

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

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ARCHIVES DIVISION
SECRETARY OF STATE

Board of Pharmacy
Agency and Division
Karen MacLean
Rules Coordinator
Board of Pharmacy, 800 NE Oregon St., # 150, Portland, OR 97232
Address

855
Administrative Rules Chapter Number
(971) 673-0001
Telephone

RULE CAPTION

Amend, adopt or repeal Division 001, 019, 021, 025, 041, 044, 080 and 110 rules.

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

Hearing Date	Time	Location	Hearings Officer
11-25-14	9:30 a.m.	800 NE Oregon St Conference Room 1A Portland, OR 97232	Courtney Wilson

RULEMAKING ACTION

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

ADOPT:

855-019-0122, 855-019-0171, 855-025-0012

AMEND:

855-001-0005, 855-019-0100, 855-019-0120, 855-019-0170, 855-019-0205,
855-021-0005, 855-021-0010, 855-021-0016, 855-021-0025, 855-021-0045, 855-021-0050, 855-021-0055, 855-025-0001, 855-025-0005, 855-025-0010, 855-025-0015, 855-025-0020, 855-025-0025, 855-025-0030, 855-025-0035, 855-025-0040, 855-025-0050, 855-025-0060, 855-041-1120, 855-044-0070, 855-080-0022, 855-110-0003, 855-110-0005

REPEAL:

855-019-0320

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.

Statutory Authority:

ORS 183.341, 183.705, 291.055, 689.205, 689.285

Other Authority:

Statutes Implemented:

ORS 183.341, 409.560, 409.565, 431.972, 475.035, 475.059, 475.065, 676.410, 689.135, 689.151, 689.155, 689.205, 689.225, 689.255, 689.275, 689.285, 689.405, 689.445, 689.455, 689.505, 689.515, 689.774

RULE SUMMARY

Amendments to Division 001 are updated to the most current version of the Attorney General's Uniform and Model Rules of Procedure under the Administrative Procedures Act. These rules are proposed to be effective January 1, 2015.

Amendments and new rules in Division 019 reflect a change in the expiration date of Pharmacist licensure. The rules propose that Pharmacist licenses will be valid for two years and will be renewed biennially. Pharmacists licenses will expire on June 30 in odd numbered years. Amendments to Division 019 also incorporate that pharmacists will be subject to a criminal background check annually. Note that this is not a new requirement. However, rules relating to criminal background checks for Pharmacists are currently in Division 010. The amendments add this information to Division 019 to clearly identify that criminal background checks are conducted annually. Other amendments include requiring Pharmacists to provide a valid email address and notify the Board in writing if they have had a change in their e-mail address. It is proposed that the existing rules for the petition for reinstatement of pharmacist licenses be repealed. A new section of rules have are proposed for the reinstatement of a suspended, revoked or surrendered license. These rules allow a Pharmacist to petition the Board for reinstatement in writing and provide a more streamlined process. These rules are proposed to be effective January 1, 2015.

Amendments in Division 021 are part of the transition to Pharmacist biennial licensure. The amendments require pharmacists to complete three continuing pharmacy education units from July 1 through June 30 of each biennial license renewal cycle in an approved continuing pharmacy education program. Rule amendments also allow pharmacists reciprocating into Oregon to not be required to submit proof of continuing pharmacy education during the initial license renewal cycle. These rules are proposed to be effective July 1, 2015.

Amendments and new rules in Division 025 require a Pharmacy Technician or Certified Oregon Pharmacy Technician to be at least 18 years of age and hold either a high school diploma or GED. This does not apply to persons currently under the age of 18 licensed by the Board as a Pharmacy Technician prior to January 1, 2015. Amendments also make the Pharmacy Technician license valid for only one year except by petition to the Board or it may be reinstated if lapsed for more than five years. Amendments and new rules in Division 025 change requirements for Certified Oregon Pharmacy Technicians. The rule amendments require Certified Oregon Pharmacy Technicians to complete 10 continuing pharmacy education hours from September 1 through August 31 of each license renewal cycle and effective January 1, 2015 national certification is no longer a requirement for renewal. However, national certification is required for initial licensure as a Certified Oregon Pharmacy Technician, as well as for Certified Oregon Pharmacy Technicians that have had a license that has been lapsed for more than four years and would like to have an active Oregon license. Reinstatement rules have been amended to provide applicants with a more streamlined process. These rules are proposed to be effective January 1, 2015.

Amendments made to the Division 041 prescription refill rules establish requirements for the use of auto-refill programs, reminders and pick-up notifications for retail pharmacies. Note that mail order pharmacies are a type of retail pharmacies'. These rules are proposed to be effective July 1, 2015.

Amendments made to the Division 044 Charitable Pharmacy rules establish a waiver clause in the records section. These rules are proposed to be effective January 1, 2015.

Amendments made to the Division 080 controlled substances rules add delta-9-tetrahydrocannabinol (THC) to Schedule II substances for clarification. These rules are proposed to be effective January 1, 2015.

Amendments made to the Division 110 fee rules reflect the fee structure for Pharmacist biennial licensure. Note that the current fee of \$120 remains the same. However, the Pharmacist license will be valid for two years. Also reflected is a biennial fee for the electronic prescription monitoring fund fee. A reduction in fees is also included for initial pharmacist licenses issued within 13 months of expiration. These rules are proposed to be effective April 1, 2015.

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>11-25-2014 4:30 p.m.</u>	<u>Karen MacLean</u>	<u>Karen.S.MacLean@state.or.us</u>
Last Day (m/d/yyyy) and Time for public comment	Rules Coordinator Name	Email Address

*The Oregon Bulletin is published on the 1st of each month and updates the rule text found in the Oregon Administrative Rules Compilation.

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT
A Notice of Proposed Rulemaking Hearing accompanies this form.

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Board of Pharmacy
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855
Administrative Rules Chapter Number

Amend, adopt or repeal Division 001, 019, 021, 025, 041, 044, 080 and 110 rules.

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

In the Matter of:

Amend, adopt or repeal Division 001, 019, 021, 025, 041, 044, 080 and 110 rules.

Statutory Authority:

ORS 183.341, 183.705, 291.055, 689.205, 689.285

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Need for the Rule(s):

Division 001 amendments are needed to reflect the most current Attorney General's Uniform and Model Rules of Procedure used by the Board.

New rules and amendments are needed in Division 019 to reflect changes needed to implement biennial licensure for Pharmacists during the 2015 renewal cycle. The rule to require Pharmacists to notify the Board of a change in email address within 15 days of the change is needed, so that the Board can send out timely electronic notifications to pharmacists. The petition for reinstatement of pharmacist licenses rules are proposed to be repealed and replaced by a new section of rules for the reinstatement of a suspended, revoked, or surrendered license. The proposed rules for the reinstatement of a suspended, revoked, or surrendered license are needed to streamline the reinstatement process.

Amendments in Division 021 are needed to implement continuing education biennial requirements for Pharmacists. However, these rules would not go into effect until July 1, 2015. The amendments are needed to ensure that Pharmacists will do three continuing pharmacy education units in an approved continuing pharmacy education program over the course of two years rather than one and one half continuing pharmacy education units over the course of one year. Rule amendments are also needed to allow a Pharmacist that reciprocates his or her license to Oregon to not be required to submit proof of continuing education during the initial renewal cycle.

New rules and amendments are needed in Division 025 to update requirements for Technicians and Certified Oregon Pharmacy Technicians based on Board discussions and feedback received from licensees as a result of the 2014 Pharmacy Technician Registration Survey. The rule amendments establish a minimum age of 18 for Pharmacy Technicians and Certified Oregon Pharmacy Technicians as well as the requirement of a high school diploma or GED. The age requirement is needed to better ensure safety to the public as well as the Technician or Certified Oregon Pharmacy Technician. The requirement of a high school diploma or GED is needed to establish minimum education requirements. To ensure continued competency continuing education rules have been amended to require 10 continuing pharmacy education hours from September 1 through August 31 of each license renewal cycle. Rule amendments are needed to the reinstatement process to streamline processes.

