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 9:00 AM on August 1, 2018 at the Philadelphia College of Osteopathic Medicine, 625 Old Peachtree Road, NW, Suwanee, GA 30024 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 July 23, 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 9:05 AM on August 1, 2018 at the Philadelphia College of Osteopathic Medicine, 625 Old Peachtree Road, NW, Suwanee, GA 30024. 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 May 16, 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 May 16, 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 <u>21</u> day of <u>June</u>, 2018.

Tanja D. Battle
Executive Director

Georgia Board of Pharmacy

Posted: <u>June</u> <u>21</u>, 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) "Dispensing Pharmacy" shall mean the licensed retail pharmacy outsourcing the prescription filling services.
- (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 a licensed retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user.
- (2) All pharmacies providing central prescription filling processing 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 a dispensing pharmacy only if the dispensing pharmacy and central fill pharmacy have a contractual relationship providing for such activities 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 compliance with federal and states laws and regulations.
- (b) Except when there is common ownership, the central fill pharmacy shall only deliver prescriptions to the dispensing pharmacy for delivery to the patient.
- (4) A licensed retail pharmacy that desires to provide and/or use central prescription filling services must submit its policies and procedures to the Georgia Board of Pharmacy for approval.

 (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.
 (5) 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 a dispensing pharmacy.

- (6) The dispensing 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.
- (7) The dispensing pharmacy must designate staff members to be responsible for signing for the receipt of prescriptions delivered from the central fill pharmacy. Such receipts must be maintained as a part of the prescription record.
- (8) A dispensing 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 dispensing 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 pharmacy's prescriptions.
- (9) 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.
- (10) The prescription label of a central fill prescription must show the name and address of both the dispensing pharmacy and the central fill pharmacy, except when there is common ownership.

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