

**TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION**

Control 680 Department or Agency: Alabama State Board of Pharmacy
 Rule No. 680-X-2-.25
 Rule Title: Drug Manufacturers; Wholesale Drug Distributors; Private Label Distributors, Repackager, Third Party Logistics, 503B Outsourcer; Reverse Distributor Permit Fees.
 _____ New ☒ Amendment _____ 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 of 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 rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? Yes

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

 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 Donna C. Gayman

Date 12/16/2020

REC'D & FILED

DEC 16 2020

Alabama State Board of Pharmacy

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Pharmacy

RULE NO. & TITLE:

680-X-2-.25 Drug Manufacturers; Wholesale Drug Distributors; Private Label Distributors, Repackager, Third Party Logistics, 503B Outsourcer; Reverse Distributor Permit Fees.

INTENDED ACTION:

Amend Rule

SUBSTANCE OF PROPOSED ACTION:

The Alabama State Board of Pharmacy proposes to amend Rule No. 680-X-2.25 - Drug Manufacturers; Wholesale Drug Distributors; Private Label Distributors, Repackager, Third Party Logistics, 503B Outsourcer; Reverse Distributor Permit Fees to correct error and provide clarity

TIME, PLACE, MANNER OF PRESENTING VIEWS:

Oppositions can be submitted to the Alabama State Board of Pharmacy office. Business hours are 8:00am - 4:00pm Monday through Friday. Please present your views in writing, fax or email. Public hearing will be held March 17, 2021 at 9:00am

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Comments concerning this change must be received by the Alabama State Board of Pharmacy no later than March 6th, 2020

CONTACT PERSON AT AGENCY:

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Donna C. Yeatman, R.Ph. Executive Secretary

**680-X-2-.25 Drug Manufacturers; Wholesale Drug Distributors;
Private Label Distributors, Repackager, Third Party Logistics, 503B
Outsourcer; Reverse Distributor Permit Fees.**

(1) PERMIT

(a) An annual permit must be obtained from the Alabama State Board of Pharmacy by any manufacturer, Wholesale Drug Distributor, Private Label Distributer, Repackager, Third Party Logistic, 503B Outsourcer or Reverse Distributor of medicines, chemicals or poisons for medicinal purposes. The permit shall be issued only after the filing of an application on a form furnished by the Alabama State Board of Pharmacy and the Board's approval of that application. The application shall be accompanied by the fee set forth in paragraph (b). The application shall contain information as required by and conform with the requirements of all applicable laws or rules of the Alabama State Board of Pharmacy.

(b) The fee for the annual permit shall be in the amount of \$750.00. The fee for any renewal permit shall be in the amount of \$500.00. The fee to transfer ownership of the permit shall be in the amount of \$750.00.

(c) All permits issued by the Alabama State Board of Pharmacy shall become due on October 31 and shall become null and void on December 31 of every year. Each application for the renewal of the permit shall be made on or before December 31 of every year, at which time the previous permit shall become null and void. A penalty of one hundred dollars (\$100.00) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits.

Author: Susan Alverson, R.Ph., Executive Director

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

History: Filed October 18, 1991. **Amended:** Filed January 6, 2005; effective February 10, 2005. **Amended:** Filed September 5, 2018; effective October 20, 2018. **Amended:** Filed June 20, 2019; effective August 4, 2019. **Amended:** Filed December 17, 2020