NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,

RULE 480-10-.12 MINIMUM EQUIPMENT FOR PRESCRIPTION DEPARTMENTS, 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 480-10-.12 MINIMUM EQUIPMENT FOR PRESCRIPTION DEPARTMENTS (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 September 16, 2020 via conference call at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street NW, 6th 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 September 9, 2020. 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 9/16/2020 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 6th 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. §§ 26-4-28.

At its meeting on June 18, 2020, 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 June 18, 2020, 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 amendment 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 4th day of August, 2020.

Eric R. Lacefield Executive Director

Georgia Board of Pharmacy

Posted: August 4, 2020

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-10-.12 MINIMUM EQUIPMENT FOR PRESCRIPTION DEPARTMENTS

Purpose of Rule: The purpose of the amendments is to clarify when a Class A balance with weights or Electronic Balance is required.

Main Features: The main feature of the amendments is to require a Class A balance with weights or Electronic Balance only if compounding onsite using components which must be weighted.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-10-.12 MINIMUM EQUIPMENT FOR PRESCRIPTION DEPARTMENTS

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

480-10-.12 Minimum Equipment for Prescription Departments

- (1) No pharmacy licensed in accordance with O.C.G.A. T. 26, Ch. 4, shall engage in the practice of filling, compounding or dispensing prescriptions unless it shall possess the following items:
 - (a) Copies of and/or computer or electronic access to current reference materials appropriate to the individual pharmacy practice. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.
 - (b) The telephone number of a poison control center. This number shall be conspicuously posted within the prescription department.
 - (c) Current copies of and/or computer or electronic access to the following:
 - 1. Georgia Pharmacy Practice Act, O.C.G.A. T. 26, Ch. 4;
 - Georgia Controlled Substances Act & Dangerous Drug Act, O.C.G.A. T. 16, Ch. 13; and
 - 3. Official Rules of the Georgia State Board of Pharmacy.
 - (d) Equipment (appliances):
 - 1. Refrigerator in operating condition with a thermometer; and
 - 2. Sink in working condition with both hot and cold running water.
 - (e) Weighing and labeling:
 - 1. Class A Balance, Class I or II Electronic Balance, or as approved in writing by the Board If compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance;
 - 2. Assortment of weights: metric and apothecary, only if utilizing a Class A Balance;
 - 32. Appropriate prescription labels consistent with the requirements of the Georgia Drug and Cosmetic Act, O.C.G.A. Title 26, Chapter 3; and
 - 4<u>3</u>. Appropriate auxiliary labels that should be used in the pharmacist's professional judgment.
 - (f) Other equipment:
 - 1. Graduates of assorted sizes;
 - 2. Two mortars and pestles of assorted sizes;

- 3. Two spatulas;
- 4. One pill counting tray;
- 5. Ointment slab, tile or ointment paper pad;
- 6. Stirring rods;
- 7. Typewriter, word processor or computer with label-printer; and
- 8. Any other equipment necessary for a specialized practice setting where such a specialized practice takes place.
- (g) Adequate supply of drugs most commonly prescribed (ONLY to be on hand after a permit has been issued by the Board).
- (h) Assorted sizes and types of child-resistant dispensing containers.
- (2) The pharmacist-in-charge of a facility may submit to the Georgia State Board of Pharmacy a typed request for a variance to these provisions relating to minimum equipment requirements. Stated reasons for application for variances must be included in submitted request. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for doing so which relate to the necessary or efficient delivery of health care.
 - (a) Any variance granted by the Board must be in writing, and this variance must be posted in the pharmacy next to the current Board issued permit/renewal certificate.

Authority: O.C.G.A. §§ 16-3-16, 26-3-8, 26-4-27, 26-4-28, 26-4-110, 50-13-9.1.