

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

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

**RULE CAPTION**

Adopt/amend central fill, remote processing, consulting pharmacies; pharmacists, controlled substances, packaging and manufacturer rules  
Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

Hearing Date	Time	Location	Hearings Officer
6-27-13	9:30 a.m.	800 NE Oregon St Conference Room 1A Portland, OR 97232	Courtney Wilson

**RULEMAKING ACTION**

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

- ADOPT:**  
855-041-3000, 855-041-3005, 855-041-3010, 855-041-3015, 855-041-3020, 855-041-3025, 855-041-3030, 855-041-3035, 855-041-3040, 855-041-3045, 855-041-3100, 855-041-3105, 855-041-3110, 855-041-3115, 855-041-3120, 855-041-3125, 855-041-3130, 855-041-3300, 855-041-3305, 855-041-3310, 855-041-3315, 855-041-3320, 855-041-3325, 855-041-3330, 855-041-3335, 855-041-3340
- AMEND:**  
855-019-0240, 855-041-1140, 855-060-0004, 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 689.205

**Other Authority:**

**Statutes Implemented:**

ORS 689.305, 475.035, 475.059, 475.065, 689.151, 689.155

**RULE SUMMARY**

Remote Processing Drug Outlet rules provide minimum requirements of operation for centralized prescription processing by a pharmacy that processes drug orders on behalf of an Oregon pharmacy.

Central Fill Drug Outlet rules provide minimum requirements of operation for centralized prescription drug filling by a pharmacy that fills drug orders on behalf of an Oregon pharmacy.

Consulting or Drugless Pharmacy rules are intended to ensure that a consulting pharmacist may safely store records and protected health information in an Oregon licensed drugless pharmacy when engaged in Independent Pharmacy Practice.

Consulting Pharmacist Practice rules are amended to establish registration requirements for a consulting pharmacist that stores health protected records outside an Oregon licensed pharmacy.

Manufacturer rules are amended to clarify that any compounded non-patient specific drug from an out-of-state drug outlet may only be distributed into the state by an Oregon registered manufacturer.



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**STATEMENT OF NEED AND FISCAL IMPACT**  
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Board of Pharmacy  
Agency and Division

855  
Administrative Rules Chapter Number

Adopt/amend central fill, remote processing, consulting pharmacies; pharmacists, controlled substances, packaging and manufacturer rules

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 central fill, remote processing, consulting pharmacies; pharmacists, controlled substances, packaging and manufacturer rules

**Statutory Authority:**

ORS 689.205

**Other Authority:**

**Statutes Implemented:**

ORS 689.305, 475.035, 475.059, 475.065, 689.151, 689.155

**Need for the Rule(s):**

The amendments to Division 019 are needed to ensure that consulting pharmacists who store health protected records outside an Oregon licensed pharmacy register as a Consulting or Drugless Pharmacy.

The Board determined that it is necessary to establish minimum requirements for remote processing drug outlets, central fill drug outlets and consulting or drugless pharmacies. These rules are needed to keep up with the pharmaceutical industry, help free up pharmacists time to allow more time for patient care and not create barriers to the industry.

The amendments to Division 041 incorporate a waiver clause to the customized patient medication packages rules.

Manufacturer rules are amended to clarify that any compounded non-patient specific drug from an out-of-state drug outlet may only be distributed into the state by an Oregon registered manufacturer.

The amendments to Division 080 are needed to include certain synthetic cannabinoids and cathinone-type derivatives.

**Documents Relied Upon, and where they are available:**

The following documents were relied upon and are available online:

Alabama Board of Pharmacy Rules: 680-X-2.08. Pharmacist Consultants of Pharmaceutical Services

Alaska Board of Pharmacy Rules: 12 AAC 52.820. Responsibilities of the Consultant Pharmacist

Arizona Board of Pharmacy Rules: R4-23-110. Non-Pharmacy Licensed Outlets-General Provisions

Arkansas Board of Pharmacy Rules: 04-02-0012 Retail Pharmacy Off Site Order Entry

California Board of Pharmacy Rules: 4052.1. Permitted Pharmacist Procedures in Licensed Health Care Facility

Colorado Board of Pharmacy Rules: 14.00.80. Consultant Pharmacist

Florida Board of Pharmacy Rules: 64B16-28.501. Institutional Permit - Consultant Pharmacist of Record. 64B16-26.300. Consultant

Pharmacist Licensure. 64B16-26.301. Subject Matter for Consultant Pharmacist Training Program. 465.0125 Consultant Pharmacist License; Application, renewal, fees; responsibilities.

Georgia Board of Pharmacy Rules: 480-24.05 Duties of Consultant Pharmacist

Idaho Board of Pharmacy Rules: 27.01.01.257 Outsourcing. 27.01.01.265. Remote Dispensing Pilot Project. 27.01.01.267. Remote Pharmacy Registration - Operating Memorandum

Indiana Board of Pharmacy Rules: 856 IAC 1-27.1-7 Pharmacist's Duties

Iowa Board of Pharmacy Rules: 657-23.1(155A) Definitions

Kentucky Board of Pharmacy Rules: 201 KAR 2:230. Special Limited Pharmacy- Central Refill Pharmacy

Minnesota Board of Pharmacy Rules: 6800.6500 Consulting Services to Licensed Nursing Homes

Mississippi Board of Pharmacy Rules: Article XXX Consultants to Institutional Facilities. Definitions

Missouri Board of Pharmacy Rules: 20 CSR 2220-2.020 Pharmacy Permits. 20 CSR 2220-2.010 Pharmacy Standards of Operation 20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy

Montana Board of Pharmacy Rules: 24.174.1302. Telepharmacy Operations  
Nevada Board of Pharmacy Rules: NAC 639.446. Consultant Pharmacist  
New Mexico Board of Pharmacy Rules: 16.19.11.7. Definitions  
North Carolina Board of Pharmacy Rules: 21 NCAC 46.1317 Definitions  
North Dakota Board of Pharmacy Rules: 61-03-02-01.1. Definitions  
Oklahoma Board of Pharmacy Rules: 535:10-3-2. Consultant Pharmacist  
South Carolina Board of Pharmacy Rules: Section 40-43-30. Definitions  
Tennessee Board of Pharmacy Rules: 1140-01-.01 Definitions  
Washington Board of Pharmacy Rules: 246-865-060. Pharmaceutical Services  
Wyoming Board of Pharmacy Rules: Chapter 2. General Practice of Pharmacy Regulations.

**Fiscal and Economic Impact:**

Central Fill, Remote Processing and Consulting or Drugless Pharmacy rules are optional and may have a fiscal or economic impact if they are implemented.

It is also optional to register as a manufacturer with the Board of Pharmacy. This registration is required only for specific activities.

**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:**

There are about 214 self identified independent pharmacies in Oregon at this time. It is unclear as to whether or not they are small businesses as defined by statute.

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

Central Fill, Remote Processing and Consulting or Drugless Pharmacy rules all have recordkeeping and documentation requirements if they are implemented.

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

None.

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

N/A

**Administrative Rule Advisory Committee consulted?: Yes**

**If not, why?:**

A work-group was established for the development of the Central Fill, Remote Processing and Consulting or Drugless Pharmacy rules.

06-27-2013 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

<b>FILED</b> 5-7-13 2:05 PM ARCHIVES DIVISION SECRETARY OF STATE
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