

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

FILED 4-15-15 8:12 AM 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

Amend or adopt Division 019, 025, 031, 041, 060, 062, 065 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
5-28-15	9:30 a.m.	800 NE Oregon St. Room 1A Portland, OR 97232	Courtney Wilson

RULEMAKING ACTION

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

ADOPT:

855-041-1036, 855-060-0002

AMEND:

855-019-0300, 855-025-0010, 855-031-0045, 855-031-0055, 855-041-1010, 855-041-1060, 855-060-0004, 855-060-0015, 855-060-0027, 855-060-0029, 855-062-0003, 855-062-0005, 855-062-0040, 855-062-0050, 855-065-0001, 855-065-0005, 855-065-0010, 855-065-0013, 855-110-0005, 855-110-0007

REPEAL:

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 183.705, 291.055, 475, 475.035, 689.151, 689.155, 689.205, 689.305, 689.315

Other Authority:

Statutes Implemented:

ORS 431.972, 676.410, 677.511, 689.135, 689.151, 689.155, 689.207, 689.225, 689.255, 689.275, 689.305, 689.315, 689.325, 689.774, 689.765

RULE SUMMARY

Amendments in Division 019 establish minimum requirements for a Pharmacist-in-Charge (PIC) to be practicing onsite at a pharmacy. These amendments also establish requirements for a Pharmacist to be designated as the PIC of more than one pharmacy.

Amendments in Division 025 make the Pharmacy Technician license expire the second June 30 from the date of issuance, which is not to exceed more than two years.

Amendments in Division 031 make the Preceptor license a biennial license which expires on June 30 in odd numbered years. This corresponds with the new Pharmacist license biennial expiration date.

Amendments in Division 041 establish requirements for when there is a change in Pharmacist-in-Charge (PIC) in a non-resident or resident pharmacy. It also requires pharmacies to notify the Board of a change in PIC within five business days and identify a Pharmacist employed at the location to serve as the Board contact person until a PIC is designated. Resident pharmacies are required to designate an Oregon licensed PIC within 60 days when there is a change. Non-resident pharmacies are required to designate an Oregon licensed PIC within 90 days when there is a change.

Rules proposed for adoption in Division 041 establish new requirements for the proper storage of drugs, cold storage and monitoring, and vaccine drug storage. The Board worked in collaboration with the Oregon Health Authority's Oregon Immunization Program in the development of these rules. They helped serve as subject matter experts as they operate immunization programs such as Vaccines for Children and perform site visits throughout the state.

Amendments in Division 060 establish new definitions in the Pharmaceutical Manufacturer rules. Amendments also incorporate outsourcing facilities as one of the Food and Drug Administration (FDA) registration types that must register with the Board as a Manufacturer. Third-party logistics providers are directed to register as a Drug Distribution Agent.

Amendments in Division 062 Drug Distribution Agent rules require a third-party logistics provider to register as a Drug Distribution Agent. In addition, new definitions are incorporated into these rules.

Amendments in Division 065 Wholesaler rules direct third-party logistics providers to register as a Drug Distribution Agent. Amendments also establish new definitions, updates minimum requirements for record keeping and inventory management, and updates prohibited practices.

Amendments in Division 110 update the Fee rules to reflect that a Pharmacy Technician license issued prior to January 1, 2015 to a person under 18 years of age expires June 30 in odd numbered years. Other updates include listing the three classifications of Manufacturers and the three classifications of Wholesalers identified in Divisions 060 and 065.

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.

05-28-2015 4:30 p.m.	Karen MacLean	Karen.S.MacLean@state.or.us
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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SECRETARY OF STATE

Board of Pharmacy
Agency and Division

855
Administrative Rules Chapter Number

Amend or adopt Division 019, 025, 031, 041, 060, 062, 065 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:

Amending or adopting rules in Division 019, 025, 031, 041, 060, 062, 065 and 110.

Statutory Authority:

ORS 183.705, 291.055, 475, 475.035, 689.151, 689.155, 689.205, 689.305, 689.315

Other Authority:

Statutes Implemented:

ORS 431.972, 676.410, 677.511, 689.135, 689.151, 689.155, 689.207, 689.225, 689.255, 689.275, 689.305, 689.315, 689.325, 689.774, 689.765

Need for the Rule(s):

Division 019 rules are needed to establish Pharmacist-in-Charge (PIC) minimum onsite practicing hours at a pharmacy.

