NOTICE OF INTENT TO ADOPT PROPOSED CHAPTER OF THE GEORGIA STATE BOARD OF PHARMACY RULES
CHAPTER 480-50 DRUG DISPOSAL AND AUTHORIZED COLLECTORS.

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 a new Chapter to the Georgia Board of Pharmacy Rules: Chapter 480-50 DRUG DISPOSAL AND AUTHORIZED COLLECTORS. (hereinafter "proposed chapter").

This notice, together with an exact copy of the proposed chapter and a synopsis of the proposed chapter, 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 proposed chapter, and a synopsis of the proposed chapter 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 11:00 AM on January 14, 2016 at the South University School of Pharmacy, 709 Mall Boulevard, Savannah, Georgia 31406 to provide the public an opportunity to comment upon and provide input into the proposed chapter. 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 January 4, 2016. 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 chapter will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 11:05 AM on January 14, 2016 at South University School of Pharmacy, 709 Mall Boulevard, Savannah, Georgia 31406. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed chapter pursuant to authority contained in O.C.G.A. §§ 16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112 and Pub. L. 111–273.

At its meeting on November 18, 2015, the Board voted that the formulation and adoption of this chapter do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed chapter 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.

Also, at its meeting on November 18, 2015, the Board 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 this chapter 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 30th day of November, 2015.

Tanja D. Battle

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: November 30, 2015

SYNOPSIS OF PROPOSED CHAPTER OF THE GEORGIA STATE BOARD OF PHARMACY RULES CHAPTER 480-50 DRUG DISPOSAL AND AUTHORIZED COLLECTORS.

Purpose of chapter: The purpose of this chapter is to permit collection of drugs by authorized collectors for the purpose of drug disposal where the authorized collectors comply with the requirements of state and federal law and regulation.

Main Features: The main feature of this chapter is to set forth the requirements for collection receptacles.

PROPOSED CHAPTER OF THE GEORGIA STATE BOARD OF PHARMACY RULES CHAPTER 480-50 DRUG DISPOSAL AND AUTHORIZED COLLECTORS.

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

480-50: Drug Disposal and Authorized Collectors

480-50-.01 Definitions.

(1) "Authorized Collectors" or "Collectors" means retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment programs, manufacturers, distributors, and reverse distributors which have registered with the DEA to become authorized collectors of drugs for disposal, are authorized to handle controlled substances, and are currently licensed by the Georgia Board of Pharmacy.
(2) "Authorized Employees" means employees of authorized collectors that have met the DEA employment standards and are pharmacists licensed by the Georgia Board of Pharmacy.
(3) "Collection Receptacle" means a lockable and sturdy container with a permanent outer container and a removable numbered inner-liner with a small opening that allows contents to be added but not removed and which container is securely fastened to a permanent structure in a secure area.
(4) "Drugs" means controlled substances and dangerous drugs (non-controlled substances) as those terms are defined in O.C.G.A. Title 16, Chapter 13.
(5) "Mail-back Packages" means pre-paid postage packages provided by authorized collectors at a price or at no cost to the patient or patient's family
(6) "Mail-back Programs" means programs that utilize mail-back packages provided by authorized collectors in which the packages are mailed directly to a reverse distributor and can never be mailed back to the authorized collector.
(7) "Numbered Inner-liner" means a removable, tamper-evident, and tear-resistant liner that bears a unique identification number that is used inside a collection receptacle and which can be securely sealed for transfer to a reverse distributor for transportation to a drug destruction site.
(8) "Ultimate user" means a person who has lawfully obtained and who possesses a drug for his/her own use or for the use of a member of his/her household or for an animal owned by him/her or a member of his/her household.
(9) "Unique Identification Number" means a number traceable to a specific authorized collector.

Authority: O.C.G.A. §§16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112 and Pub. L. 111–273

480-50-.02 Collection Receptacles Located at Authorized Collectors.

