NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-9-.03 CONDITIONS, 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 480-9-.03 CONDITIONS (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 9:00 AM on January 19, 2022 at South University, 709 Mall Blvd., Rooms 306/308, Savannah, GA 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 12, 2022. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, 6th Floor, Atlanta, Georgia 30303. You may email your comments to elacefield@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 9:05 AM on January 19, 2022 at South University, 709 Mall Blvd., Rooms 306/308, Savannah, GA 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. §§ 16-13-34, 26-4-27, 26-4-28, and 26-4-80.

At its meeting on January 19, 2022, 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.

Also, at its meeting on January 19, 2022, 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 14th day of December, 2021.

Eric R. Lacefield
Executive Director
Georgia Board of Pharmacy

Posted: December 14, 2021

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-9-.03 CONDITIONS

Purpose of Rule: The purpose of this amendment is to make some clean up edits and adjust the allotted supply for dispensing multiple drugs in single dose containers.

Main Feature: The main feature of this amendment is to increase the allotted days supply from 34 days to 96 days.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-9-.03 CONDITIONS

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

480-9-.03 Conditions

The conditions for allowing Multi-drug Single-dosing containers shall be as follows:

(a) The number of drugs placed in one package cannot exceed the capacity of the container in order to prevent damage to the individual dosage forms;

(b) The total quantity of drugs dispensed may not be more than a ~~thirty-four (34)~~ ninety-six (96) day supply;

(c) The labels must be of sufficient size to properly and clearly label each container of a ~~thirty-four (34)~~ ninety-six (96) day~~s~~ or less drug supply with all information required by state and federal law and rules;

(d) The integrity of each individual multi-drug single-dosing container shall be maintained until the last drug dose is administered to or taken by the patient;

(e) Once a multi-drug single-dosing container has been properly labeled and dispensed to a patient, and this same container is returned to the pharmacy, the drugs packaged in such container are considered adulterated and may not be returned to the pharmacy stock. Drugs may be redispensed only under the following conditions:

1. Drugs repackaged for and redispensed only to the same patient to which the drugs were originally dispensed or;
2. Whenever a patient has an allergic reaction to any drug contained in a multi-drug single-dosing container and this drug is discontinued from the patient's treatment, a pharmacy cannot repackage and redispense any drug(s) which were packaged with the discontinued drug in the single-dosing container, because any such drug is then considered to be adulterated as defined under O.C.G.A. 26-3.
3. Unopened unit-dose drugs packaged only by the original drug manufacturer dispensed to and returned only by a Long Term Care facility patient for Medicaid credit;
4. A multi-drug single-dosing container must be tamper evident in such a manner to prevent the container from being either reclosed or designed to show evidence of having been opened;

(f) Whenever a drug(s) in such a container previously dispensed to a patient has/have been discontinued, the remaining container(s) must be returned to the dispensing pharmacy for the removal of the discontinued drug(s) from the container for destruction. Except as provided for in paragraph 480-9-.03(5)(a)1, once the discontinued drug(s) has/have been removed, the pharmacy may repackage the drug(s) to be continued and once again only dispense them to the patient to whom they were originally dispensed. Under no circumstances may any of the re~~n~~maining or discontinued drug(s) be returned to the drug stock of the pharmacy or dispensed to any patient other than the patient to whom the drugs were originally dispensed, as specified in 480-9-.03(5), (6) and (7).

(g) At the time of administration, nothing in this rule is meant to prevent a nurse or a patient specified caregiver from removing a discontinued drug(s) from a container to be wasted as directed by a pharmacist or from retaining up to a 72-hour supply of the continued drug(s) in the original container in order to maintain a patient on his or her continuing drug administration schedule;

(h) Any pharmacist or pharmacy using multi-drug single-dosing container must implement policies and procedures which will exclude any drug(s) which have the following characteristics from being utilized in such packaging:

1. The USP-DI monograph or official labeling requires dispensing in the original container;
2. The drugs are incompatible with packaging components or each other;
3. The drugs require special packaging.

Authority: O.C. G.A. Secs. 26-3-8, 26-3-16, 26-4-27, 26-4-28, 26-4-80, 16-13-34, 16-13-73, 16-13-15.