Division 025 rule amendments are needed to allow for additional time for a Pharmacy Technician to qualify and transition to a Certified Oregon Pharmacy Technician. In addition, the expiration date of a Pharmacy Technician is changed to a fixed date rather than expiring one year from the date of issuance.

Division 031 rule amendments are needed to correlate the expiration date of the Preceptor license with the Pharmacist biennial expiration date which is June 30 in odd numbered years.

Division 041 rule amendments are needed to establish specific onsite hour requirements for Pharmacists serving as the Pharmacist-in-Charge (PIC) of resident and non-resident pharmacies registered by the Board. A contact person is also required when there is a change in PIC and a pharmacy has not yet designated an Oregon licensed PIC. The contact person is needed to ensure that the pharmacy has a contact on staff to respond to Board correspondence and inquiries, supervise pharmacy staff, and ensure compliance with Oregon laws and rules until an Oregon licensed PIC is designated.

Division 041 proper storage of drugs, cold storage and monitoring, and vaccine drug storage rules are needed to provide more guidance to Pharmacists on proper drug storage. The Board currently has limited requirements on drug storage.

Division 060, 062, and 065 rule amendments are needed as a result of the Drug Quality and Security Act (DQSA). Rule amendments implements standards of the Federal law or exceed Federal requirements.

Division 110 are needed to reflect that the Pharmacy Technician license expires June 30 in odd numbered years for licenses initially issued prior to January 1, 2015 to a person under 18 years of age. Rule amendments are also needed to reflect the three classifications of Manufacturers and the three classifications of Wholesalers.

Documents Relied Upon, and where they are available:

Drug Supply Chain Security Act (DSCSA) available at: <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>

Title II of the Drug Quality and Security Act (DQSA) available at: <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm>

Fiscal and Economic Impact:

The Division 041 proper storage of drugs, cold storage and monitoring, and vaccine drug storage rules require pharmacies who are storing

drugs that must be refrigerated or frozen, to be stored in a drug refrigeration system that utilizes a centrally placed, accurate, and calibrated thermometer or utilize system of continuous temperature monitoring with automated data logging. Therefore, if pharmacies do not have this equipment, they would incur an expenditure to comply with these requirements. This cost may vary from outlet to outlet.

Statement of Cost of Compliance:

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

Depending on the equipment in various state and local government settings modifications may be required. The cost of compliance is unknown.

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 onsite Pharmacist-in-Charge (PIC) and drug storage requirements. The Board's current PIC rules require the PIC to be onsite the majority of the time. It is assumed that most pharmacies are complying with this requirement. New rules require pharmacies to store all drugs at the proper temperature according to manufacturer's published guidelines. Therefore drugs that must be refrigerated or frozen, must be stored in a drug refrigeration system that utilizes a centrally placed, accurate, and calibrated thermometer. Pharmacies that store drugs that require refrigeration or to be frozen would be required to ensure that they utilize a refrigeration system that contains a centrally placed, accurate, and calibrated thermometer.

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

Amendments in the Division 062 Drug Distribution Agent, Division 060 Manufacturer, and Division 065 Wholesale Drug Outlet rules require third-party logistics providers to register as a Drug Distribution Agent rather than an Wholesale Distributor. Therefore third-party logistics providers that are currently registered as a Wholesale Distributor will need to change their registration type to a Drug Distribution Agent. This will increase administrative activities as these outlets will need to submit a Drug Distribution Agent application to change their registration type.

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

Outlets will be required to comply with onsite Pharmacist-in-Charge (PIC) requirements. The Board's current PIC rules require the PIC to be onsite the majority of the time. It is assumed that most pharmacies are complying with this requirement.

Depending on the equipment in various pharmacy settings modifications may be required. The cost of compliance for equipment is unknown.

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

An organization representing small wholesale distributors was a stakeholder involved with the development of the Drug Distribution Agent, Manufacturer, and Wholesaler rules.

Administrative Rule Advisory Committee consulted?: Yes

If not, why?:

A Rule Advisory Committee was consulted on the development of the Drug Distribution Agent, Manufacturer and Wholesaler rules.

05-28-2015 4:30 p.m.	Karen MacLean	Karen.S.MacLean@state.or.us
Last Day (m/d/yyyy) and Time for public comment	Printed Name	Email Address