(1) Authorized collectors may place, utilize, and maintain collection receptacles at their DEA registered location. Receptacles can only be available to receive drugs when the collector is open for business and only when an authorized employee is present.
(a) An authorized collector may only begin receiving drugs for disposal at the facility after providing thirty (30) days of advance notification to the Board and the Georgia Drugs and Narcotics Agency of its qualification for and intention to serve as an authorized collector.
(2) Collection receptacles must be lockable, sturdy, securely fixed within the collector's location. If the authorized collector is in a pharmacy, then the collection receptacle must be in the immediate vicinity of and can be observed from the prescription department areas where controlled substances are stored by registrants and where an authorized employee is present, and display a sign stating that non-controlled and controlled drugs in Schedule II, III, IV, or V can be accepted and placed in the receptacle. If the collection receptacle is in a hospital/clinic, it must be in an area monitored by employees, but shall not be in an area where emergency or urgent care is provided. If the collection receptacle is in an opioid treatment facility, it must be located in a room that does not contain other controlled substances and is securely locked with controlled access.
(3) Each receptacle must also be capable of holding a removable, tamper-evident, and tear- resistant inner-liner bearing a unique identification number to receive the drugs.
(a) To dispose of the contents of a receptacle, the sealed liners may be promptly delivered or transferred to a representative for a licensed reverse distributor for destruction. No on-site disposal of any drug is permitted. Only authorized employees can remove and seal an inner-liner and maintain records required by this rule.
(b) Authorized collectors may store inner-liners that have been sealed upon removal from a collection receptacle in a securely locked, substantially constructed cabinet or a securely locked room with controlled access for up to three business days until the liners can be transferred for destruction, and then transferred to a representative for a licensed reverse distributor for destruction.
(c) Collectors are encouraged to schedule inner-liner removals and installations as frequently as necessary.
(d) Drugs placed in the authorized receptacle and stored in secure inner-liners can only be removed from the authorized collector location for destruction by transfer to a reverse distributor with a current permit issued by the Board and authorized by the DEA as a collector.
(e) The date and time that the numbered inner-liners were taken from the collector and the numbers of the inner-liners must be recorded in logs: one maintained by the collector for two years and one maintained by the reverse distributor for each facility for two years.
(f) The name, Board permit/license number, address, and telephone number of the reverse distributor removing the drugs must be recorded in logs maintained by the collector and by the reverse distributor for a period of at least two years; and
(g) The name and signature of the responsible person representing the reverse distributor physically removing the inner-liners must be recorded in logs maintained by the collector and by the reverse distributor for a period of at least two years. Nothing in this rule shall prevent a DEA authorized common carrier from serving as the authorized representative of the reverse distributor.

Authority: O.C.G.A. §§16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112 and Pub. L. 111–273

480-50-.03 Collection Receptacles Located at Long Term Care Facilities (LTCF).
(1) Collection receptacles in long-term care facilities ("LTCF") must be located in a secured area monitored by long-term care facility employees. Collection receptacles can only be used in facilities where a consultant pharmacist's services are required.

(a) A LTCF may only begin receiving drugs for disposal at the facility after providing thirty (30) days of advance notification to the Board and the Georgia Drugs and Narcotics Agency of its qualification for and intention to set up a collection receptacle.
(2) A LTCF may dispose of drugs on behalf of an ultimate user who resides, or has resided, at such LTCF by transferring those drugs into an authorized collection receptacle located at such LTCF. When using this method of destruction, the drugs must be transferred into the collection receptacle within three (3) business days after discontinuation of use by the ultimate user. This provision applied to drugs that are expired, discontinued from use, or when the patient for whom they were ordered is no longer a patient.
(3) When the 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 by one supervisor-level employee, and a copy shall be kept with the drugs until their final disposition. Once inventoried, these drugs must be placed in a collection receptacle at the facility containing a numbered secure Inner-liner which has been provided by an authorized collector (retail pharmacy).
(a) If the numbered inner-liner becomes full prior to collection by a reverse distributor, one supervisor-level employee of the LTCF (e.g., charge nurse or supervisor) and one authorized employee designated by the authorized collector or two authorized employees of the authorized collector pharmacy may change the collection receptacle inner-liner. Upon removal, sealed inner-liners may be stored at the LTCF for up to three (3) business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access.
(4) The drugs placed in the authorized receptacle and stored in secure inner-liner and those secured inner-liners stored by the LTCF can only be removed from the LTCF for disposal for destruction by transfer to a representative for a reverse distributor with a current permit issued by the Board and authorized by the DEA as a collector.
(a) The date and time that the numbered inner-liners 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;
(b) The name, Board permit/license number, address, and telephone number of the reverse distributor removing the drugs;
(c) The name and signature of the responsible person representing the reverse distributor physically removing the Inner-liners; and
(d) The name and signature of the persons transferring the drugs Inner-liners to the reverse distributor.
(5) Authorized collectors may not transfer sealed inner-liners from LTCFs to their primary registered location (i.e., the hospital/clinic or retail pharmacy location). Instead, collectors should deliver sealed inner-liners to a reverse distributor or distributor's registered location by common or contract carrier pick-up or by reverse distributor or distributor pick-up at the LTCF.

