**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,**
**RULE 480-11-.04 FACILITIES 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 480-11-.04 FACILITIES 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 480-11-.04 FACILITIES 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 480-11-.04 FACILITIES AND EQUIPMENT

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

**480-11-.04 Facilities and Equipment**

(1) Facilities.
- (a) Pharmacies engaging in compounding shall have an adequate area for the orderly compounding of prescriptions, including the placement of equipment and materials. The drug compounding area for sterile preparations shall be separate and distinct from the area used for the compounding of non-sterile drug preparations. The area(s) used for compounding of drugs shall be maintained in a good state of repair.
- (b) Bulk drugs and other chemicals or materials used in the compounding of prescription drug orders must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.
- (c) Adequate lighting and ventilation shall be provided in all drug-compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute to contamination of any compounded drug preparation. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air dryers or single-use towels.
- (d) Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.

(2) Equipment.
- (a) Equipment used in the compounding of drug preparation shall be of appropriate design, appropriate capacity, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug preparations shall be of suitable composition so that surfaces that contact components, in-process materials, or drug preparations shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond that desired.
- (b) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug preparation beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of

sterile drug preparations, cleaning, sterilization, and maintenance procedures as set forth in Board Rules.

(c) Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.

(d) Automatic, mechanical, electronic, or other types of equipment other than commercial scale manufacturing or testing equipment, may be used in the compounding of drug preparations. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

(3) Physical requirements for pharmacies compounding sterile parenteral preparations.

(a) A pharmacy compounding or preparing sterile parenteral preparations shall have a designated area for preparing compounded, sterile parenteral preparations as defined in USP 797. This area shall be physically separate from other areas and should be designed to avoid unnecessary traffic and airflow disturbances. It shall be used only for the preparation of sterile parental preparations.

(b) Equipment and supplies for compounding sterile parenteral preparations. A equipment and supplies:

1. Laminar airflow hood (ISO 5) located within a clean room, or barrier isolator as described in USP 797;
2. Infusion pumps, if appropriate;
3. Sink, in working condition, with hot and cold running water, which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;
4. Facility for light/dark field examination;
5. Appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapy agents;
6. A Class II, vertical flow biological safety cabinet or appropriate barrier isolator, if chemotherapy agents are routinely prepared;
7. Refrigerator/freezer in working condition;
8. ~~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;
9. Disposable needles, syringes and other supplies needed for aseptic admixture;
10. Disinfectant cleaning solutions;
11. Handwashing agent with bactericidal action;
12. Disposable, lint free towels or an automatic hand dryer;
13. Appropriate filters and filtration equipment;
14. Disposable masks and sterile, disposable gloves, gowns, hair and shoe covers and goggles when indicated;
15. An oncology drug spill kit, if chemotherapy agents are routinely prepared.
16. For the purpose of emergency or immediate patient care, compounded sterile preparations are exempted from the requirements as outlined in USP 797.

(4) Minimum equipment for pharmacies compounding non-sterile preparations.

(a) A compounding pharmacy must have all equipment required of a pharmacy in Chapter 480-10 of the Board Rules.

(b) Additionally, a compounding pharmacy must have the appropriate equipment for use in compounding as defined in USP Chapters 795 and 797.

(5) References. In addition to references required of a pharmacy, pharmacies compounding sterile pharmaceuticals shall also have a current edition of or electronic access to an established reference on IV stability and incompatibility, such as, Handbook on Injectable Drugs or King's Guide to Parenteral Admixtures, current Federal requirements for sterile compounding and other reference material including but not limited to:
(a) "USP Pharmacists Pharmacopeia",

(6) Variances.
(a) The pharmacist-in-charge may submit to the Georgia State Board of Pharmacy 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 in the submitted request. A variance shall 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 requestor 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 the variance indicated in the letter, and must be posted next to the inspection report.

Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-86, 26-4-110.