

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-10-.02 PRESCRIPTION DEPARTMENT, REQUIREMENT, SUPERVISION,
HOURS CLOSED., 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-.02 PRESCRIPTION DEPARTMENT, REQUIREMENT, SUPERVISION, HOURS CLOSED. (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 11:30 AM on February 8, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th 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 February 1, 2017. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, Atlanta, Georgia 30303 FAX: 678-717-6694. 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 11:35 AM on 2/8/2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th 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, 26-4-82, 26-4-110, 26-4-110.1.

At its meeting on December 20, 2016, 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.

At its meeting on 12/20/2016, the Board also 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

these amendments 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 January, 2017.


Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: January 4, 2017

**SYNOPSIS OF PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-10-.02 PRESCRIPTION DEPARTMENT, REQUIREMENT, SUPERVISION,
HOURS CLOSED.**

Purpose of Rule: The purpose of this rule is to define direct supervision by a pharmacist over authorized personnel.

Main Features: The main feature of this rule is to distinguish between permissible and impermissible absences by a pharmacist.

**DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-10-.02 PRESCRIPTION DEPARTMENT, REQUIREMENT, SUPERVISION,
HOURS CLOSED.**

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

480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed.

(1) For the purpose of this rule, the following definitions shall apply:

(a) “Direct supervision” shall mean that a pharmacist is physically present, providing care at the address listed on the pharmacy license, and is in the prescription department, consultation room, vaccination room, or areas where over-the-counter drugs, devices, or durable medical equipment are displayed. The supervising pharmacist is professionally responsible and accountable for all activities performed by authorized pharmacy personnel and is available to provide assistance and direction to authorized pharmacy personnel. This shall not require a pharmacist to maintain a direct line of sight to authorized pharmacy personnel. The supervising pharmacist shall provide a final check of prepared products and document final checks before any prescription drug is dispensed.

(b) “Pharmacy care” shall mean those services related to the interpretation, evaluation, or dispensing of prescription drug orders, the participation in drug and device selection, drug administration, and drug regimen reviews, and the provision of patient counseling related thereto.

(c) “Preparation” shall mean the functions of preparing a prescription to be dispensed, including product selection, data entry into a pharmacy dispensing system, and any other functions required to have the prescription ready to be verified, checked, and dispensed by a pharmacist or pharmacy intern working under the direct supervision of a pharmacist

(d) “Pharmacy” shall mean all areas of a facility when the prescription department is not closed or locked separately from the facility or only the area of the prescription department in those facilities where the prescription department is locked and separated.

(e) “Prescription Department” shall mean an area set aside for the preparation and dispensing of prescription drugs. In a facility offering other departments and types of merchandise not requiring a pharmacist to be open for business, this term shall apply only to the area in which prescriptions are prepared and dispensed.

(f) “Vaccination room” is an area adjacent to the pharmacy where vaccinations are administered.

(g) "Consultation room" is an area adjacent to the pharmacy where patient or customer consultations are done, and more in-depth pharmacy care may be provided.

(2) Except for pharmacy benefit manager retail pharmacies, the owner, manager or proprietor of each pharmacy shall designate an area, room or rooms, which shall be known as the "Prescription Department," and which is primarily devoted to activities related to prescriptions, including preparation and dispensing.

~~(2)~~(3) A licensed pharmacist shall be in charge of each pharmacy. His or her name shall be upon the application for the license of the pharmacy; he or she shall be the pharmacist in charge of and have supervision of not more than one pharmacy at one time; and he or she shall be responsible and accountable for the conduction of business related to prescriptions within and access to said retail pharmacy.

(a) This regulation is not intended to prohibit any pharmacist from engaging in the practice of pharmacy at more than one pharmacy, if conducted in compliance with the other provisions of this rule and regulation.

(b) This regulation does not prohibit a pharmacist from being in charge of one separately licensed Home Health Care Pharmacy, as defined by Board Rule 480-21, and/or one Nursing Home Pharmacy, and/or one Long Term Health Care Facility Pharmacy, as both are defined in Board Rule 480-24, in addition to being in charge of a retail pharmacy, licensed under Rule 480-10, as long as each pharmacy is operated under the same ownership and is located under the same roof, provided that there is a physical separation of the two pharmacies and separate inventories are maintained for the two pharmacies.

~~(3)~~(4) Except for pharmacy benefit manager retail pharmacies, a Licensed Pharmacist shall be present and on duty in a licensed retail pharmacy as follows:

(a) Entire business establishments which are licensed under O.C.G.A. § 26-4-110 as a pharmacy shall have a pharmacist on duty at all times the pharmacy is open for business as follows:

1. Such times when the pharmacist is absent from the pharmacy cannot exceed three (3) hours daily, or more than one and one half (1 1/2) hours at any one time. If a pharmacist is absent less than five minutes from the prescription department, this absence is not considered an "absence" within the meaning of this rule and will not require a posted notice, provided that the prescription department's security is not compromised.

2. In the absence of a pharmacist from the pharmacy, the area designated as the prescription department shall be closed and locked in such a manner as to prevent unauthorized entry; and

3. Whenever the pharmacist is absent from the pharmacy, a sign shall be prominently displayed on the entrance to the prescription department announcing "Prescription Department Closed" and such sign shall be clear and legible with letters not less than three (3) inches in size.

4. The pharmacist on duty shall be responsible and accountable for the direct supervision of all personnel working in the pharmacy or prescription department. Pharmacy technicians and pharmacy interns/externs can continue preparation of a prescription when the pharmacist is in the immunization or consultation room or is providing pharmacy care services.

(b) If a pharmacy is located in a general merchandising establishment, or if the owner of a business licensed as a pharmacy so chooses, a portion of the space in the business establishment may be set aside and permanently enclosed or otherwise secured; only the permanently enclosed area shall be subject to provisions of this rule and shall be licensed as a pharmacy;

1. In such cases, the area to be licensed or registered as a pharmacy shall be permanently enclosed with a partition built from the floor to the ceiling or in a manner which meets security guidelines submitted to and approved by the Board and upon inspection by the GDNA;

2. In the absence of a pharmacist from the Prescription Department, consultation room, vaccination room, and area where over-the-counter drugs, devices, and durable medical equipment are displayed, the area designated as the Prescription Department shall be closed and locked in such a manner as to prevent unauthorized entry; and

3. Whenever the pharmacist is absent from the Prescription Department, consultation room, vaccination room, and area where over-the-counter drugs, devices, and durable medical equipment are displayed, a sign shall be prominently displayed on the entrance to the Prescription Department announcing "Prescription Department Closed" and such sign shall be clear and legible with letters not less than three (3) inches in size.

4. If a pharmacist is absent less than five minutes from the prescription department, this absence is not considered an "absence" within the meaning of this rule and will not require a posted notice, provided that the prescription department's security is not compromised.

~~(c) No prescriptions shall be filled, compounded, or dispensed in the absence of a licensed pharmacist, but prescriptions may be dropped off by patients provided there is a "drop box" which can only be accessed by a licensed pharmacist.~~ No prescription shall be dispensed in the absence of a licensed pharmacist. The pharmacist on duty shall be responsible and accountable for the direct supervision of all personnel working in the pharmacy or prescription department. Pharmacy technicians and pharmacy interns/externs can continue preparation of a prescription when the pharmacist is in the immunization or consultation room or is providing pharmacy care services.

Authority: O.C.G.A. §§26-4-27, 26-4-28, 26-4-82, 26-4-110, 26-4-110.1