NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-24-.06 DESTRUCTION OF DRUGS. AMENDED., AND NOTICE OF PUBLIC HEARING

TO ALL INTERESTED PERSONS AND PARTIES:
Notice is hereby given that pursuant to the authority set forth below, the Georgia State Board of Pharmacy (hereinafter "Board") proposes amendments to the Georgia Board of Pharmacy Rules, Rule 480-24-.06 DESTRUCTION OF DRUGS. AMENDED. (hereinafter "proposed amendments").

This notice, together with an exact copy of the proposed amendments and a synopsis of the proposed amendments, is being forwarded to all persons who have requested, in writing, that they be placed on an interested parties list. A copy of this notice, an exact copy of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments may be reviewed during normal business hours of 8:00 a.m. to 5:00 p.m. Monday through Friday, except official State holidays, at the Department of Community Health at 2 Peachtree Street, NW, Atlanta, Georgia, 30303. These documents will also be available for review on the Georgia State Board of Pharmacy's web page at www.gbp.georgia.gov.

A public hearing is scheduled to begin at 11:30 AM on July 12, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th Floor, Atlanta, Georgia 30303 to provide the public an opportunity to comment upon and provide input into the proposed amendments. At the public hearing, anyone may present data, make a statement, comment or offer a viewpoint or argument whether orally or in writing. Lengthy statements or statements of a considerable technical or economic nature, as well as previously recorded messages, must be submitted for the official record. Oral statements should be concise and will be limited to 5 minutes per person. Additional comments should be presented in writing. Written comments are welcome. To ensure their consideration, written comments must be received prior to July 5, 2017. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, Atlanta, Georgia 30303 FAX: 678-717-6435. You may email your comments to tbattle@dch.ga.gov.

The proposed amendments will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 11:35 AM on 7/12/2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, Georgia 30303. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed amendments pursuant to authority contained in O.C.G.A. §§ 16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, 26-4-110, 26-4-113, 26-4-115.

At its meeting on February 13, 2017, the Board voted that the formulation and adoption of these rule amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22.

At its meeting on 2/13/2017, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A§ 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these amendments will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

For further information, contact the Board office at 404-651-8000.

This notice is given in compliance with O.C.G.A. §50-13-4.

This 8th day of May, 2017.

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: May 8, 2017

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-24-.06 DESTRUCTION OF DRUGS. AMENDED.

Purpose of Rule: The purpose of this rule is to permit methods of destruction for controlled and non-controlled substances.

Main Features: The main feature of this rule is to permit the use of collection receptacles.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-24-.06 DESTRUCTION OF DRUGS. AMENDED.

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

480-24-.06 Destruction of Drugs. Amended.

(1) The following methods of destruction of controlled substances and non-controlled substances are approved by the Board for medications dispensed to patients residing in long term care facilities (nursing home or skilled nursing facility) or other facility where a consultant pharmacist's services are required under state or federal regulations:
(a) When controlled substances or non-controlled drugs are expired, discontinued from use or the patient for whom they were ordered is no longer a patient, the drugs shall be immediately removed from the active stock and inventoried by two people who shall be licensed either as a pharmacists, a nurses, or a licensed practical nurses. The completed inventory record shall be signed and dated by these two individuals. The original inventory record shall be maintained by the facility for two years, one kept by a supervisor-level facility member and a copy shall be kept with the drugs until their final disposition. Once inventoried, these drugs can either be:
1. Placed in a collection receptacle at the facility containing a numbered secure inner-liner which has been provided by an authorized collector (retail pharmacy). One supervisor-level employee of the LTCF (e.g., charge nurse or supervisor), designated by the authorized collector, may assist in changing the collection receptacle inner liner under the supervision of one pharmacist representative for the authorized collector pharmacy.
(i) Upon removal, sealed inner liners may be stored at the LTCF for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access.
~~1. Placed in a secure storage area at the facility separated from medications with active orders. The drugs can be destroyed at the facility by the consultant pharmacist and another pharmacist, nurse, or licensed practical nurse designated by the facility. However, before~~
(ii) Before the ~~destruction~~ drugs can ~~take~~ be placed in an authorized receptacle, each drug ~~it~~ must be verified ~~that~~ and an inventory of the drug ~~has been~~ taken and recorded. The facility must maintain a written record of the destruction along with the inventory record for two years. This record shall include at a minimum the date, time, personnel involved with placing the drug in the receptacle.~~the destruction and the method of destruction~~; or
2. ~~Removed~~ Secured in a storage area at ~~from~~ the facility separated from medications with active orders. The controlled and/or non-controlled drugs and kept by the consultant pharmacist until they can be destroyed at the facility by the consultant pharmacist and another pharmacist, nurse,

