

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control _____ Department or Agency: Alabama State Board of Pharmacy
Rule No. 680-X-2-.42
Rule Title: Requirements for Return and Destruction of Drugs by Pharmacies.

X New _____ Amend X 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 Luan Alverson

Date 7-19-2018

(DATE FILED)
(STAMP)

Alabama State Board of Pharmacy

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Pharmacy

RULE NO. & TITLE:

680-X-2-.42 Requirements for Return and Destruction of Drugs By Pharmacies.

INTENDED ACTION:

Repeal and Replace

SUBSTANCE OF PROPOSED ACTION:

The proposal will outline methods for pharmacies to take back outdated or unused drugs. There is great concern that drugs stored in homes can be used by unintended family members or used for the wrong purpose. On the other hand, it is no longer acceptable to flush or pour into sewers or put into regular trash, items which can be abused or harmful. This rule describes how pharmacies can collect such drugs and then have them in-turn collected by specialty drug handling companies. It requires a record of the eventual destructions of the drugs.

TIME, PLACE, MANNER OF PRESENTING VIEWS:

Oppositions can be submitted to the Alabama State Board of Pharmacy, 111 Village Street, Birmingham Alabama 35242. Office business hours are 8:00am - 4:00pm Monday through Friday. Please present your views in writing, fax or email. Public hearing will be September 19th, 2018 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 September 15th, 2018

CONTACT PERSON AT AGENCY:

Wendy Passmore, Chief Operations Officer
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Susan Alverson, R.Ph. Executive Secretary

680-X-2-.42 Requirements For Return And Destruction Of Drugs
By Pharmacies.

REPEALED

(1) This rule shall apply 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 Chapter 680-X-2 Pharmacy Board Supp. 9/30/162-92 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

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

1. General description of returned drugs.

2. Date of return.

3. Date and method of destruction of drugs.

4. The above referenced log shall be available for inspection in the same manner as set forth in the Code of Ala. 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.

NEW RULE

680-X-2-.42 Requirements for the Disposal of Prescription Drug by
Pharmacies Collected from Ultimate User(s) or Person(s) Entitled to
Dispose of Drugs

(1) This Rule shall apply only to the collection and disposal of prescription drugs by pharmacies returned or received from an ultimate user or a person entitled to dispose of prescription drugs.

(2) An ultimate user is a person who has lawfully obtained and who possesses the controlled substance for his own use or for the use of a member of his/her household or an animal owned by him/her or a member of his/her household.

(3) A person entitled to dispose of prescription drugs is one lawfully entitled to dispose of a decedent's property if that decedent was an ultimate user who died while in possession of prescription drugs (hereinafter referred to as Other Person(s)).

(4) Any pharmacy which intends to receive, collect and dispose of controlled substances from an ultimate user(s) or Other Person(s) shall comply with the applicable provisions of any existing rule or regulation or any amendment or revision thereto adopted pursuant to the Secure and Responsible Drug Disposal Act of 2010. Each such pharmacy shall submit to the Board the necessary authorization to be a collector issued by the DEA within ten (10) days of the receipt thereof. In the event any such pharmacy ceases activities as a collector the Board shall be notified in the same manner as required by the applicable Federal rule or regulation.

(5) Any pharmacy who also intends to receive, collect and dispose of non-controlled prescription drugs from ultimate user(s) or from Other Person(s) shall also comply with the same requirements relating to controlled substances with the exception of any requirement for authorization from the DEA. Each such pharmacy shall notify the Board at the same time of the submission of the Authorization referenced in Paragraph 3 above as well as the notification at the same time if such pharmacy ceases activities as a collector referenced in Paragraph 3 above.

Author: David Darby, R.Ph., President

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

History: New Rule: Filed November 25, 2013; effective December 30, 2013. Repealed: effective: