NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-37-.03 MINIMUM REQUIREMENTS, 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 480-37-.03 MINIMUM REQUIREMENTS (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 August 18, 2021 at The University of Georgia College of Pharmacy, Pharmacy South Building, Room 303, 240 W. Green Street, Athens, GA 30602 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 August 11, 2021. 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 August 18, 2021 at The University of Georgia College of Pharmacy, Pharmacy South Building, Room 303, 240 W. Green Street, Athens, GA 30602. 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. §§ 26-4-5, 26-4-27, and 26-4-28.

At its meeting on April 14, 2021, 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 April 14, 2021, 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 13th day of July, 2021.

Eric R. Lacefield
Executive Director
Georgia Board of Pharmacy

Posted: July 13, 2021

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-37-.03 MINIMUM REQUIREMENTS

Purpose of Rule: The purpose of this amendment is to make some clean up edits and bring the rule in alignment with the law, specifically O.C.G.A. § 26-4-28(a)(12.1).

Main Feature: The main feature of this amendment is to clarify who may stock/restock a RAMS and under what circumstances as provided for by GA law.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-37-.03 MINIMUM REQUIREMENTS

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

480-37-.03 Minimum Requirements

Minimum Requirements. A pharmacy may use a RAMS provided that:

(a) The pharmacy has a policy and procedure manual at the skilled nursing facility or hospice that includes:
   1.) The type or name of each RAMS including a serial number or other identifying nomenclature.
   2.) A method to ensure security of a RAMS to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.
   3.) A process of filling and stocking a RAMS with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.
   4.) Documentation of inventory procedures including removal of any discontinued/out-dated medications.
   5.) Compliance with a Continuous Quality Improvement Program.
   6.) A method to ensure that patient confidentiality is maintained.

(b) No more than a 30-day supply of each individual medication may be stocked in a RAMS at one time.

(c) All drugs in a RAMS must inventoried no less than once every 30 days and documentation must be maintained of the inventories including the removal of any discontinued/out of date medications.

(d) All the registered pharmacists, licensed pharmacy interns or registered pharmacy technicians involved in the process of stocking, entering information into RAMS, or inventorying the RAMS must be identified. No person shall be permitted to perform a function related to the machine that they are not authorized to do in the pharmacy. Specifically, where direct supervision is required in the pharmacy, such supervision must occur in duties related to the RAMS.

(e) Patient confidentiality must be maintained.

(f) The PIC, or a pharmacist designated by the PIC, must be ablet to revoke, add, or change access to RAMS at any time.

(g) Only a Georgia registered nurses or a Georgia licensed practical nurse may be assigned to access to and remove dangerous drugs from a RAMS.

(h) Only a Georgia registered nurse may access and remove ~~a~~ controlled substances from a RAMS.

(i) The system ensures that each prescription is dispensed in compliance with the definition of dispense and the practice of the profession of pharmacy.

(j) The system shall maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, or registered pharmacy technicians involved in the processing of the prescription order.

(k) A RAMS shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(l) The stocking or restocking of a dangerous drug or controlled substances shall ~~only~~ be completed by ~~a Georgia pharmacist or a pharmacy intern/extern under the direct on-site supervision of a Georgia licensed pharmacist.~~:

1) A Georgia licensed pharmacist,
2) A Georgia licensed pharmacy intern/extern under the direct ~~on-site~~ supervision of a Georgia licensed pharmacist, or
3) A Georgia registered pharmacy technician only under the following circumstances:
    a. If the remote automated medication system utilizes radio frequency identification or bar coding in the filling process, the pharmacy shall retain an electronic record of the filling activities of the pharmacy technician; or
    b. If the remote automated medication system does not utilize radio frequency identification or bar coding in the filling process, a pharmacist shall supervise continuously the filling activities of the pharmacy technician through a two-way audiovisual system.

(m) A RAMS must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the proper medication is being dispensed from a RAMS.

(o) All medication shall be packaged and labeled in compliance with Board rules and laws for patient specific labeled medication and/or unit of use medication.

(p) The licensed pharmacist responsible for filling, verifying, or loading the RAMS shall be responsible for their individual action.

(q) A prescription drug dispensed by the RAMS pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

(r) A licensed pharmacist may remove discontinued and/or out-dated medications from the RAMS and return such medications to the licensed pharmacy for proper disposition. A registered or licensed practical nurse may remove discontinued and/or out-dated medications and place them in the designated secured return bin in a RAMS.

Authority: O.C.G.A. Secs. 26-4-5, 26-4-27, 26-4-28, 26-4-80, 26-4-110.