NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES, RULE 480-16-.03 RETURN OF PREVIOUSLY DISPENSED DRUGS OR DEVICES., 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 480-16-.03 RETURN OF PREVIOUSLY DISPENSED DRUGS OR DEVICES. (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 11:00 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 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 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 amendments will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 11:05 AM on 1/14/2016 at the 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 amendments pursuant to authority contained in O.C.G.A. §§ 26-3-3, 26-4-27, 26-4-28, 26-4-60, 26-4-80, and Pub. L. 111–273.

At its meeting on November 18, 2015, 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 11/18/2015, 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 30th day of November, 2015.

Jain D. Buttle

Executive Director Georgia Board of Pharmacy

Posted: November 30, 2015

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-16-.03 RETURN OF PREVIOUSLY DISPENSED DRUGS OR DEVICES.

Purpose of Amendments: The purpose of these amendments is to prohibit a licensed pharmacist or pharmacy to accept previously dispensed drugs except where permitted by state or federal law or regulation.

Main Features: The main feature of these amendments is to permit an authorized collector to collect controlled substances for the purposes of destruction as authorized under federal law, regulation, and state regulation.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-16-.03 RETURN OF PREVIOUSLY DIPSENSED DRUGS OR DEVICES.

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

480-16-.03 Return of Previously Dispensed Drugs or Devices.

- (1) It shall be unlawful, and a violation of these rules, for any licensed pharmacist or pharmacy licensed under O.C.G.A. 26-4 to accept for refund purposes, or otherwise, any unused portion of a drug which has been previously dispensed via a prescription drug order and delivered to the patient or patient's caregiver, except where permitted under state and/or federal law or regulation.
- (a) Such receipt is deemed detrimental to the public health due to the likelihood that such drugs, once out of the control of the pharmacy, could have been tampered with, been adulterated, or become contaminated with communicable diseases and/or contagious diseases under the holder thereof; (b) In addition, such receipt would tend to create a health problem if placed in stock and could be

reused by any licensed pharmacist or pharmacy;

- (e)(2) Nothing in this Rule shall be meant to be in conflict with Board Rule 480-10-. 17, which allow a pharmacy to receive unused, manufacturer's unit-dose packaged drugs from a Medicaid patient residing in a long term care facility.
- (3) Nothing in this Rule shall prohibit an authorized collector from collecting controlled substances for the purposes of destruction as authorized in the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act"), any regulations promulgated thereunder, and Ga. Comp. R. & Regs. c. 480-50.

Authority: O.C.G.A. §§ 26-3-3, 26-4-27, 26-4-28, 26-4-60, 26-4-80, and Pub. L. 111-273.