or licensed practical nurse designated by the facility. Non-controlled drugs may be removed from the facility and ~~are~~ returned to the vendor pharmacist for destruction. The facility licensed staff or consultant pharmacist shall make a receipt for the drugs removed.~~, and t~~The original receipt to be kept by the facility and a copy of the receipt kept by the consultant pharmacist, and a copy of the receipt kept with the returned drugs. The receipt shall reflect: the date the drugs were removed from the facility, the name of the person removing the drugs, the name and address of the pharmacy to which the drugs have been removed. Both the receipt and its copy must be maintained for two years. Before any drugs can be removed for destruction, their inventory must be verified by at least one pharmacist and one other licensed health care practitioner. Once taken to the vendor pharmacy, the drugs must be stored in a secure, location, separate from active inventory, within the pharmacy. When the drugs are destroyed, a record of the manner of disposal of the drugs must be maintained by the vendor pharmacy for two years. The disposal record shall include at a minimum, whether:

(i) The drugs are destroyed at the pharmacy, and

(I) Manner of destruction;

(II) Date and time of destruction~~;~~ or

(III) Names of at least one pharmacist and one other licensed health care practitioner witnessing the destruction; ~~or~~

~~(2) The~~ (b) Any drugs for destruction placed in an authorized receptacle and stored in secure inner liner can only be removed from the facility for disposal ~~are removed from the pharmacy~~ by transfer to a representative of a reverse distributor with a current permit issued by the Board and authorized by the DEA as a collector as follows:~~; and~~

~~(I)~~1. The date and time the numbered inner liners ~~drugs~~ were taken from the facility and the numbers of the inner liners recorded in logs, one maintained by the facility for two years and one maintained by the reverse distributor for each facility for two years ~~pharmacy;~~

~~(II)~~2. The name, Board permit number, address, and telephone number of the reverse distributor removing the drugs;

~~(III)~~3. The name and signature of the responsible person representing the reverse distributor physically removing the drugs;

~~(IV)~~4. The name and signature of the persons ~~pharmacist~~ transferring the ~~drugs~~inner-liners to the reverse distributor.

~~(2)~~(c) The following methods of on-site destruction of controlled substances are approved by the Board:

~~(a)~~1. When controlled drugs are expired, discontinued from use or the patient for whom they are ordered is no longer a patient, the medication shall be removed from the active stock immediately and inventoried and verified by two people who shall be licensed either as a pharmacist, a nurse, or a licensed practical nurse. The completed inventory record shall be signed and dated by those two individuals. An inventory form will be established by the pharmacist, which must include the following data:

~~1.~~(i) Date of discontinuance or inventory date;

~~2.~~(ii) Name of patient;

~~3.~~(iii) Name of issuing pharmacy;

~~4.~~(iv) Identifying serial numbers of the prescriptions;

~~5.~~(v) Name and strength of drug; and

~~6.~~(vi) Quantities of drugs in containers when inventoried.

