

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

FILED 4-15-16 2:17 PM ARCHIVES DIVISION SECRETARY OF STATE
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Board of Pharmacy Agency and Division	855 Administrative Rules Chapter Number
Karen MacLean Rules Coordinator	(971) 673-0001 Telephone
Board of Pharmacy, 800 NE Oregon St., # 150, Portland, OR 97232 Address	

RULE CAPTION

Adopt, amend and repeal various rules in Divisions 006, 025, 041, 043 and 110.

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

Hearing Date	Time	Location	Hearings Officer
5-24-16	9:30 a.m.	800 NE Oregon St., Conf Rm 1A, Portland, OR 97232	Staff

RULEMAKING ACTION

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

ADOPT:

855-006-0020, 855-043-0700, 855-043-0705, 855-043-0710, 855-043-0715, 855-043-0720, 855-043-0725, 855-043-0730, 855-043-0735, 855-043-0740, 855-043-0745, 855-043-0750

AMEND:

855-006-0005, 855-006-0015, 855-025-0001, 855-025-0005, 855-025-0010, 855-025-0012, 855-025-0015, 855-025-0060, 855-041-2320, 855-041-4200, 855-110-0003, 855-110-0005, 855-110-0007, 855-110-0010,

REPEAL:

855-043-0110, 855-043-0130, 855-043-0300, 855-043-0310

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 689.205, 291.055, 183.705

Other Authority:

Statutes Implemented:

ORS 689.005, 689.151, 689.155, 689.135, 689.225, 689.305, 689.405, 689.455, 689.505, 689.645, 689.486, 689.774, 433.825, 431.972, 676.410

RULE SUMMARY

Amendments to Division 006 - Definitions rules add a definition for Quality Assurance Plan and move the definition of Unprofessional Conduct to its own rule number for agency recordkeeping purposes.

Amendments to Division 025 - Pharmacy Technicians rules are updated bring additional clarification and update requirements. The rules also propose that a Certified Oregon Pharmacy Technician (CPT) license will be valid for up to two years and will be renewed biennially; rules also reflect a change in the date of expiration to June 30th in even numbered years. Amendments require CPTs to complete 20 continuing education (CE) hours during the period from July 1 through June 30 of each biennial license renewal cycle as defined. This means that upon renewal in 2016, a CPT licensed before 7/1/16 will renew, complete CE and the license will expire June 30, 2018 in order to make this shift to biennial licensure. All CPT licenses issued beginning on 7/1/16 will expire 6/30/18. Rules also update requirements for CPT reinstatement.

Amendments to Division 041 - Operation of Pharmacies update rules related to the distribution of emergency medication to allow an entity to acquire and possess epinephrine; and housekeeping corrections to the Remote Distribution Facilities rules.

Amendments to Division 043 - Practitioner Dispensing repeal the existing County Health Clinic and Family Planning Clinic rules and establish a new section of rules to combine these two licenses into one category that will be called a Community Health Clinic Drug Outlet. A facility must register when medication dispensing is performed by a Registered Nurse (RN). The new rules provide minimum requirements of operation and define requirements for personnel, policies and procedures, security, drug acquisition, storage of drugs, labeling, dispensing and drug delivery, disposal of drugs and recordkeeping.

Amendments to Division 110 - Fee rules reflect the fee structure for Certified Oregon Pharmacy Technician licensure; note that the current fee of \$50.00 remains the same. The CPT license will be valid for up to two years. A reduction in fees is also included for initial CPT licenses issued within 180 days of expiration. The Workforce Data Collection fee has been reduced for pharmacists and CPTs. The name has been changed to reflect the new Community Health Clinic license. The name of the Remote Distribution Facility fee in rule -0010 was corrected.

The intention is for all of the proposed rules to be effective on July 1, 2016.

Complete text of the proposed rules is available 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 negative economic impact of the rule on business.

<u>05-24-2016 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
Agency and Division

855
Administrative Rules Chapter Number

Adopt, amend and repeal various rules in Divisions 006, 025, 041, 043 and 110.

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 and repeal various rules in Divisions 006, 025, 041, 043 and 110.

