

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-18-.05 PHYSICAL REQUIREMENTS AND EQUIPMENT, 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 480-18-.05 PHYSICAL REQUIREMENTS AND EQUIPMENT (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 480-18-.05 PHYSICAL REQUIREMENTS AND EQUIPMENT**

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 480-18-.05 PHYSICAL REQUIREMENTS AND EQUIPMENT**

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

480-18-.05 Physical Requirements and Equipment

- (1) Physical Area. An OTP clinic pharmacy shall have within the clinic which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed space, and which meet the other requirements of this section, the Georgia Pharmacy laws, and other applicable state and federal laws and rules. Such space shall be at a minimum 150 square feet. Such space shall include all areas which are assigned and under the direct control of the Director.
- (2) Minimum equipment. No OTP clinic pharmacy licensed in accordance with O.C.G.A. Title 26, Ch. 4 shall engage in the practice of filling, compounding or dispensing prescription drugs for an OTP Clinic unless it shall possess the following items:
 - (a) Copies of and/or electronic access to current reference materials appropriate to the practice of pharmacy related to OTP. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.
 - (b) Authoritative, current antidote information as well as the telephone number of the regional poison control information center shall be posted or readily available in areas both inside and outside of the pharmacy where drugs are stored or patients are being cared for.
 - (c) Current copies or electronic or computer access to the following:
 1. The Georgia Pharmacy Practice Act/Drug and Cosmetic Act, O.C.G.A. §§ 26-4 and 26-3;
 2. The Georgia Controlled Substances Act/Dangerous Drug Act, O.C.G.A. § 16-13;
 3. The official rules of the Georgia State Board of Pharmacy.
 - (d) Equipment:
 1. Sink in working condition with both hot and cold running water;
 2. Two spatulas;
 3. One oral solid counting tray;
 4. Typewriter, word processor or computer with label printer;
 5. A refrigerator in working order with a thermometer.

6. Any other equipment the Board may deem necessary for a specialized practice setting where such a specialized practice takes place.
- (e) Weighing and labeling:
 1. Appropriate prescription labels consistent with the requirements of O.C.G.A. §§ 16-13, 26-3 and 26-4; and
 2. Appropriate auxiliary labels that should be used in the pharmacist's professional judgement.
 3. ~~A class A balance with metric and apothecary weights or an electronic class I or II balance~~ 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.
 - (f) An adequate supply of drugs used in an OTP Clinic setting.
 - (g) Assorted sizes and types of appropriate dispensing containers.
- (3) The Director in an OTP clinic pharmacy may submit to the Board a typed request for a variance to the provisions relating to the minimum equipment requirements.
 - (a) The reason for requesting each variance must be included in the typed request;
 - (b) A variance shall be granted by the Board only when, in the judgement of the Board, there are sound reasons for doing so which relate to the necessary or efficient delivery of health care.
 - (c) Any variance granted by the Board shall be in writing, and the variance must be posted in the pharmacy next to the current Board issued license certificate.

Authority: O.C.G.A. §§ 16-13-34, 26-4-27, 26-4-28, 26-4-110, 26-4-111.