Amendments to the Division 041 prescription refill rules are needed to ensure that auto refill programs in retail pharmacies are not used without the prior authorization of the patient or the patient's agent. These rule amendments are also needed to ensure that auto refill programs in retail pharmacy practice settings are not used for controlled substances in order to help limit the potential for abuse. Additionally, these rule amendments are needed to ensure that outlets appropriately enroll medications in their retail auto refill programs and that they ensure they are consistent with the patient's current medication therapy so that patients receive accurate medications.

Amendments in the Division 044 Charitable Pharmacy rules are needed to establish a waiver clause in the records session. If adopted the Board will review waivers and approve them on a case-by-case basis.

Amendments in the Division 080 controlled substance rules are needed to add delta-9-tetrahydrocannabinol (THC) to Schedule II controlled

substances for clarification purposes. Note that marijuana is currently listed as a Schedule II controlled substance.

Amendments in the Division 110 fee rules are needed to reflect the fee structure for Pharmacist biennial licensure. The amendments are also needed to collect the electronic prescription monitoring fund fee on a biennial basis. Additionally, the amendments are needed to allow Pharmacists who have been issued an initial license within 13 months of the expiration date to pay a reduced fee rather than the full biennial fee.

Documents Relied Upon, and where they are available:

The 2014 Pharmacy Technician Registration Survey available at:

Oregon Board of Pharmacy
800 NE Oregon St Ste 150
Portland, OR 97232

Pharmacist Renewal Customer Service Survey 2014

Oregon Board of Pharmacy
800 NE Oregon St Ste 150
Portland, OR 97232

Fiscal and Economic Impact:

The amendments in Division 025 will provide a savings to Certified Oregon Pharmacy Technicians as they currently are required to maintain their national pharmacy technician certification. The amendments in Division 025 no longer requires the maintenance of national certification for renewal effective January 1, 2015. However, national certification remains a requirement for initial licensure and reinstatement of a license that has been lapsed for more than four years. No longer requiring national certification for renewal will provide Certified Oregon Pharmacy Technicians with a fiscal savings.

There may be a cost associated with the Division 041 prescription refill rules as retail pharmacies may need to make changes to their auto refill programs to accommodate new requirements.

Division 110 amendments will provide a fiscal savings to Pharmacists during this transition as they will receive a license that is valid for two years upon renewal at the cost of \$120. Pharmacists currently pay \$120 for a license that is valid for one year upon renewal.

Statement of Cost of Compliance:

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

The amendments in the Division 110 fee rules collect the electronic prescription monitoring fund fee on a biennial basis. Therefore the Prescription Drug Monitoring Program would receive their fees on a biennial basis rather than annually.

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:

Approximately 50-100 pharmacy outlets registered with the Board are classified as a small business. These outlets will be required to comply with the auto refill requirements. It is unknown how many of these pharmacies utilize auto refill programs and is assumed that most pharmacies that utilize auto refill programs are not small businesses, but are part of a pharmacy chain.

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

The proposed rule amendments will require Pharmacists to keep records of their continuing education. They will be required to attest to satisfying their continuing education requirements at renewal and those who are audited will have to provide evidence of completion.

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

Auto Refill rules may require retail pharmacies to make adjustments to their auto-refill programs, reminder systems, and pick-up notifications in order to be in compliance with the proposed rules.

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

Small businesses were not involved in the development of these rules.

Administrative Rule Advisory Committee consulted?: No

If not, why?:

A rules advisory committee was not consulted. The Board has sought input on some of the proposed rules through online surveys and at various pharmacy related meetings.

