

**NOTICE OF INTENT TO ADOPT PROPOSED CHAPTER OF THE GEORGIA STATE
BOARD OF PHARMACY RULES
CHAPTER 480-10A CENTRAL FILLING REGULATIONS**

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 a new chapter to the Georgia Board of Pharmacy Rules: Chapter 480-10A CENTRAL FILLING REGULATIONS (hereinafter "proposed chapter").

This notice, together with an exact copy of the proposed chapter and a synopsis of the proposed chapter, 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 proposed chapter, and a synopsis of the proposed chapter 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 9:30 AM on December 12, 2018 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 chapter. 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 December 5, 2018. 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 tbattle@dch.ga.gov.

The proposed rule will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:35 AM on December 12, 2018 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 chapter pursuant to authority contained in O.C.G.A. § 26-4-60.


At its meeting on October 10, 2018, the Board voted that the formulation and adoption of this chapter do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed chapter 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 October 10, 2018, 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 7th day of Nov., 2018.



Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: November 7, 2018

**SYNOPSIS OF PROPOSED CHAPTER OF THE
GEORGIA STATE BOARD OF PHARMACY RULES
CHAPTER 480-10A CENTRAL FILLING REGULATIONS**

Purpose of Chapter: The purpose of this chapter is to establish definitions of and requirements for the process of central filling prescriptions.

Main Features: The main feature of this chapter is to set forth definitions of and requirements for the process of central filling prescriptions.

**PROPOSED CHAPTER OF THE GEORGIA STATE BOARD OF PHARMACY RULES
CHAPTER 480-10A CENTRAL FILLING REGULATIONS**

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

CHAPTER 480-10A: CENTRAL FILLING REGULATIONS

Rule 480-10A-.01 Central Filling of Prescriptions

(1) Definitions

(a) "Board" shall mean the Georgia Board of Pharmacy

(b) "Originating Pharmacy" shall mean the licensed retail pharmacy outsourcing the prescription filling services. This pharmacy shall be considered the dispensing pharmacy.

(c) "Central Fill Pharmacy" shall mean a pharmacy which is permitted by the state in which it is located to prepare prescription orders for dispensing pursuant to a valid prescription transmitted to it by an originating pharmacy and to return the labeled and filled prescriptions to the originating pharmacy for delivery to the ultimate user.

(2) All pharmacies providing central prescription filling services to retail pharmacies in Georgia must be appropriately licensed in Georgia.

(3) A central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of an originating pharmacy only if the originating pharmacy and central fill pharmacy have a contractual relationship for such activities or are under common ownership.

(a) The contract or agreement shall outline the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and states laws and regulations.

(4) Each pharmacy engaging in or utilizing central prescription filling services shall be jointly responsible for properly filling prescriptions.

(5) The originating pharmacy's pharmacist is responsible to perform a drug utilization/regimen review of prescriptions received from a central fill pharmacy prior to delivering prescriptions to the ultimate user as well as patient counseling.

(6) A licensed retail pharmacy that desires to provide and/or use central prescription filling services must maintain policies and procedures, which are readily retrievable for submission to the Board or Georgia Drugs and Narcotics Agency ("GDNA") upon request.

(a) The policies and procedures must include:

1. A clear description of the activities in the prescription filling process to be performed by each pharmacy;

2. An outline of the responsibilities of each pharmacy;

3. An outline of the accountabilities of each pharmacy;

4. A list of the names, addresses, telephone numbers, and all license/registration numbers for the pharmacies participating in the central fill prescription filling;

5. Guidelines for:

(i) Protection of the confidentiality and integrity of patient information;

(ii) Maintenance of appropriate records to identify the names, initials, or identification codes and specific activities of each pharmacist who performed any processing;

(iii) Compliance with all federal and state laws, regulations, and rules;

(iv) Operation of a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolved and identify problems; and

(v) Annual review of the written policies and procedures and documentation of such review.

(7) Central prescription filling of controlled substances requires compliance with all Drug Enforcement Administration ("DEA") regulations permitting a central fill pharmacy to fill prescriptions for controlled substances on behalf of an originating pharmacy as well as state laws, rules and regulations

(a) The pharmacist filling a prescription for a controlled substance listed in Schedule II shall affix to the container a label showing the date of filling, the pharmacy name, address, and telephone number, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, expiration date of the dispensed drug, and the directions for use and cautionary statements, if any, contained in such prescription or required by law.

