# 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 <a href="https://www.gbp.georgia.gov">www.gbp.georgia.gov</a>.

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, 5<sup>th</sup> 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 April 10, 2019. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, 6<sup>th</sup> Floor, Atlanta, Georgia 30303 FAX: 470-386-6137. 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 9:05 AM on April 17, 2019 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5<sup>th</sup> 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 March 6, 2019, 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 March 6, 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 14th day of March, 2019.

Tanja D. Battle
Executive Director

Georgia Board of Pharmacy

Posted: <u>March</u> 14, 2019

## 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 Definitions

For purposes of these Rules and Regulations, the following definitions apply:

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

(2) "Originating Pharmacy" shall mean the licensed retail pharmacy from which a prescription is physically received and dispensed to the patient or patient's caregiver which is outsourcing prescription filling services. This pharmacy shall be the dispensing pharmacy.

(3) "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.

# Rule 480-10A-.02 Licensing and Contracting

- (1) All pharmacies providing central filling services to retail pharmacies in Georgia must be appropriately licensed in Georgia.
- (2) A central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of an originating pharmacy only if the parties have a contractual relationship permitting such activity or share a common owner.
- (a) The contract or agreement shall outline the services to be provided and the responsibilities and accountabilities of each pharmacy, in relation to such services, in compliance with federal and state laws, rules and regulations.
- (b) 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.
- (3) The originating and central fill pharmacy shall be jointly responsible for all prescriptions filled utilizing central fill services.

Rule 480-10A-.04 Policies and Procedures

(1) 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 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; and
- (iii) Compliance with all federal and state laws, rules, and regulations pertaining to the central filling of prescriptions.

Rule 480-10A-.05 Transmission and Labeling

- (1) The transmission and labeling of controlled substance prescriptions processed utilizing central fill services must comply with all federal and state laws, rules, and regulations.
- (2) The originating pharmacy must comply with the minimum required information for the patient record system and all requirements of a prescription drug order as outlined in the Georgia law and Board rules prior to sending a prescription to the central fill pharmacy.
- (3) All prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile.
- (4) All transmission records must include the following:
- (a) "CENTRAL FILL" written on the face of a prescription if it is a hard copy prescription,
- (b) 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.
- (c) Number of refills already dispensed and number of refills remaining (if applicable),
- (d) The name of the originating pharmacy pharmacist transmitting the prescription, and
- (e) The date of transmittal.
- (5) All receipt of transmission records must include all information included in subsection 4 and 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.
- (6) The label affixed to the container of a dangerous drug or other non-controlled substance filled by a central fill pharmacy must contain the following:
- (a) Date of fill or refill,
- (b) The originating pharmacy name, address, and telephone number,
- (c) The central fill pharmacy's unique identifier,
- (d) The serial number of the prescription,
- (e) The name of the patient,
- (f) The name of the prescribing practitioner,

- (g) Name of supervising physician if applicable,
- (h) Expiration date of the dispensed drug, and
- (i) The directions for use and cautionary statements, if any, contained in such prescription or required by law.

## Rule 480-10A-.06 Information Systems, Record Keeping, and PDMP Compliance

- (1) 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 process and dispense the prescription.
- (2) The originating pharmacy shall be responsible for maintaining compliance with the Prescription Drug Monitoring Program for all qualifying prescriptions pursuant to O.C.G.A. § 16-13-59 including those filled utilizing central fill services.
- (3) The record keeping of prescriptions processed utilizing central fill services must comply with all federal and state laws, rules, and regulations.
- (4) The originating pharmacy must have a pharmacist, pharmacy intern, pharmacy extern, or pharmacy technician sign for the receipt of all prescriptions received from the central fill pharmacy.
- (a) Such receipts must be maintained as a part of the prescription record. Receipts shall include the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the originating pharmacy employee accepting delivery.
- (b) The pharmacist on duty at the originating pharmacy must verify the receipt of all controlled substances.
- (5) The originating pharmacy 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 information system must have the ability to audit the activities of the individuals at the central fill pharmacy filling the originating pharmacy's prescriptions.

# Rule 480-10A-.07 Patient Counseling

- (1) It shall be the responsibility of the pharmacist on duty at the originating pharmacy to perform patient counseling of all prescriptions.
- (2) The central fill pharmacy shall not perform patient counseling on behalf of the originating pharmacy.

## Rule 480-10A-.08 Notification to Patients

- (1) An originating pharmacy that utilizes central 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.
- (b) Notification may be provided through the use of a sign located in the originating pharmacy which is clearly visible to and readable by the public.

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