

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

FILED
10-15-15 1:00 PM
ARCHIVES DIVISION
SECRETARY OF STATE

Board of Pharmacy
Agency and Division

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855
Administrative Rules Chapter Number

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RULE CAPTION

Amend, adopt, repeal rules in Divisions 006, 019, 025, 041, 043, 062 and 090.

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

Hearing Date	Time	Location	Hearings Officer
11-24-15	9:30 a.m.	800 NE Oregon St., Room 1A, Portland, OR 97232	Staff

RULEMAKING ACTION

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

ADOPT:

855-019-0264

AMEND:

855-006-0005, 855-019-0110, 855-019-0200, 855-019-0270, 855-019-0280,
855-025-0015, 855-041-1120, 855-043-0130, 855-062-0040

REPEAL:

855-090-0005

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 433.441, 433.443, 468, 689.205, 689.605

Other Authority:

Statutes Implemented:

ORS 676.350, 689.005, 689.025, 689.151, 689.155, 689.305, 689.405, 689.455, 689.505, 689.515, 689.645, 2015 OL Chapter 362, 2015 OL Chapter 295

RULE SUMMARY

Proposed amendments in Division 006 Definitions rules establish definitions for clinical pharmacy agreements and the practice of clinical pharmacy. Proposed amendments also clarify compounding under a shared pharmacy service agreement is only allowed by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon for Oregon outlets and practitioners located in Oregon only. These amendments are primarily related to 2015 House Bill 2028.

Proposed amendments in the Division 019 Pharmacist rules establish definitions for clinical pharmacy agreements and practice of clinical pharmacy. Amendments also define the type of activities that require the professional judgment of a pharmacist. Other amendments allow a pharmacist to permit an intern to perform the duties of a pharmacist under their direction and supervision after the intern has successfully completed his or her first academic year and only after successful completion of coursework corresponding to the specific duties. However, an intern may not perform final verification. State Drug Therapy Management Protocol rules are proposed for adoption. Rules proposed for adoption are related to 2015 House Bill 2028.

Proposed amendments in the Division 019 Pharmacist rules allow a pharmacist to administer vaccines to persons who are at least seven years of age and maintain CPR certification intended for a Healthcare Provider. Amendments also allow a pharmacist to prescribe

immunizations, including oral vaccines, as established by written protocols approved by the Oregon Health Authority. These amendments are related to 2015 Senate Bill 520.

Proposed amendments in the Division 025 Certified Oregon Pharmacy Technicians rules clarify in rule that newly licensed Certified Oregon Pharmacy Technicians do not need to complete the annual continuing education requirements prior to their first renewal. These amendments are currently a temporary rule.

The Board proposed a revised effective date change for the Division 041 Auto Refill rules. At the October 8, 2015 Board meeting, the Board considered a number of extension requests related to the 1/1/16 effective date. The Board voted to extend the effective date for the Auto Refill associated rules in OAR 855-041-1120 (5)-(8) from January 1, 2016 to July 1, 2016 to allow more time for implementation. The Board expects full compliance with these rules by July 1, 2016.

Proposed amendments in the Division 043 Practitioner Dispensing Rules establish a waiver clause in the Drug Delivery and Control rule. The waiver clause allows for requests for exemption of certain requirements if the waived requirements will further public health and safety. These amendments are currently a temporary rule.

Proposed amendments in the Division 062 Drug Distribution Agent rules update record keeping requirements. They also identify the information that a Drug Distribution Agent who distributes product to a Wholesaler or Pharmacy must contain in their records. Amendments also reflect that a pedigree must be maintained if a Drug Distribution Agent distributes product to another Drug Distribution Agent. These amendments are currently a temporary rule.

Division 090 Aerosol Sprays rules are proposed to be repealed. This is because all fluorocarbon aerosol sprays which contain a medication are no longer manufactured in the United States. The rules were established in 1977 as an exception to the banned use of fluorocarbon aerosol sprays which delivered a medication.

Full text of these proposed rules can be viewed 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>11-24-2015 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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Administrative Rules Chapter Number

Amend, adopt, repeal rules in Divisions 006, 019, 025, 041, 043, 062 and 090.

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

In the Matter of:

Amending, adopting or repealing rules in Division 006, 019, 025, 041, 043, 062 and 090.

Statutory Authority:

ORS 433.441, 433.443, 468, 689.205, 689.605

Other Authority:

Statutes Implemented:

ORS 676.350, 689.005, 689.025, 689.151, 689.155, 689.305, 689.405, 689.455, 689.505, 689.515, 689.645, 2015 OL Chapter 362, 2015 OL Chapter 295

Need for the Rule(s):

Division 006 and 019 definition rules are needed as a result of 2015 House Bill 2028 which newly defines clinical pharmacy agreements, the practice of clinical pharmacy and state drug therapy management protocols. The Division 006 rules also clarify the conditions for compounding under a shared pharmacy service agreement. The compounding shared pharmacy agreement amendments coincide with other definitions of compounding under a shared pharmacy service agreements throughout the Board's existing rules. Division 019 rules also clarify activities that require professional judgment and when an intern may perform certain duties. Division 019 rules are needed as a result of 2015 Senate Bill 520 which lowers the age for pharmacists to administer vaccines and allows pharmacists to prescribe immunizations under OHA protocols.

