

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control _____ Department of Agency: Alabama State Board of Pharmacy

Rule No. 680-X-2-.43

Rule Title: Requirements for Compounding

X New _____ Amend _____ Repeal _____ Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? YES

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect or directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule. NO

Are all facets of the rule making process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer *Season Alvarson*

Date April 9, 2018

REC'D & FILED

APR 12 2018

LEGISLATIVE SVC AGENCY

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**ALABAMA STATE BOARD OF PHARMACY
NOTICE OF INTENDED ACTION**

AGENCY NAME: ALABAMA STATE BOARD OF PHARMACY
RULE NO. AND TITLE: 680-X-2-.43 REQUIREMENTS FOR COMPOUNDING
INTENDED ACTION: ADOPTION OF NEW RULE

SUBSTANCE OF PROPOSED ACTION:

To adopt a new rule reinforcing the requirements that all pharmacies and pharmacists that engage in compounding of drugs must comply with all applicable and current requirements of United States Pharmacopeia- National Formulary USP-NF.

TIME, PLACE, MANNER OR PRESENTING VIEW:

Oppositions can be directed to Wendy Passmore at the Alabama Board of Pharmacy from May 1st, 2018 until June 5th, 2018. Please present your views in writing, fax or email.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Final date to present your views will be June 20th, 2018.

CONTACT PERSON AT AGENCY:

Wendy Passmore
Chief Operations Officer
111 Village Street
Birmingham, Al 35242
Phone 205-981-4764
Fax 205-803-6481
Email - wpassmore@albop.com


Susan Alverson, Executive Secretary

ECONOMIC IMPACT STATEMENT
FOR APA RULE
(Section 41-22-23(f))

Control No. _____ Department of Agency: ALABAMA STATE BOARD OF PHARMACY

Rule No.: 680-X-2.43

Rule Title: _____

New Amend Repeal Adopt by Reference

NO This rule has no economic impact.

_____ This rule has an economic impact, as explained below:

1. NEED/EXPECTED BENEFIT OF RULE:
2. COSTS/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE:
3. EFFECT OF THIS RULE ON COMPETITION:
4. EFFECT OF THIS RULE ON COST-OF-LIVING AND DOING BUSINESS IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:
5. EFFECT OF THIS RULE ON EMPLOYMENT IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:
6. SOURCE OF REVENUE TO BE USED FOR IMPLEMENTING AND ENFORCING THIS RULE:
7. THE SHORT-TERM/LONG-TERM ECONOMIC IMPACT OF THIS RULE ON AFFECTED PERSONS, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE:
8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:
9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:
10. DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:

**** Additional pages may be used if needed.**

ALABAMA STATE BOARD OF PHARMACY

NOTICE OF INTENDED ACTION

RULE NUMBER: **680-X-2-.43**

TITLE OF RULE: **REQUIREMENTS FOR COMPOUNDING**

680-X-2-.43

All pharmacies and pharmacists that engage in the compounding of drugs or drug products shall comply with all applicable and current regulations of United States Pharmacopeia- National Formulary (USP-NF)

Author: Susan Alverson R.Ph, Executive Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92

History: Filed May 1, 2018 Effective