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the container a label showing the originating pharmacy name, address, telephone number and a unique identifier (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

(c) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile.

1. The originating pharmacy transmitting the prescription information must:

(i) Write the words "CENTRAL FILL" on the face of the original paper prescription and record the name, address, telephone number, Georgia license number, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the originating pharmacy pharmacist transmitting the prescription, and the date of transmittal. For electronic prescriptions, the name, address, telephone number, Georgia license number, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the originating pharmacy pharmacist transmitting the prescription, and the date of transmittal must be added to the electronic prescription record;

(ii) Maintain the original prescription for a period of two years from the date the prescription was filled;

(iii) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the originating pharmacy employee accepting delivery.

2. The central fill pharmacy receiving the transmitted prescription must:

(i) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, telephone

number, Georgia license number, and DEA registration number of the originating pharmacy transmitting the prescription:

(ii) Keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist filling the prescription, and the date of filling of the prescription:

(iii) Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (i.e. private, common or contract carrier).

(d) The pharmacist filling a prescription for a dangerous drug or controlled substance listed in Schedule III, IV, or V shall affix to the container a label showing the pharmacy name, address, and telephone number, the serial number of the prescription, date of initial fill or refill, the name of the patient, the name of the practitioner issuing the prescription, name of supervising physician if applicable, expiration date of dispensed drug, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

(e) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the container a label showing the originating pharmacy name, address, telephone number, Georgia license number, and a unique identifier (i.e. the central fill pharmacy's DEA registration number if the prescription is a controlled substance) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under (d) of this section.

(f) Prescriptions for dangerous drug or controlled substances listed in Schedule III, IV, or V may be transmitted electronically from an origination pharmacy to a central fill pharmacy including via facsimile.

1. The originating pharmacy transmitting the prescription information must:

(i) Write the words "CENTRAL FILL" on the face of the original prescription and record the name, address, telephone number, Georgia license number, and DEA registration number (if the prescription is a controlled substance) of the central fill pharmacy to which the prescription has been transmitted and the name of the originating pharmacy pharmacist transmitting the prescription, and the date of transmittal:

(ii) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining:

(iii) Maintain the original prescription for a period of two years from the date the prescription was last refilled:

(iv) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the originating pharmacy employee accepting delivery.

2. The central fill pharmacy receiving the transmitted prescription must:

(i) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, telephone number, Georgia license number, and DEA registration number (if the prescription is a controlled substance) of the originating pharmacy transmitting the prescription:

(ii) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription:

(iii) Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (i.e. private, common or contract carrier).

(8) The originating and central fill pharmacies must share common electronic files or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the prescription.

(a) Prescriptions filled at a central fill pharmacy must be reported to the PDMP administered by the Georgia Department of Public Health at least every 24 hours pursuant to § 16-13-59 and must include all required information. It is the responsibility of the dispensing (originating) pharmacy to ensure compliance with PDMP reporting.

(9) The originating pharmacy must have a pharmacist, pharmacy intern, pharmacy extern, or pharmacy technician sign for the receipt of prescriptions delivered from the central fill pharmacy. Such receipts must be maintained as a part of the prescription record.

(10) An originating pharmacy using central prescription filling services is responsible for maintaining records of the processing of all prescriptions entered into their information system including prescriptions filled at a central fill pharmacy.

(a) The pharmacist at the originating pharmacy must comply with the minimum required information for the patient record system and all requirements of a prescription drugs order as outlined in the Georgia law and Board rules prior to sending a prescription to the central fill pharmacy.

(b) The information system must have the ability to audit the activities of the individuals at the central fill pharmacy filling the originating pharmacy's prescriptions.

(11) A pharmacy that utilizes central prescription filling services must, prior to outsourcing the prescription, notify patients that prescription filing may be outsourced to another pharmacy.

(a) The patient shall have the choice to not have the prescription outsourced.

Authority: O.C.G.A. Section 26-4-60.