

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

FILED 10-14-16 7:10 PM ARCHIVES DIVISION SECRETARY OF STATE

<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

Adopts and amends various rules in Divisions 007, 019, 041, 043, 044 and 080

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

Hearing Date	Time	Location	Hearings Officer
11-22-16	9:30 a.m.	800 NE Oregon St., Room 1A	Karen MacLean

RULEMAKING ACTION

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

ADOPT:
855-019-0450, 855-019-0455, 855-019-0460; 855-041-2340, 855-019-0123, 855-041-1046, 855-043-0505, 855-043-0515, 855-043-0520, 855-043-0525, 855-043-0530; 855-043-0535; 855-043-0540; 855-043-0545; 855-043-0550; 855-043-0555; 855-043-0560

AMEND:
855-007-0060, 855-041-1001, 855-041-1036, 855-041-5005, 855-019-0120, 855-041-1010, 855-041-1045, 855-080-0105; 855-041-4100, 855-041-4120, 855-044-0001, 855-044-0030, 855-080-0021

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 401.065, 433.441, 689.205, 689.325, 689.522, 689.305, 676.340

Other Authority:

Statutes Implemented:
ORS 475.035, 475.059, 475.065, 689.151, 689.155, 689.305, 689.522, 689.681, 2016 OL Ch. 100, 676.340, 676.345, 689.772, 689.774

RULE SUMMARY

Div. 007 and Div. 041 - The proposed rule amendments update rules related to the registration and regulation of Drug Rooms. The rule (1) describes oversight of long-term storage of state and federal emergency medications in a Drug Room (2) clarifies that secondary storage areas related to Retail Pharmacies that can register as a Drug Room; and (3) allows a Drug Room to be affiliated with an Institutional Pharmacy.

Div. 019 - The proposed rule amendments reduce the number of days before eligibility to retake the NAPLEX exam. Amendments also limit the number of retakes on the NAPLEX and MPJE exams to no more than three times in one year for a lifetime maximum of five attempts. The changes match NABP's new policies.

Div. 019 - The proposed rules add a no cost legislatively approved registration for liability limitations for pharmacist volunteers. A pharmacist who is registered and who provides health care services without compensation is not liable for any injury, death, or other loss arising out of the provision of those services, unless the injury, death or other loss results from the gross negligence of the pharmacist.

Div. 019 and Div. 041 - The proposed rule amendments permanently incorporate new statutory language put forth by House Bill 4124 (2016). The bill permits pharmacists to prescribe and distribute unit-of-use packages of naloxone to individuals who conduct or complete OHA approved training. It allows a trainer to possess and distribute naloxone to trainees, and allows trainees to possess and administer naloxone to

an individual experiencing an opiate overdose. The rule (1) gives the purpose; (2) specifies the qualifications of participating pharmacists and individuals; and (3) outlines the delivery of care expectations for the pharmacist and pharmacy, including documentation and recordkeeping. (This rule is currently a Temporary Rule).

855-041-1010 - The proposed rule amendments add a requirement for outlets to notify the Board within 10 days of a Board licensee's termination or resignation in lieu of termination.

Div. 041 - The proposed rule amendments put forth the requirements for a pharmacy to lawfully participate in Drug Take Back initiatives. The rule (1) states that a pharmacy must comply with all DEA regulations for secure and responsible drug disposal (2) directs a pharmacy to notify the Board of its Take Back program (3) outlines the minimum policies and procedures to be established by the pharmacy, including recordkeeping; and (4) prohibits pharmacy staff from handling collected drugs and using the receptacles to dispose of pharmacy stock.

Div. 041 - The proposed rule amends the Remote Dispensing Machine (RDM) rules to allow use of new technology in licensed residential facilities.

Div. 043 - These rules are intended to distinguish between traditional and non-traditional dispensing of drugs by a health care practitioner who has been granted dispensing privileges from their licensing board and dispenses from their practice location. A health care practitioner who participates in non-traditional dispensing must register the dispensing outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

Div. 044 - The proposed rule amendments incorporate new statutory language put forth by Senate Bill 1514 (2016). The rule (1) clarifies that this is an Oregon specific program that allows donations and distribution of donated drugs within Oregon; and (2) prohibits a Charitable Pharmacy from accepting an FDA REMS drugs.

