

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-33-.05 PHYSICAL 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 480-33-.05 PHYSICAL 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 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.

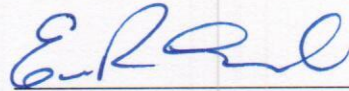
At its meeting on June 18, 2020, the Board voted that the formulation and adoption of these rule amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives 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 480-33-.05 PHYSICAL REQUIREMENTS**

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 weighed.

**DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-33-.05 PHYSICAL REQUIREMENTS**

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

480-33-.05 Physical Requirements

- (1) Area. An outpatient 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 places, and which meet the other requirements of this section and the Georgia Pharmacy Laws. The outpatient clinic pharmacy space requirements shall be a minimum of 150 square feet. Such space shall include all areas which are assigned and under the direct control of the pharmacist-in-charge.
- (2) Minimum Equipment. No outpatient clinic pharmacy licensed in accordance with Title 26, Chapter 4 of the Official Code of Georgia Annotated shall engage in the practice of filing, compounding or dispensing prescription drugs unless it shall possess the following items:
 - (a) Copies of and/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 pharmacy and at other locations within the clinic facility.
 - (c) Current copies of or computer or electronic access to the following:
 1. The Georgia Pharmacy Practice Act, O.C.G.A. Title 26, Chapter 4;
 2. The Georgia Controlled Substances Act/Dangerous Drug Act, O.C.G.A. Title 16, Chapter 13;
 3. Official Rules of the Georgia State Board of Pharmacy.
 - (d) Equipment (appliances):
 1. Refrigerator in operating condition and 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 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;~~

32. Appropriate prescription labels consistent with the requirements of the Georgia Drug and Cosmetic Act, O.C.G.A. Title 26, Chapter 3; and
43. 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 oral solid counting tray;
 5. Ointment slab, tile or ointment paper pad;
 6. Typewriter, word processor or computer with label printer; and
 7. Any other equipment necessary for a specialized practice setting where such a specialized practice takes place.
- (g) Adequate supply of drugs most commonly prescribed.
- (h) Assorted sizes and types of appropriate dispensing containers.
- (3) Variances.
- (a) The pharmacist-in-charge in an outpatient clinic facility may submit to the Georgia State Board of Pharmacy a typed request for a variance to these provisions relating to minimum equipment requirements. The reasons for the request for the variance must be included in the 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 that relate to the necessary or efficient delivery of health care. After consideration by the Board, the requester will be notified of the Board's decision in writing.
- (b) If approved, said letter(s) will serve as the proof of the Board's approval for the variances indicated in the letter, and must be posted next to the facility's inspection report.
- (4) The compounding, admixture, and quality control of large volume parenterals is the responsibility of a pharmacist and shall be prepared under a laminar flow hood within the pharmacy. Other licensed healthcare professionals who are authorized by law to prepare or administer large volume parenterals must have special training to do so. These functions of compounding shall be done primarily by the pharmacy department with exceptions allowed for specialty-care areas, emergency situations, and during unattended hours of the pharmacy department. The pharmacist-in-charge shall be responsible for providing written guidelines and for approving the procedure to assure that all pharmaceutical requirements are met when any part of the above functions (preparing, sterilizing and labeling parenteral medications and solutions) is performed within the clinic by other licensed healthcare professionals who are authorized by law to prepare parenteral medications and solutions.
- (5) Storage. All drugs shall be stored in designated areas within the clinic pharmacy which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage areas shall be locked or otherwise secured when health care professionals are not present.
- (6) Controlled drug storage for Schedule II drugs. An enclosed controlled room or space with limited access capable of showing forced entry is preferable. However, a safe or metal cabinet that can be locked and that is permanently affixed to the structure is acceptable.

- (7) Unattended areas. Whenever any area of a clinic pharmacy is not under the personal and direct supervision of authorized personnel, such areas shall be locked.
- (8) Security. All areas occupied by a clinic pharmacy shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel by force. The director of pharmacy shall designate in writing, the name and specific area, of persons who shall have access to particular areas within the pharmacy. These areas shall meet the security requirements of Federal and State Laws and Regulations. Only those persons so authorized shall be permitted to enter these areas.

Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-37, 26-4-100, 26-4-110, 26-4-111, 50-13-9.1.