Statutory Authority:

ORS 689.205, 291.055, 183.705

Other Authority:

Statutes Implemented:

ORS 689.005, 689.151, 689.155, 689.135, 689.225, 689.305, 689.405, 689.455, 689.505, 689.645, 689.486, 689.774, 433.825, 431.972, 676.410

Need for the Rule(s):

Division 006 revisions are necessary for clarification and agency recordkeeping purposes.

Division 025 amendments are needed to update requirements for Pharmacy Technicians and reflect the changes needed to implement biennial licensure for Certified Oregon Pharmacy Technicians (CPT) and transition the expiration date to 6/30. Renewal, continuing education and reinstatement rules are updated for clarification. The change to biennial licensure is approved in our biennial budget.

Division 041 rules related to epinephrine incorporate needed clarification from a 2013 statute implementation in ORS 433.825 that specifically allows an entity to acquire epinephrine with a valid prescription when they employ a person who has completed an OHA approved training program for the treatment of allergic emergencies. The Remote Distribution Facilities rules include minor corrections.

Division 043 rules combine the County Health Clinic and Family Planning Clinic drug outlets into one category that will be called a Community Health Clinic Drug Outlet. The new rules essentially restate minimum requirements of operation and define requirements for personnel, policies and procedures, security, drug acquisition, storage of drugs, labeling, dispensing and drug delivery, disposal of drugs and recordkeeping. The new rules will afford some licensees the opportunity to only maintain one license rather than the two they have had under the old licensing structure.

Division 110 rules are needed to reflect the fee structure for CPT biennial licensure. At this time, the fee will remain the same at \$50. Amendments are needed to allow CPTs who have been issued an initial license within 180 days of the expiration date to pay a reduced fee rather than the full biennial fee. The Oregon Health Authority reduced the fee for the Workforce Data Collection to \$4; this adjustment is reflected for pharmacists and CPTs. The fee name needs to be changed to reflect the new Community Health Clinic license. The name of the Remote Distribution Facility fee in rule -0010 is corrected.

Documents Relied Upon, and where they are available:

ORS Chapters 433, 689 and OAR Chapter 855

Fiscal and Economic Impact:

Overall, the fiscal and economic impact for the proposed rules will result in a fiscal reduction for licensees and improved public safety. All of these rules either clarify or streamline rules or licensure requirements or result in fee reductions.

Statement of Cost of Compliance:

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

The impact on state agencies is minimal to none associated with all of the rules. The Division 043 rules will have some additional requirements for Community Health Clinics (formerly County Health Clinics), however they are not likely to result in a "cost of compliance" and are necessary for public safety and they will also likely realize a savings associated with the licensing change that combines two separate licenses into one. Certified Oregon Pharmacy Technicians will benefit from an overall reduction in fees with the move to biennial licensure.

None of the proposed rules are not expected to have a negative or fiscal impact on the public.

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 small businesses. For the Division 041 rules, outlets will be required to ensure that a prescription for an entity to possess epinephrine includes proof of training for an employee prior to dispensing a prescription. This is a due diligence requirement and should not result in an increased cost of compliance. The Division 025 Certified Oregon Pharmacy Technician transition to biennial licensure and change in expiration date should result in a time savings and better overall licensing compliance for small businesses.

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

No additional costs expected. The same reporting and recordkeeping requirements exist.

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

No additional supplies are required. If anything, some outlets will experience a reduction in labor costs because the requirement to hire a consultant pharmacist for Family Planning Clinics does not exist in the new Community Health Clinic rules.

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

With the exception of the Division 043 rules, small businesses were not involved in the development of these rules. There has been outreach to stakeholders related to the expected transition to biennial licensure in Division 025 for the past year. Various stakeholders representing the County and Family Planning Clinics registrants were included in conversation about the Division 043 rule changes as well as individuals from the Oregon Health Authority, Oregon Board of Nursing and Local Public Health Authorities.

Administrative Rule Advisory Committee consulted?: No

If not, why?:

A formal advisory committee was unnecessary based on stakeholder input.

<u>05-24-2016 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	Printed Name	Email Address