

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-13-.05 PHYSICAL REQUIREMENTS. AMENDED, 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 480-13-.05 PHYSICAL REQUIREMENTS. AMENDED (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 April 17, 2019 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th 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 April 10, 2019. 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 FAX: 470-386-6137. You may email your comments to tbattle@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 4/17/2019 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th 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. §§ 26-4-27, 26-4-28, 26-4-80, and 26-4-110.

At its meeting on February 13, 2019, 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.

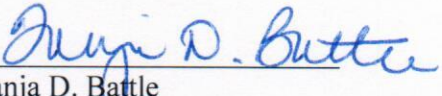
Also, at its meeting on February 13, 2019, the Board voted that it is not legal or feasible to meet the objectives of O.C.G.A. §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A. § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption 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 14 day of March, 2019.


Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: March 14, 2019

**SYNOPSIS OF PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-13-.05 PHYSICAL REQUIREMENTS. AMENDED**

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

Main Features: The main feature of these 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
480-13-.05 PHYSICAL REQUIREMENTS. AMENDED**

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

Rule 480-13-.05. Physical Requirements. Amended

(1) Area. A hospital pharmacy shall have within the hospital 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 hospital pharmacy space requirements should be a minimum of 10 square feet per hospital bed, which includes all areas assigned and under the direct control of the Director of Pharmacy.

(a) The pharmacy of substance abuse treatment or mental health facility shall be exempt from the minimum square footage requirement provided that the pharmacy receives a satisfactory inspection from the Georgia Drugs and Narcotics Agency that shows that the pharmacy space is sufficient to supply the needs of the patients and that all aspect of the management and operations of the pharmacy comply with the law and the rules of the Board to ensure that the health, safety, and welfare of the patients served by the pharmacy are protected. No application for licensure of a pharmacy of a substance abuse treatment or mental health facility seeking an exemption shall be approved without a satisfactory inspection.

(b) "Mental health facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with psychiatric disorders.

(c) "Substance abuse treatment facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with substance use disorders.

(2) Equipment and supplies. Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations. The equipment and physical facilities shall include the following:

(a) Compounding and dispensing area:

1. A refrigerator in operating condition with a thermometer, preferably a biological refrigerator;
2. A sink in operating condition with hot and cold running water;
3. A Class A Balance and an assortment of metric weights if utilizing a Class A Balance or a Class I or II Electronic Balance ~~as approved in writing by the Board,~~ if compounding onsite using components which must be weighed;
4. Graduates of assorted sizes;

5. Mortar and pestle;
 6. Two (2) spatulas and a counting tray;
 7. Typewriter, word processor, or computer with a label printer;
 8. Pill tile; and
 9. Other equipment as deemed necessary by the Director of Pharmacy.
- (b) Parenteral solution additives area as required in 480-13-.06 (2)(a);
1. Laminar flowhood; and
 2. Facility for light-dark field examination.
- (c) Storage and receiving area;
- (d) Manufacturing and packaging area; and
- (e) Office space area.
- (3)
- (a) The pharmacy of a substance abuse treatment or mental health facility shall be exempt from (2)(a)(3.), (2)(b)(1.), and (2)(b)(2.) under the following terms and conditions:
1. The Director of Pharmacy attests that the pharmacy will purchase only commercially prepared medications and intravenous preparations;
 2. The Director of Pharmacy attests that no compounding will occur on-site;
 3. The pharmacy includes the attestations in its application for licensure as a hospital pharmacy; and
 4. The pharmacy receives a satisfactory inspection from the Georgia Drugs and Narcotics Agency that shows that in the absence of the equipment, the pharmacy is sufficient to supply the needs of the patients and that all aspect of the management and operations of the hospital pharmacy comply with the law and rules of the Board to ensure that the health, safety, and welfare of the patients served by the pharmacy are protected.
- (b) No application for licensure of a pharmacy of a substance abuse treatment or mental health facility seeking an exemption shall be approved without a satisfactory inspection.
- (c) "Mental health facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with psychiatric disorders.
- (d) "Substance abuse treatment facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with substance use disorders.
- (4) Each hospital pharmacy shall maintain a reference library which includes, at a minimum, the following:
- (a) Copy of and/or electronic or computer access to the latest edition of the Georgia Pharmacy Practice Act, the Georgia Controlled Substances Act and the Rules and Regulations of the Georgia State Board of Pharmacy;
 - (b) Copies of and/or electronic or computer access to current reference materials appropriate to the practice of the hospital pharmacy;
 - (c) Copy of and/or electronic or computer access to the latest edition of the American Society of Health-system Pharmacists Formulary Service;
 - (d) Compatibility charts;
 - (e) Current drug interaction references;
 - (f) Current antidote information;
 - (g) Copy of and/or electronic access or computer access to the latest edition of text and reference works covering theoretical and practical pharmacy, reference materials on general, organic,

pharmaceutical and biological chemistry, toxicology, pharmacology, sterilization and disinfection.

(5) Storage. All drugs shall be stored in the hospital pharmacy within designated areas which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage cabinets and unit dose carts at the nursing station shall be locked when the station is not in attendance by nursing personnel.

(6) Controlled drug storage for Schedule II drugs. An enclosed controlled room with limited access capable of showing forced entry is preferable. However, a safe or metal cabinet adequately locked that is permanently affixed to the structure is acceptable.

(7) Unattended areas. Whenever any area of a hospital pharmacy is not under the personal and direct supervision of authorized personnel, such areas shall be locked.

(8) Security. All areas occupied by a hospital 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, by name and specific area, those 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.

(9) Variances.

(a) The Director of Pharmacy may submit to the Board a typed request for a variance to the provisions relating to minimum equipment requirements. The reasons for the request for a variance must be included. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for granting the variance which relate to the necessary or efficient delivery of health care. After consideration by the Board, the Director of Pharmacy will be notified of the Board's decision in writing.

(b) If approved, said letter(s) will serve as proof of the Board's approval for each variance(s) indicated in the letter, and shall be posted next to the Georgia Drugs and Narcotics Agency inspection report.

Authority: O.C.G.A. §§26-4-27, 26-4-28, 26-4-80 and 26-4-110.