

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

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

RULE CAPTION

Amend, adopt, renumber or repeal Emergency Department Dispensing, Fees, Wholesaler Definition and Division 041 rules.

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

Hearing Date	Time	Location	Hearings Officer
11-29-12	9:00 a.m.	800 NE Oregon St. Conf. Rm 1A, Portland, OR 97232	Courtney Wilson

RULEMAKING ACTION

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

ADOPT:

AMEND:

855-041-6410
855-065-0005
855-110-0007

REPEAL:

855-041-0007
855-041-0030

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.

855-041-0005 to 855-041-1080
855-041-0015 to 855-041-1090
855-041-0026 to 855-041-1020
855-041-0035 to 855-041-2100
855-041-0060 to 855-041-1040
855-041-0060 to 855-041-1160
855-041-0060 to 855-041-1165
855-041-0065 to 855-041-1105
855-041-0065 to 855-041-1120
855-041-0065 to 855-041-1125
855-041-0065 to 855-041-1130
855-041-0135 to 855-041-6800
855-041-0145 to 855-041-7050
855-041-0160 to 855-041-7060
855-041-0162 to 855-041-7070
855-041-0165 to 855-041-8050
855-041-0360 to 855-041-4045
855-041-0620 to 855-041-4120

Statutory Authority:

ORS 475.035, 689.205

Other Authority:

Statutes Implemented:

ORS 689.135, 689.151, 689.155, 689.205, 689.225 689.305, 689.505, 689.508, 689.515, 689.774, 2012 Oregon Laws Chapter 34

RULE SUMMARY

The Division 041 Emergency Department Dispensing amendments are needed to update labeling and record requirements. These rules also propose to establish requirements for Automated Dispensing Machines (ADM) within the Emergency Department.

The Board is in the process of reorganizing and renumbering Division 041 to provide greater clarity, order and consistency with Drug Enforcement Administration (DEA) and Food and Drug Administration (FDA) regulations. For those rules that only required renumbering, they have been filed and updated with the Secretary of State. This filing includes rules that have been both renumbered and amended. Also reflected are rules that are proposed to be repealed because they are outdated. The Board intends to develop new rules to accommodate new business models and will review the Division in its entirety to ensure that the rules accurately reflect current pharmacy practice standards.

The proposed amendments in Division 065 permanently amend the definition of Class II Wholesaler to include Oxygen USP and medical gases which is currently a Temporary Rule. The Temporary Rule will expire on December 16, 2012.

The proposed amendments in Division 110 establish a permanent licensing and delinquent fee for the registration and renewal of Supervising Physician Dispensing Outlets as required by 2012 Senate Bill 1565. This rule is currently a Temporary Rule and will expire on December 16, 2012.

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.

11-29-2012 4:30 p.m.	Karen MacLean	Karen.S.MacLean@state.or.us	10-11-12 9:39a.m.
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 5:00pm on the preceding workday. ARC 923-2003

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

Board of Pharmacy
Agency and Division

855
Administrative Rules Chapter Number

Amend, adopt, renumber or repeal Emergency Department Dispensing, Fees, Wholesaler Definition and Division 041 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, renumber or repeal Emergency Department Dispensing, Fees, Wholesaler and Division 041 rules.

Statutory Authority:

ORS 475.035, 689.205

Other Authority:

Statutes Implemented:

ORS 689.135, 689.151, 689.155, 689.205, 689.225, 689.305, 689.505, 689.508, 689.515, 689.774, 2012 Oregon Laws Chapter 34

Need for the Rule(s):

The Division 041 Emergency Department Dispensing amendments are needed to update labeling and record requirements. These rules also propose to establish requirements for Automated Dispensing Machines (ADM) within the Emergency Department.

The Board is in the process of reorganizing and renumbering Division 041 to provide greater clarity, order and consistency with Drug Enforcement Administration (DEA) and Food and Drug Administration (FDA) regulations. For those rules that only required renumbering, they have been filed and updated with the Secretary of State. This filing includes rules that have been both renumbered and amended. Also reflected are rules that are proposed to be repealed because they are outdated. The Board intends to develop new rules to accommodate new business models and will review the Division in its entirety to ensure that the rules accurately reflect current pharmacy practice standards.

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Documents Relied Upon, and where they are available:

2012 Senate Bill 1565, <http://www.leg.state.or.us/12reg/measpdf/sb1500.dir/sb1565.en.pdf>

Fiscal and Economic Impact:

The proposed Division 041 Emergency Room Dispensing amendments have a small fiscal/economic impact on Emergency Departments that choose to utilize an Automated Dispensing Machine (ADM).

The proposed Division 041 reorganization and amendments have a small fiscal/economic impact as the rules require staff time to contact prescribers for re-authorization of prescriptions that expire after one year.

The proposed Division 065 Wholesaler amendments potentially reduce expenditures associated with licensure requirements.

The proposed Division 110 Fee amendments require Supervising Physician Dispensing Outlets to pay a registration and renewal fee. Such outlets are also required to pay a delinquent fee if their renewal application is received after the postmark deadline.

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:

Amongst the Board's hospital pharmacy outlets there are no such outlets that have been identified as a small business per ORS 183.336.

Approximately 50-100 pharmacy outlets are classified as a small business. These outlets will be required to contact prescribers as applicable for re-authorization as a result of the validity of a prescription changing from two years to one.

Approximately 20 wholesalers are classified as a small business. There will not be a cost of compliance associated with the proposed wholesaler rule amendments. Instead these outlets will be able to reduce expenditures associated with licensure as they will no longer be required to secure a \$100,000 surety bond or irrevocable letter of credit if they choose to register as a Wholesaler Class II Outlet.

The number of Supervising Physician Dispensing Outlets in Oregon that are small businesses is unknown. Only Supervising Physician Dispensing Outlets that are located in Oregon may apply for registration. To date the Board has not received any applications from small businesses.

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

There are reporting, recordkeeping and other administrative activities required for compliance for Emergency Departments that utilize ADMs.

Within the Division 041 renumber/amended rules, the time a prescription may be valid is modified and may require pharmacists to contact the prescriber for reauthorization.

Wholesale outlets that elect to change their classification of licensure because they distribute Oxygen USP and medical gases are required to perform an administrative activity which consists of completing a new Wholesaler Class II Application.

Supervising Physician Dispensing Outlets will need to perform an administrative activity of paying for an initial registration as well as the annual renewal fee in order to maintain licensure.

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

Emergency Departments that choose to utilize an ADM will require various equipment, labor and administrative functions to satisfy compliance requirements.

The Board anticipates that the proposed amendments in Division 041 will require a small amount of administrative time associated with having to contact prescribers for prescription reauthorization when applicable.

There are no anticipated equipment, supplies, labor or increased administrative requirements associated with the proposed Wholesaler and Fee rules.

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

The amendments for the Division 065 Wholesaler rules are being proposed as a result of feedback received from small businesses distributing Oxygen USP and medical gases that had to register as a Wholesaler Class I Outlet. This classification required such outlets to obtain a \$100,000 surety bond or irrevocable letter of credit which name the Board of Pharmacy as its sole beneficiary. Wholesaler Class II outlets do not have this monetary requirement.

Administrative Rule Advisory Committee consulted?: Yes

If not, why?:

A Rule Advisory Committee was consulted for the Division 041 re-organization rules.

11-29-2012 4:30 p.m.	Karen MacLean	Karen.S.MacLean@state.or.us	10-11-12 9:39 AM
Last Day (m/d/yyyy) and Time for public comment	Printed Name	Email Address	Date Filed