,

Stats. Implemented: ORS 689.151, 689.155, 689.207, 689.225, 689.255, 689.275, 689.645, 689.505

RULE SUMMARY

Division 019 rules amend to clarify the requirements for Collaborative Therapy and Administration of Vaccines. Division 031 Intern rules are amended for clarification. Division 041 Pharmacy Depot rules are amended to update and allow for exceptions. Division 060 updates the Manufacturer rules to more clearly identify which entities must register as drug manufacturers. Division 080 amends the Animal Euthanasia rules to reflect changes that were made to the Veterinary Medical Examining Board and the elimination of Certified Animal Euthanasia Technicians. Division 110 rules propose to permanently adopt fees that were previously established by temporary rule in June 2011. These rules include fee increases that were necessary and included in the Board's 2011-13 Budget. The rules amend licensing fees for the registration and renewal for individuals and certain drug outlets. The temporary rule also included minor housekeeping changes. A complete copy of these proposed rules may be found on the Board's web site 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.

11/22/11 at 4:30PM Comments may be sent to Karen.S.Maclean@state.or.us

Last Day for Public Comment (Last day to submit written comments to the Rules Coordinator)

	Gary A. Schnabel R.Ph., R.N.	10/13/11
Signature	Printed name	Date

*Hearing Notices published in the Oregon Bulletin must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, upon which the deadline is 5:00 pm the preceding workday. ARC 920-2005

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT

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

Oregon Board of Pharmacy

Chapter 855

Agency and Division

Administrative Rules Chapter Number

Amend or adopt new Collaborative Therapy, Immunization, Intern, Pharmacy Depots, Manufacturer, Controlled Substance and Fee Rules

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

In the Matter of: Various rules for all licensees

Statutory Authority: ORS 689.205

Other Authority: 2009 OL Ch. 536

Stats. Implemented: ORS 689.151, 689.155, 689.207, 689.225, 689.255, 689.275, 689.645, 689.505

Need for the Rule(s):

Division 019 rules are needed to clarify the requirements for Collaborative Therapy and Administration of Vaccines. Division 031 Intern rules are needed to clarify requirements. Division 041 Pharmacy Depot rules are needed to update and provide an exception clause. Division 060 Manufacturer updates are needed to more clearly identify which entities must register as drug manufacturers. Division 080 Animal Euthanasia rules are needed to reflect changes that were made to the Veterinary Medical Examining Board rules and the elimination of Certified Animal Euthanasia Technicians. Division 110 rules are needed propose to permanently adopt fees that were previously established by temporary rule in June 2011. These rules include fee increases that are necessary and are included in the Board's 2011-13 Budget. The rules amend licensing fees for the registration and renewal for individuals and certain drug outlets. The temporary rule also included minor housekeeping changes.

Documents Relied Upon, and where they are available:

2011 SB 5536 (Oregon Legislative website)

Fiscal and Economic Impact:

Division 019 amendments have minimal to no fiscal/economic impact.

Division 031 amendments have no fiscal/economic impact.

Division 041 Pharmacy Depot rules will have no fiscal impact.

Division 060 amendments may have a fiscal impact on Manufacturers that should have been registered with the Board in accordance with the Pharmacy Act and were not.

Division 080 amendments will require additional time for training and education in animal shelters and Humane Societies, but will eliminate the need for Certified Animal Euthanasia Technicians to be licensed by the Veterinary Medical Examining Board and report to the Oregon Board of Pharmacy. The fiscal is indeterminate.

Division 110 amends and increases agency licensing/renewal fees. The Board has not increased fees more than once in the last 20 years. The fee increases were necessary for the ongoing operations of this agency and part of the agencies 11-13 Legislatively Adopted Budget.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

None, fees were established by Temporary Rule.

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule: Approximately 10% or 1000 of our licensees are small businesses.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services: Aside from the licensing fee increases, there are no or minimal reporting, recordkeeping and other administrative activities required for compliance for small businesses.

c. Equipment, supplies, labor and increased administration required for compliance: none or minimal

How were small businesses involved in the development of this rule?

Small businesses were not involved in the development of these rules. All licensees were advised of the need for fee increases through the Board's newsletter at least twice in the last two years.

Administrative Rule Advisory Committee consulted?: None

If not, why?: There was no demand or request by stakeholders to participate in an advisory capacity.



Gary A. Schnabel R.Ph., R.N.

10/13/11

Signature

Printed name

Date

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310. ARC 925-2007