

Secretary of State
Certificate and Order for Filing
TEMPORARY ADMINISTRATIVE RULES
A Statement of Need and Justification accompanies this form.

I certify that the attached copies are true, full and correct copies of the TEMPORARY Rule(s) adopted on 02/14/2013 by the
Board of Pharmacy 855
Agency and Division Administrative Rules Chapter Number
Karen MacLean (971) 673-0001
Rules Coordinator Telephone
800 NE Oregon St., # 150, Portland, OR 97232
Address
To become effective 03/07/2013 through 09/03/2013.

RULE CAPTION

Registration requirements for the compounding of any drug not based on a patient specific prescription
Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

RULEMAKING ACTION

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

ADOPT:

AMEND:

855-060-0004

SUSPEND:

Statutory Authority:

689.205

Other Authority:

Statutes Implemented:

689.155, 689.305

RULE SUMMARY

This rule defines the requirements for licensure for any out-of-state outlet that compounds a drug that is distributed in Oregon to be administered or dispensed and is not based on a patient specific prescription.

The complete text of these rules is available on the Board's website at: www.pharmacy.state.or.us.

Karen MacLean
Rules Coordinator Name

Karen.S.MacLean@state.or.us
Email Address

| |
|---|
| <p>FILED 3-6-13 4:06 PM ARCHIVES DIVISION SECRETARY OF STATE</p> |
|---|

Secretary of State
STATEMENT OF NEED AND JUSTIFICATION
A Certificate and Order for Filing Temporary Administrative Rules accompanies this form

Board of Pharmacy
Agency and Division

855
Administrative Rules Chapter Number

Registration requirements for the compounding of any drug not based on a patient specific prescription

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

In the Matter of:

Registration requirements for specific out-of-state compounding activities.

Statutory Authority:

689.205

Other Authority:

Statutes Implemented:

689.155, 689.305

Need for the Temporary Rule(s):

This rule clarifies that any out-of-state outlet that compounds a drug that is distributed into Oregon and is based on a non-patient specific order must register as a Manufacturer.

Documents Relied Upon, and where they are available:

None.

Justification of Temporary Rule(s):

Without this temporary rule, out-of-state outlets may apply for a registration that is not appropriate for their activities.

Karen MacLean

Printed Name

Karen.S.MacLean@state.or.us

Email Address

FILED

3-6-13 4:06 PM

ARCHIVES DIVISION
SECRETARY OF STATE