

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-.42

Rule Title: **REQUIREMENTS FOR RETURN AND DESTRUCTION OF DRUGS
BY PHARMACIES**

XX 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 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: September 9, 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-.42 REQUIREMENTS FOR RETURN
AND DESTRUCTION OF DRUGS BY PHARMACIES

INTENDED ACTION: NEW

SUBSTANCE OF PROPOSED ACTION:

The Alabama State Board of Pharmacy proposes this new rule as requirements to Code of Alabama 1975, §34-23-70(2) passed by Act 2013-198 effective August 1, 2013.

TIME, PLACE, MANNER OR PRESENTING VIEW:

Comments can be presented at the public hearing scheduled at 7:30 a.m. on October 23, 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 November 4, 2013.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

November 4, 2013

CONTACT PERSON AT AGENCY:
Mitzi Ellenburg, Interim Secretary
205/981-4760


Mitzi Ellenburg, Interim Secretary

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CHAPTER 680-X-2
PRACTICE OF PHARMACY
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680-X-2-.42	Requirements For Return And Destruction Of Drugs By Pharmacies

680-X-2-.42 REQUIREMENTS FOR RETURN AND DESTRUCTION OF DRUGS BY PHARMACIES

(1) This rule shall apply only to unused or expired non-controlled legend drugs. The return of controlled drugs shall not be authorized until the adoption of applicable regulations pursuant to the Secure and Responsible Drug Disposal Act of 2010, at which time there must be compliance with the provisions of any such regulation(s) or any subsequent amendments thereto.

(2) The following requirements shall apply whenever an individual desires to return unused or expired drugs to a pharmacy and if the pharmacy agrees to accept the return.

(a) Drugs may only be returned for the sole purpose of destruction.

(b) It shall be the pharmacist(s) responsibility to ensure compliance with the requirements of this Rule.

(c) The pharmacy shall maintain a separate log of all returned drugs which shall include the following information.

1. Name, address and telephone number of patient returning the drugs, if available.
2. Name, address and telephone number of original dispensing pharmacy, if known.
3. The prescription number of the original dispensing pharmacy, if available.
4. Name of returned drug and reason for return.
5. Date of return.
6. Date and method of destruction of drug.
7. The above referenced log shall be available for inspection in the same manner as set forth in the Code of Alabama 1975, § 34-23-70(k).

(3) Any returned drug must be maintained and stored in an area within the pharmacy which is separate and apart from the regular inventory of the pharmacy.

(4) No returned drugs shall be dispensed for any purpose.

(5) Any returned drugs shall be destroyed within 180 days of their return to the pharmacy.

Author: Kenny Sanders, R.Ph., President
Statutory Authority: Code of Alabama 1975, §34-23-92.
History: Adopted:

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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-.42

Rule Title: **REQUIREMENTS FOR RETURN AND DESTRUCTION
OF DRUGS BY PHARMACIES**

XX New Amend Repeal Adopt by Reference

 X 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.**