

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

Oregon Board of Pharmacy
Agency and Division

OAR Chapter 855
Administrative Rules Chapter Number

In the Matter of:

Amending, renumbering and repealing rules in Divisions 19, 41 and 42, and the adoption of rules in Divisions 19 and 45.

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

Adopt new rules, and renumber and amend existing rules regarding pharmacists and compounding of drugs.

Statutory Authority:

ORS 689.205

Other Authority:

Stats. Implemented:

ORS 689.151, 689.155, 689.225, 689.255, 689.265, 689.275, 689.305, 689.315, 689.405, 689.505, 689.508, 689.605, 689.645,

Need for the Rules:

- Within current rule structure, rules pertaining to pharmacists are partly in Division 19 and partly spread throughout Division 41 with one rule in Division 42. Since these rules were last amended, there have been numerous changes in pharmacist licensing procedures, pharmacy practices and in pharmacy technology. The proposed changes will gather all rules pertaining to pharmacists into Division 19 and will update them to reflect current practice and Board policy. These rules were developed with the assistance of an advisory group that contained pharmacists from all the major practice settings and retail industry.
- In recent years, United States Pharmacopeia has revised its standards for the compounding of drugs (USP 795 & USP 797). Division 45 is a new division that encompasses those standards that the Board and its advisory group of experienced compounding pharmacists believe should be mandatory for compounding pharmacists doing business in Oregon or for the citizens of Oregon.

Documents Relied Upon, and where they are available:

1. Minutes of the Board of Pharmacy USP 797 Research Council meetings dated 7/12/06, 10/11/06 and 11/15/06 available from the Board office.
2. USP 795, 797 and 1075 available from U.S. Pharmacopeia at www.usp.org.

Fiscal and Economic Impact, including Statement of Cost of Compliance:

Compounding pharmacies that already meet the cleanliness standards of USP 797 or these rules will have no additional cost of compliance. Those that do not meet these standards will be faced with either potentially significant costs to upgrade their facilities, or they will need to change the type of products they produce to those that may be compounded within the limitations of their facility. The costs of upgrading existing facilities to meet clean air standards can not be accurately quantified as each case would be individually based on the existing design and the scope of products that the business intends to compound. Typical costs for a pharmacy to construct a new "clean room" might be \$12,000 - \$20,000. There may be ongoing costs for environmental monitoring and testing from \$50 to several hundred dollars per week.


The changes to Division 19 should not have any fiscal impact on Oregon pharmacists, as the new rules only address practices that Pharmacists are already doing, or should be doing. Out-of-state pharmacies doing business in Oregon that do not currently have a pharmacist licensed by this Board will incur licensing by reciprocity costs of \$820 initially, and an annual renewal fee of \$120. There will be no additional costs for state or local government agencies although there will be additional workload at this agency because of new out-of-state pharmacists applying for licensure. It is not possible to estimate how many out-of-state pharmacies do not currently comply with this requirement that will now need to do so.

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

There were four owners and managers of small businesses on the Division 45 Advisory Committee. A small business owner and two representatives of the retail trade were on the Division 19 Advisory Committee. Many small business owners are members of the Oregon State Pharmacists Association which was represented on both rules advisory committees.

Administrative Rule Advisory Committee consulted?

Yes. Advisory committees representing small businesses, institutions and hospitals were deeply involved in the rule development.



Authorized Signer

Gary A. Schnabel, Executive Director September 12, 2007

Printed name

Date