

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-.07

Rule Title: **MAIL ORDER PRESCRIPTIONS**

 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, Secretary/Director of Operations

Date: December 20, 2013

(DATE FILED)
(STAMP)

REC'D & FILED

DEC 26 2013

LEGISLATIVE REF SERVICE

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

AGENCY NAME: ALABAMA STATE BOARD OF PHARMACY

RULE NO. AND TITLE: 680-X-2-.07 MAIL ORDER PRESCRIPTIONS

INTENDED ACTION: AMENDED

SUBSTANCE OF PROPOSED ACTION:

The Alabama State Board of Pharmacy proposes to amend this rule to require out-of-state mail order pharmacies to designate a supervising pharmacist who shall be licensed by the Alabama State Board of Pharmacy.

TIME, PLACE, MANNER OR PRESENTING VIEW:

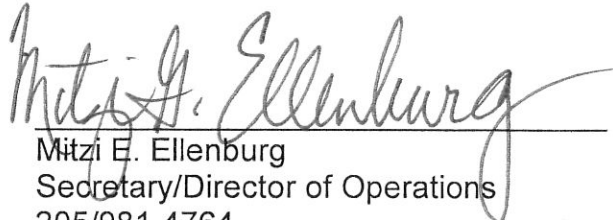
Comments can be presented at the public hearing scheduled at 8:00 a.m. on February 19, 2014 at the Alabama State Board of Pharmacy located at 111 Village Street, Hoover, Alabama 35242. Additionally, written comments may be addressed to Mitzi Ellenburg, Secretary/Director of Operations, Alabama State 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 March 7, 2014.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

March 7, 2014

CONTACT PERSON AT AGENCY:

Mitzi Ellenburg
Secretary/Director of Operations
205/981-4764


Mitzi E. Ellenburg
Secretary/Director of Operations
205/981-4764

680-X-2-.07. MAIL ORDER PRESCRIPTIONS.

(1) Every applicant for a Mail Order Permit or Permits pursuant to the provisions of Code of Alabama 1975, §§34-23-30, 34-23-31, shall obtain a permit biennially. On the first registration by a Pharmacy located outside of the State of Alabama, the provisions of Code of Alabama 1975, §34-23-30 shall apply to such first registration.

(2) Registration. No Nonresident Pharmacy shall ship, mail or deliver prescription drugs and/or devices to a patient in this state unless registered by the Alabama State Board of Pharmacy.

(3) Agent of Record. Each Nonresident Pharmacy that ships, mails, or delivers prescription drugs and/or devices to a patient in the state of Alabama shall designate a resident agent in Alabama for service of process. Any such Nonresident Pharmacy that does not so designate a registered agent and that ships, mails or delivers prescription drugs and/or devices in the state of Alabama shall be deemed an appointment by such Nonresident Pharmacy of the Secretary of State to be its true and lawful attorney upon whom may be served all legal process in any action or proceedings against such pharmacy growing out of or arising from such delivery. A copy of any such service of process shall be mailed to the Nonresident Pharmacy by the complaining party by certified mail, return receipt requested, postage prepaid, at the address of such Nonresident Pharmacy as designated on the pharmacy's application for registration in this state. If any such pharmacy is not licensed in this state, service on the Secretary of State of Alabama only shall be sufficient service.

(4) Conditions of Registration. As conditions of receiving a permit, the Nonresident Pharmacy or a renewal if applicable must comply with the following:

(a) Be registered and in a good standing in the State in which such pharmacy is located;

(b) Maintain, in readily retrievable form, records of legend drugs and/or devices dispensed to Alabama patients;

(c) Supply upon request, all information needed by the Alabama Board of Pharmacy to carry out the Board's responsibilities under the statutes and regulations pertaining to Nonresident Pharmacies;

(d) Maintain pharmacy hours that permit the timely dispensing of drugs to Alabama patients and provide reasonable access for the Alabama patients to consult with a licensed pharmacist about such patients' medications.

(e) Provide toll-free telephone communication consultation between an Alabama patient and a pharmacist at the pharmacy who has access to the patient's records, and ensure that said telephone number(s) will be placed upon the label affixed to each legend drug container;

(f) Designate a supervising pharmacist who shall be licensed by the Alabama State Board of Pharmacy. The supervising pharmacist shall be responsible for ensuring that the holder of the permit referenced herein complies with the requirements of this rule and all applicable statutory provisions and rules;

5. Compliance. Each nonresident Pharmacy shall comply with the following:

(a) All statutory and regulatory requirements of the State of Alabama for controlled substances, including those that are different from federal law or regulation.

(b) All the statutory and regulatory requirements of the state of Alabama regarding drug product selection laws.

(c) Labeling of all prescriptions dispensed, to include but not limited to identification of the product and quantity dispensed.

(d) All the statutory and regulatory requirements of the State of Alabama for the dispensing of prescriptions in accordance with the quantities indicated by the prescriber.

6. Policy and Procedure Manual. Each Nonresident Pharmacy shall develop and provide the resident board of pharmacy with a policy and procedure manual that sets forth:

(a) Normal delivery protocols and times;

(b) The procedure to be followed if the patient's medication is not available at the Nonresident Pharmacy, or if delivery will be delayed beyond the normal delivery time;

(c) The procedure to be followed upon receipt of a prescription for an acute illness, which policy shall include a procedure for delivery of the medication to the patient from the Nonresident Pharmacy at the earliest possible time (i.e. courier delivery), or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time;

(d) The procedure to be followed when the Nonresident Pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mailed prescription drugs become available.

7. Disciplinary Action. Except in emergencies that constitute an immediate threat to public health and require prompt action by the Board, the Alabama Board of Pharmacy shall file a complaint against any Nonresident Pharmacy that violates any statute or regulation of Alabama for conduct which causes serious bodily or psychological injury to a resident of this state. This complaint shall be filed with the Board in which the Nonresident Pharmacy is located. If the Board in the state in which the Nonresident Pharmacy is based fails to resolve the violation complained of within a reasonable time, (not less than forty-five (45) days from the date that the complaint is filed), disciplinary proceedings may be instituted in Alabama before the Board.

Author: Jerry Moore, R.Ph., J.D., Executive Director

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

History: Adopted July 17, 1967; Effective October 1, 1967; Amended: Filed June 1, 1982; Amended: April 15, 1986; Amended: Filed March 28, 1990; Effective: September 1, 1990; Amended 17 December 2004; Effective 18 January 2005; Amended

APA-6

**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-.07

Rule Title: **MAIL ORDER PRESCRIPTIONS**

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.**