Div. 080 - The proposed rule amendments permanently add synthetic opioids/fentanyl derivatives (known as U-47700 and W-18) to Oregon Schedule CI drugs. Schedule I also includes any substituted derivatives of fentanyl that are not specifically listed, or are not FDA approved. (This rule is currently a Temporary Rule).

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>11-22-2016 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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ARCHIVES DIVISION
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Board of Pharmacy
Agency and Division

855
Administrative Rules Chapter Number

Adopts and amends various rules in Divisions 007, 019, 041, 043, 044 and 080

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

In the Matter of:

Adopts and amends various rules in Divisions 007, 019, 041, 043, 044 and 080

Statutory Authority:

ORS 401.065, 433.441, 689.205, 689.325, 689.522, 689.305, 676.340

Other Authority:

Statutes Implemented:

ORS 475.035, 475.059, 475.065, 689.151, 689.155, 689.305, 689.522, 689.681, 2016 OL Ch. 100, 676.340, 676.345, 689.772, 689.774

Need for the Rule(s):

Div. 007 and Div. 041 - The proposed rule amendments are needed to ensure oversight of long-term storage of state and federal emergency medications in a Drug Room, clarifies that secondary storage areas related to Retail Pharmacies can register as a Drug Room; and allows a Drug Room to be affiliated with an Institutional Pharmacy.

Div. 019 - The proposed rule amendments reduce the number of days before eligibility to retake the NAPLEX exam pursuant to a policy change at the National Association of Boards of Pharmacy (NABP), the Board's pharmacist test administrator. Amendments also limit the number of retakes on the NAPLEX and MPJE exams to no more than three in one year for a lifetime maximum of five attempts.

Div. 019 - The proposed rules are needed to add a no cost legislatively approved registration for liability limitations for pharmacist volunteers. Once registered, pharmacists may claim the state liability limitation for volunteer services provided under ORS 676.340-676.345.

Div. 019 and Div. 041 - The proposed rule amendments are needed implement 2016 legislation to permit pharmacists to prescribe and distribute unit-of-use packages of naloxone to individuals who conduct or complete OHA approved training which expands access to naloxone. It allows a trainer to possess and distribute naloxone to trainees, and allows trainees to possess and administer naloxone to an individual experiencing an opiate overdose.

Div. 019 and Div. 041 - The proposed rule amendments are needed to provide better communication with the Board regarding licensees who are terminated or resign in lieu of termination.

Div. 041 - The proposed rule amendments are needed to allow a pharmacy to lawfully participate in Drug Take Back initiatives. Pharmacies must comply with all DEA regulations for secure and responsible drug disposal and notify the Board of its Take Back program.

Div. 041 - Remote Dispensing Machine (RDM) rules are needed to allow use of new technology and procedures in licensed residential facilities.

Div. 043 - These rules are needed to help distinguish between traditional and non-traditional dispensing of drugs by a healthcare practitioner who has been granted dispensing privileges from their licensing board and dispenses from their practice location. Rules establish registration requirements and guidelines for policies & procedures, security, drug acquisition, drug storage, labeling, dispensing & drug and drug delivery, disposal of drugs, recordkeeping and self-inspection requirements.

Div. 044 - The proposed rule amendments incorporate new statutory language put forth by Senate Bill 1514 (2016), that this is an Oregon specific program that allows donations and distribution of donated drugs within Oregon; and (2) prohibits a Charitable Pharmacy from accepting an FDA REMS drug.

Div. 080 - The proposed rule amendment adds synthetic opioids/fentanyl derivatives (known as U-47700 and W-18) to Oregon Schedule CI

drugs. Schedule I also includes any substituted derivatives of fentanyl that are not specifically listed, or are not FDA approved. There is a potential public health emergency with the increasing detection of potentially fatal synthetic drugs and drug analogues.

