

Secretary of State
NOTICE OF PROPOSED RULEMAKING HEARING*
 A Statement of Need and Fiscal Impact accompanies this form

<u>Board of Pharmacy</u>	<u>855</u>
Agency and Division	Administrative Rules Chapter Number
<u>Karen MacLean</u>	<u>(971) 673-0001</u>
Rules Coordinator	Telephone
<u>Board of Pharmacy, 800 NE Oregon St., # 150, Portland, OR 97232</u>	
Address	

RULE CAPTION

Adopt/amend rules related to Drug Outlet conduct, Pharmacy Depots, Technician Checking Validation Programs etc.

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

Hearing Date	Time	Location	Hearings Officer
3-22-12	09:30 AM	800 NE Oregon St., Portland, OR 97232 Conf. Rm. 1A	Courtney Frank

Auxiliary aids for persons with disabilities are available upon request.

RULEMAKING ACTION

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

ADOPT:

855-041-0016, 855-041-5100, 855-041-5120, 855-041-5130, 855-041-5140, 855-041-5150, 855-041-5160, 855-041-5170,

AMEND:

855-041-0095

REPEAL:

855-041-0110

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

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

855-041-0105 to 855-041-5005, 855-041-0115 to 855-041-5015

Statutory Authority:

ORS 689.151, 689.155(2), 689.205, 689.225(4)

Other Authority:

Statutes Implemented:

ORS 689.151, 689.155, 689.205, 689.225

RULE SUMMARY

The Board amends, adopts, repeals and renumbers a variety of rules in Division 041. The Div. 041 Pharmacy Depot Rules previously amended in December 2011 are amended to further clarify where a patient may designate delivery of a prescription. The Div. 041 Residential Drug Outlet rules are renumbered, amended and repealed to update rules that have not been updated since 1990. The Div 041 Drug Outlet conduct rules are new rules that define the Grounds for Discipline for outlets that fail to provide a working environment that protects the health, safety and welfare of patients. The Div 041 Technician Checking Validation Program (TCVP) rules will allow hospitals to implement TCVP's to allow the redirection of a pharmacist from a distributive task to a cognitive task.

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

<u>03-22-2012 4:30 p.m.</u>	<u>Karen MacLean</u>	<u>Karen.S.MacLean@state.or.us</u>	<u>2-15-12 2:57p.m.</u>
Last Day (m/d/yyyy) and Time for public comment	Printed Name	Email Address	Date Filed

*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 5:00 pm on the preceding workday.

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

Adopt/amend rules related to Drug Outlet conduct, Pharmacy Depots, Technician Checking Validation Programs etc.

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

In the Matter of:

Adopt/amend rules related to Drug Outlet conduct, Pharmacy Depots, Technician Checking Validation Programs etc.

Statutory Authority:

ORS 689.151, 689.155(2), 689.205, 689.225(4)

Other Authority:

Stats. Implemented:

ORS 689.151, 689.155, 689.205, 689.225

Need for the Rule(s):

The Board determined it is necessary to establish grounds for discipline for Drug Outlets due to the letters of concern received and Workforce survey results expressing concern for public safety. The Pharmacy Depot rules are revised to clarify where a patient may designate delivery of a prescription. The Board is in the process of re-numbering and re-naming the Institutional Drug Outlets to Residential Drug Outlets. The Technician Checking Validation Program (TCVP) rules are necessary to allow hospitals to implement TCVP's to allow the redirection of a pharmacist from a distributive task to a cognitive task.

Documents Relied Upon, and where they are available:

7/2011 Board of Pharmacy Workforce Survey results

Fiscal and Economic Impact:

Pharmacy Depot Rules - should not have a fiscal or economic impact.

Drug Outlet Rules - will have a fiscal impact if the Board determines there has been a violation of its rules.

Institutional Drug Outlets - should not have a fiscal or economic impact.

TCVP Rules - are optional and may have a fiscal or economic impact if they are implemented.

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):

a. Estimate the number of small business and types of businesses and industries with small businesses subject to the rule:

There are 214 self-identified "independent pharmacies" in Oregon at this time. It is unclear whether or not they are actually "small businesses" as defined by statute.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

The TCVP rules do have recordkeeping requirements if they are implemented. Documentation of any errors, irregularities and a result of each initial validation check as well as documentation of quality assurance and forms used to evaluate the technician. Again, the TCVP is an optional program.

c. Equipment, supplies, labor and increased administration required for compliance:

None

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

If not, why?:

Pharmacists from independent pharmacies were invited to participate in the 2011 survey mentioned above.

Administrative Rule Advisory Committee consulted?: Yes

We did have a workgroup and Rules Advisory Committee for the TCVP rules.

03-22-2012 4:30 p.m.	Karen MacLean	Karen.S.MacLean@state.or.us	2-15-12 2:57 PM
Last Day (m/d/yyyy) and Time for public comment	Printed Name	Email Address	Date Filed

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

ARC 925-2007