Authority: O.C.G.A. §§16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112 and Pub. L. 111–273

480-50-.04 Numbered Inner-Liner Requirements.
(1) A numbered inner-liner shall meet the following requirements:
(a) The inner-liner shall be waterproof, tamper-evident, and tear-resistant;
(b) The inner-liner shall be removable and sealable immediately upon removal without emptying or touching the contents;

(c) The contents of the inner-liner shall not be viewable from the outside when sealed;
(d) The size of the inner-liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.); and
(e) The inner-liner shall bear a permanent, unique identification number that enables the inner-liner to be tracked.
(2) Access to the inner-liner shall be restricted to authorized employees for the collector.
(3) The inner-liner shall be sealed by two authorized employees immediately upon removal from the permanent outer container, and the sealed inner-liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.
(4) The authorized collector shall maintain a sequential log of all numbered inner-liners. The log shall indicate, at a minimum:
(a) If the Inner-liner has been placed in a receptacle;
(b) If the Inner-liner has been damaged and rendered not usable;
(c) If the Inner-liner has been sealed and removed from the receptacle;
(d) The names of the collector employees sealing and removing the inner-liner from the collector; and
(e) The date and name of the reverse distributor, and authorized representative, by which the inner-liner was removed from the collector's facility.

Authority: O.C.G.A. §§16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112 and Pub. L. 111–273

480-50-.05 Mail-back Programs
(1) Pre-paid mail-back packages may be provided by authorized collectors to patients and their families for a price or at no cost to the patient.
(2) In Georgia, mail-back packages cannot be returned or mailed back to the authorized collector, unless that collector is a licensed reverse distributor. Collectors that are pharmacies cannot receive or dispose of mail back packages. All such mail-back packages must be shipped directly to a licensed reverse distributor for disposal.

Authority: O.C.G.A. §§16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112 and Pub. L. 111–273

480-50-.06 Reverse Distributors
(1) Any person that reverse distributes a controlled substance shall be registered with the United States Drug Enforcement Administration as a reverse distributor and actively licensed by the Georgia Board of Pharmacy as a reverse distributor.
(2) A reverse distributor shall acquire controlled substances and non-controlled drugs from a collector in the following manner:
(a) Pick-up of sealed inner liner from a collector at the collector's licensed location or authorized receptacle collection site such as a LTCF; or
(b) Receive a sealed inner-liner delivered by common or contract carrier or delivered directly by a registrant or a LTCF to the reverse distributor.
(i) Delivery to the reverse distributor by common or contract carrier may only be made to the reverse distributor at the reverse distributor's registered location. Once *en route*, such deliveries may not be re-routed to any other location or person, regardless of registration status.
(ii) All controlled substance and non-controlled drug deliveries to a reverse distributor shall be personally received by an employee of the reverse distributor at the registered location.
(3) Upon acquisition of a drug by delivery or pick-up, a reverse distributor shall:

(a) Immediately store the controlled substance, in accordance with the security controls in accordance with DEA rules at the reverse distributor's registered location or immediately transfer the drugs to the reverse distributor's registered location for secure storage, in accordance with the security controls in DEA rules, until timely destruction.
(4) A reverse distributor shall destroy or cause the destruction of any drug received for the purpose of destruction no later than 30 calendar days after receipt.

Authority: O.C.G.A. §§16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112 and Pub. L. 111–273

480-50-.07 Inspections
(1) The Georgia Drugs and Narcotics Agency (GDNA) shall have the authority to conduct inspections of any place, premises, or receptacle utilized by any authorized collector in relation to collection, retention, and disposal of drugs.
(2) GDNA shall have the authority to examine, copy, or remove all records required by this rule, and to examine, remove, or inventory all numbered inner-liners.
(3) It shall be the responsibility of any authorized collector to make same available for such inspection, copying, examination, or inventorying by said GDNA.
(4) Following any such examination, inventory, or inspection of records or receptacles, GDNA shall provide to the authorized collector a copy of any written inspection report produced on which any deficiencies or violations are made along with any recommendations, if any, concerning the satisfactory storage, record-keeping, handling, and security of drugs for disposal.
(5) The Pharmacist-in-Charge of each authorized collector shall obtain a copy of the current Board permit of every reverse distributor to which inner-liners are returned. Such copies shall be made available during the GDNA's inspection.
(6) The Pharmacist-in-Charge of each authorized collector shall respond in a written report addressing any discrepancies or deficiencies noted in a GDNA inspection report within two weeks after receipt of the inspection notice. The deficiencies shall be corrected within ten (10) business days.

Authority: O.C.G.A. §§16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112 and Pub. L. 111–273