Documents Relied Upon, and where they are available:

ORS 689, OAR 855

2016 HB 4124

2016 SB 1514

<https://public.health.oregon.gov/ProviderPartnerResources/EMSTraumaSystems/Documents/naloxone-training-protocol.pdf>

Oregon State Police Forensics Lab Request - April 2016 (On file with Board)

<https://www.dea.gov/divisions/hq/2015/hq031815.shtml>

http://www.deadiversion.usdoj.gov/drug_chem_info/fentanyl.pdf

http://articles.philly.com/2016-05-25/news/73318625_1_naloxone-narcan-tainted-heroin

<http://vancouversun.com/news/local-news/0530-amazon-but-for-deadly-drugs-why-fentanyl-and-w-18-are-here-to-stay>

<https://www.theguardian.com/world/2016/apr/11/synthetic-opiates-drug-laws-w-18-fentanyl>

<http://www.forbes.com/sites/davidkroll/2016/04/30/w-18-the-high-potency-research-chemical-making-news-what-it-is-and-what-it-isnt/#596f4dfe2354>

DEA Press Release, Sep. 8, 2014, DEA Releases New Rules That Create Convenient But Safe and Secure Prescription Drug Disposal Options (On file with Board)

DEA notice of Final Rules Regarding Drug Take Back https://www.deadiversion.usdoj.gov/drug_disposal/dear_registrant_disposal.pdf

2/13/2013 Department of Justice Opinion OP-2013-1

12/4/2014 Non Pharmacy Dispensing Concept

Fiscal and Economic Impact:

Overall, the fiscal and economic impact for the proposed rules will result in improved public safety. Proposed rules incorporate new legislation in Divisions 019, 041, and 044; the rules have a fiscal or economic impact to the extent that licensees or outlets participate or offer services. Rules in Divisions 007, 019, 041, 044 and 080 update and bring clarification, options and new requirements or restrictions. Proposed rules in Division 043 establish a new type license category called Dispensing Practitioner Drug Outlet. This has the potential to impact health care practitioners who dispense FDA approved drugs as part of their day-to-day practice. The proposed fiscal/economic impact is minimal.

Statement of Cost of Compliance:

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

The cost of compliance and impact on state agencies and local governments is minimal. If any state agency Board of Pharmacy licensees or local governments make access available to the new opportunities with public health emergency/drug room, naloxone, drug take back or charitable pharmacy activities, the cost of compliance would be related to each individual activity such as: training, developing policies and procedures, recordkeeping etc. and the general cost of doing business.

None of the proposed rules are 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, these would be impacted primarily by the various Division 007, 041 and possibly 044 rules. The Board has not been able to determine the number of Dispensing Practitioner Drug Outlets that exist and would be impacted by the rules in Division 043, nor how many of those are small businesses. However, we do not anticipate the number to be large at this point.

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

The Div. 019/041 naloxone rules add a few new policy & procedure and recordkeeping requirements for pharmacies that offer pharmacist

prescription services. The service is optional.

Div. 041 rules that relate to the reporting requirement to the Board upon termination or resignation in lieu of termination of Board licensees is in effect for some licensees now, but this rule will include all Board licensees. The impact is expected to be minimal.

Div. 041 rules for Drug Take Back are optional, there are costs associated with implementing a program and a number of recordkeeping and administrative activities.

Div. 043 rules for Dispensing Practitioner Drug Outlets (DPDOs) will have a variety of new requirements for reporting, recordkeeping and other administrative activities associated with dispensing drugs that are not likely part of current practice. The cost of an annual license is projected to be \$100 or less for each outlet. Outlets will be required to complete a self-inspection form for Board Inspectors to review with them upon arrival for inspection.

Div. 044 rules for Charitable Pharmacies provide clarification & guidelines and will not likely result in additional reporting, recordkeeping or administrative activities.

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

The Div. 041 rules for Drug Take Back will require additional equipment, supplies and administration for compliance if an outlet elects to implement a program.

The Div. 043 rules for DPDO's as noted above will likely have increases associated with compliance for outlets that qualify for licensure where non-traditional dispensing is occurring.

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

Representatives from the each of the health care regulatory Boards and associations with licensees and members that may potentially be effected by the DPDO registration requirements have been met as a work group for the past few years to build consensus, eliminate barriers and develop workable solutions. This was done at the Board's request initially and again at the Legislature's request.

Administrative Rule Advisory Committee consulted?: No

If not, why?:

A formal advisory committee was unnecessary based on the nature of the rules being implemented and as noted above, the ongoing workgroup that has met specifically regarding the DPDO's has served as an advisory workgroup on the development of these rules.

11-22-2016 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