

APA-1
11/96

**TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION**

Control 680 Department of Agency: Alabama State Board of Pharmacy

Rule No. 680-X-2-.41

Rule Title: PHARMACY SERVICES PERMIT.

 New XX 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 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 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 Reference Service.

Signature of certifying officer Mitzi G. Ellenburg
Mitzi G. Ellenburg, Interim Secretary

Date: July 18, 2013

(DATE FILED)
(STAMP)

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

AGENCY NAME: ALABAMA STATE BOARD OF PHARMACY

RULE NO. AND TITLE: 680-X-2-.41 PHARMACY SERVICES PERMIT.

INTENDED ACTION: AMENDMENT

SUBSTANCE OF PROPOSED ACTION:

The Alabama State Board of Pharmacy proposes to amend Rule 680-X-2-.41 PHARMACY SERVICES PERMIT to allow an application by a non-resident pharmacy.

TIME, PLACE, MANNER OR PRESENTING VIEW:


Comments can be presented at the public hearing scheduled at 7:30 a.m. on August 21, 2013 at the Alabama State Board of Pharmacy located at 111 Village Street, Hoover, Alabama 35242. Additionally, written comments may be addressed to Mitzi Ellenburg, Interim Secretary, Alabama State Board of Pharmacy, P. O. Box 381988, Birmingham, Alabama 35238-1988. Written comments must be received in the Board Office no later than 4:00 p.m. on September 4, 2013.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

September 4, 2013

CONTACT PERSON AT AGENCY:

Mitzi Ellenburg, Interim Secretary
205/981-4760


Mitzi Ellenburg, Interim Secretary

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

Control No. 680 Department of Agency: Alabama State Board of Pharmacy

Rule No.: 680-X-2-.41

Rule Title: PHARMACY SERVICES PERMIT.

New Amend Repeal Adopt by Reference

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.**

680-X-2-.41 PHARMACY SERVICES PERMITS

(1) The Board may issue on a case by case basis a Pharmacy Service Permit for the limited purpose of allowing pharmacists and pharmacy technicians to provide pharmacy services to patients and clients. Nothing in this rule shall limit the board's ability to issue any Pharmacy Service Permit the Board deems appropriate.

(2) The Board has determined that, at a minimum, the holder of a Pharmacy Service Permit must designate a Supervising Pharmacist, on site, who is responsible for ensuring that the processes and compliance standards are maintained within limits set by the Board for the permit holder.

(3) Nothing in this rule restricts the Board from setting pharmacist and technician ratios.

~~(4) Nothing in this rule shall authorize any individual to perform any activity beyond their scope of practice pursuant to any license or registration issued to them. The following items pertain to a permit issued for a customer care call center services for incoming patient calls.~~

~~(a) The following functions are not authorized under this permit~~

- ~~1. Consulting patients on medication issues,~~
- ~~2. Correcting a medication error,~~
- ~~3. Generating a prescription, or~~
- ~~4. The marketing of prescription drug products or services.~~
- ~~5. Receiving prescription~~

(5) In the event the application for a Pharmacy Services Permit is by a non-resident pharmacy, in addition to the requirements set out in Paragraphs (1) through (4) above, if applicable, the applicant must comply with to the following requirements:

(a) Complete an application furnished by the Board and be issued the referenced permit. Any application which is not full and complete will not be processed.

(b) Pay the fee set out in Code of Alabama, (1975) §34-23-30.

(c) The Pharmacy Services Permit issued by the Board shall become void on December 31st of even numbered years unless renewed in compliance with Code of Alabama, (1975) §34-23-30.

(d) Submit documentation from the applicant's home state verifying any applicable license or permit is valid and in good standing.

(e) Designate a resident agent in Alabama for service of process. The failure to include this information shall result in the denial of the application.

(f) In the event the applicant will be involved or participate in any remote order processing and not actually shipping, mailing or delivering any drug from its location to a citizen in this State, there shall also be compliance with the following:

1. All statutory and regulatory requirements of the State of Alabama relating to controlled substances, including those that are different from federal law or regulation.

2. All the statutory and regulatory requirements of the State of Alabama regarding drug product selection laws.

3. All Board of Pharmacy requirements for data submission related to volumes of orders processed as specified at the time of approval.

(g) Submission with the application a policy and procedure manual for Board approval which must, at a minimum, include the following:

1. Hours of operation.

2. On-Call Pharmacist. For the protection of patients, when orders are being processed remotely and no pharmacist is onsite at the resident Pharmacy, a pharmacist must be on-call to respond to situations that arise that cannot be addressed through remote services, such as patient needing a specific medication which is not available until the resident Pharmacy opens, or a healthcare provider urgently needing information that cannot be provided by the pharmacists performing remote order processing.

3. Procedures to be following in case of downtime.

4. The system to be used to identify and respond to medication errors arising from mistakes from remote order processing.

5. The system to be used to insure initial and ongoing quality of remote order processing.

6. The means by which compliance with HIPPA requirements will be met.

(h) Designate a supervising pharmacist who shall be responsible for ensuring compliance with this rule and all applicable laws and rules.

(i) Compliance with any other requirement deemed necessary by the Board, to include but not limited to required technician to pharmacist ratios.

Author: Herb Bobo, R.Ph., Secretary Kenny Sanders, R.Ph., President
Statutory Authority: Code of Alabama 1975, § 34-23-92.
History: Adopted: 26 September 2012; Effective 1 November 2012; Amended.