Division 025 rules are currently temporary rules that need to be made permanent rules for clarification relating to Certified Oregon Pharmacy Technicians continuing education reporting.

Division 041 rules are needed to extend the effective date of the Auto Refill rules from 1/1/16 to 7/1/16 due to the number of extension requests the Board received.

Division 043 rules are currently temporary rules that need to be made permanent to allow for waiver requests associated with this rule.

Division 062 rules are currently temporary rules that need to be made permanent to update record keeping requirements associated with Drug Distribution Agents (DDA's). These rules are needed as a result of the DQSA and rules implement standards of the federal law or exceed federal requirements. Without these rules DDA's aren't required to keep adequate records and they will be inconsistent with other related rules.

Division 090 rules are being repealed to update the out of date rules.

Documents Relied Upon, and where they are available:

2015 Oregon Laws, Chapter 362 re: House Bill 2028 available at:
https://www.oregonlegislature.gov/bills_laws/lawsstatutes/2015orLaw0362.pdf

2015 Oregon Laws, Chapter 295 re: Senate Bill 520 available at:
https://www.oregonlegislature.gov/bills_laws/lawsstatutes/2015orLaw0295.pdf

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 006 and 019 rules may require pharmacies to update policies and procedures to incorporate the new authority that is allowed with 2015 legislation related to definitions, immunizations and training. This is not anticipated to be a significant fiscal or economic impact. Individual pharmacists may need to update their CPR Certification to the Advanced Cardiovascular Life Support certification intended for Healthcare Providers for more technical CPR needs. The Division 025 rules will save Certified Oregon Pharmacy Technicians the cost of continuing education requirements within the first year of licensure. The Division 041 rules allow more time for pharmacies to adjust their Auto Refill practices as required by the rules to be implemented. Depending on the individual or corporate system requirements, there may be a significant fiscal impact for the outlets. The public may be affected by the timing of implementation of this rule depending on the extent of their pharmacy's implementation in the changes required for auto refill notification and required response. The Division 043 rules will not have a fiscal or economic impact. The Division 062 rules are anticipated to have a minimal fiscal and economic impact for Drug Distribution Agents as the record keeping standards have changed and increased due in part to the federal changes associated with the DQSA. The Division 090 rules are not anticipated to have a fiscal or economic impact.

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, and local government is limited to the extent to which they are licensed with the Board. Division 006 and 019 rules may require pharmacies to update policies and procedures to incorporate the new definitions and criteria; pharmacists at these locations may need to update their CPR Certification intended for Healthcare Providers. The Division 041 rules allow more time for the Auto Refill rules adopted in 2014 to be implemented. Pharmacies that are involved in retail distribution are primarily impacted by this rule related to prescription refills. The public may be affected by the timing of implementation of this rule depending on the extent of their pharmacy's implementation in the changes required for prescription auto refill notification. The remainder of the rules are not anticipated to have an impact on state agencies, local government or 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.

It is unknown the extent to which these outlets utilize auto refill programs that may benefit by the extended effective date of implementation.

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

The Division 006 and 019 rules may require pharmacies generally to update policies and procedures to incorporate the new definitions and criteria; pharmacists at these locations may need to update their CPR Certification intended for Healthcare Providers. The Division 025 rules will save Certified Oregon Pharmacy Technicians the cost of obtaining and maintaining records of continuing education prior to their first renewal. The Division 041 rules allow more time for the Auto Refill rules to be implemented. This rule primarily affects pharmacies that are part of a pharmacy chain. The Division 043 rules do not have a projected impact required for compliance. The Division 062 rules are anticipated to have an impact for Drug Distribution Agents as the record keeping standards have changed and increased due in part to the federal changes associated with the DQSA. The Division 090 rules do not have an impact for this category. The cost of compliance for the professional services may vary depending on the outlet and the complexities of their recordkeeping activities.

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

The Division 006 and 019 rules may require a minimal one time administrative labor cost for pharmacies to update policies and procedures unique to their specific settings. Pharmacies will likely need to review their pharmacists CPR Certifications to ensure they are current with CPR intended for Healthcare Providers. The Division 025 rules do not have an impact for this category. The Division 041 rules may require retail pharmacies to make adjustments to their auto-refill programs, reminder systems, and pick up notifications in order to be compliance with the previously noticed rules depending on their unique environments. The cost will vary from location to location. This rule allows an additional six months to attain compliance. The Division 043 do not have an impact for this category. As noted above, the Division 062 rules will have an anticipated impact for Drug Distribution Agents as the recordkeeping standards have changed; this will likely result in additional labor and administrative costs depending on how they chose to achieve these new standards. The Division 090 rules do not have an impact for this category.

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?:

Generally, these rules did not require Advisory Committees. However, the Board did work with the OHA Immunization Program on the development of the immunization rules.

11-24-2015 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