~~(b)~~2. After being removed from active stock, controlled substances to be destroyed must be placed in a secure cabinet or area as identified by the consultant or vendor pharmacist.
~~(c)~~3. On-site controlled substance destruction can be as follows:
~~1.~~(i) The consultant or vendor pharmacist will notify the GDNA as to the date and time the destruction will take place at least two weeks prior to destruction at the facility. (Please note that the consultant may set up a specific schedule of destruction - an example would be the first Tuesday in each month at 10:00 a.m.)
~~2.~~(ii) ~~Three~~Two licensed professionals or law enforcement officers, one of whom must be a pharmacist, must witness the destruction of these drugs.
~~3.~~(iii) Destruction must take place within the facility.
~~4.~~(iv) Inventory of final destruction must be taken in duplicate, one copy shall be retained by the facility, and one copy shall be retained by the consultant pharmacist. The inventory shall be certified by all three witnesses present at the destruction in the following format: "We, whose signatures appear below, certify that these controlled substances have been reconciled, accounted for, and destroyed at _____(location) on
_____(date) at _____o'clock."
_____(Signature) and
_____(Signature)
~~_____(Signature)~~
~~5.~~(v) The Board and/or the GDNA, or the DEA, may prohibit any consultant pharmacist or facility from utilizing this method.
~~(3) Methods of off site destruction as follows:~~
~~(a) When controlled substances are expired, discontinued from use or the patient for whom they are ordered is no longer a patient, the medication shall be removed from the active stock immediately and inventoried and verified by two people who shall be licensed either as a pharmacist, a nurse, or a licensed practical nurse. The completed inventory record shall be signed and dated by those two individuals. An inventory form will be established by the pharmacist, which must include the following data:~~
~~1. Date of discontinuance or inventory date;~~
~~2. Full name of patient;~~
~~3. Name of issuing pharmacy;~~
~~4. Identifying serial numbers of the prescriptions;~~
~~5. Name and strength of drug; and~~
~~6. Quantities of drugs in containers when inventoried.~~
~~(b) After being removed from active stock, controlled substances to be destroyed must be placed in a secure cabinet or area as identified by the consultant or vendor pharmacist.~~
~~(c) The drugs, along with a copy of the permanent record, can then be transferred to the vendor pharmacy by the consultant pharmacist to hold for disposal by a Board licensed reverse drug distributor or by a GDNA Agent. The consultant pharmacist shall make a receipt for the drugs removed, and the original receipt is to be kept by the facility and a copy of the receipt kept by the consultant pharmacist, both for two years. The receipt shall reflect at a minimum:~~
~~1.The date the drugs were removed from the facility;~~
~~2. The name and signature of the consultant pharmacist removing the drugs;~~
~~3. The name and signature of the Director of Nursing witnessing the drug removal;~~
~~4. The name and address of the pharmacy to which the drugs are being removed.~~

~~(d) Once received by the pharmacy, the drugs for disposal must be stored in a secure location within the pharmacy. When disposal of the drugs takes place, a record of the disposal will be maintained by the pharmacy for two years. The type of disposal record shall be, either:~~
~~1. On a separate receipt showing the drugs for destruction were removed from the pharmacy by transfer to a Board licensed reverse distributor, showing:~~
~~(i) The date and time the drugs were taken from the pharmacy;~~
~~(ii) The name, address, telephone number and Board permit number of the reverse distribution firm taking possession of the drug;~~
~~(iii) The name and signature of the responsible person representing the reverse distributor firm and physically removing the drugs;~~
~~(iv) The name and signature of the pharmacy representative transferring possession of the drugs; and~~
~~(v) A copy of the permanent drug inventory destruction record from the facility; or~~
~~2. On the permanent record showing the drugs were destroyed by a GDNA Agent with:~~
~~(i) The signature of the GDNA Agent;~~
~~(ii) The signature of the pharmacy manager as listed on the pharmacy license; and~~
~~(iii) The date and time of the drug destruction.~~

Authority: O.C.G.A. §§16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, 26-4-110, 26-4-113, 26-4-115.