NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,

RULE 480-22-.06 PARTIAL FILLING OF A SCHEDULE II (C-II) CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER, 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 adoption of new Georgia Board of Pharmacy Rules, Rule 480-22-.06 PARTIAL FILLING OF A SCHEDULE II (C-II) CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER (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 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. 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 April 10, 2024 at Department of Community Health, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, Georgia 30334 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 April 5, 2024. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. You may email your comments to james.joiner@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 9:00 AM on April 10, 2024 at Department of Community Health, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, Georgia 30334. 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. §§ 16-13-34, 16-13-39, 16-13-41, 26-4-27, 26-4-80, 26-4-83, & 43-1-25.

At its meeting on February 14, 2024, 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 February 14, 2024, 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 II day of March, 2024.

Eric R. Lacefield Executive Director

Georgia Board of Pharmacy

Posted: March 11, 2024.

SYNOPSIS OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-22-.06 PARTIAL FILLING OF A SCHEDULE II (C-II) CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER

Purpose: To remove barriers to care and to streamline the pharmacy care process

for patients in Georgia. To amend the language of the rule to more closely

track federal regulation.

Main Features: Removal of language which acts to void the remaining portion of a

partially filled C-II prescription when said remaining portion is not filled within 72 hours. Addition of language allowing for partial filling of a C-II

prescription at the request of the patient.

TEXT OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-22-.06 PARTIAL FILLING OF A SCHEDULE II (C-II) CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER

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

Text of the proposed rule is attached hereto.

Rule 480-22-.06. Partial Filling of a Schedule II (C-II) Controlled Substance Prescription Drug Order

- (1) The partial filling of a schedule II (C-II) prescription drug order is permissible, if the pharmacist is unable to supply the full quantity prescribed in a written or emergency oral prescription drug order, and the pharmacist makes a notation of the quantity dispensed on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record.makes a notation on the face of the written prescription drug order of the quantity supplied (dispensed).
 - (a) Except as provided for in paragraph (b), tThe remaining portion of the prescription drug order may be filled within 72 hours of the first partial filling.
 - (b) If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner After this 72-hour period, the remaining quantity shall not be dispensed, thereby causing the remaining quantity to be void. No additional quantity may be dispensed without receipt of a new prescription drug order.
 - (b)(c) No further quantity may be supplied beyond 72 hours without a new prescription drug order.
- (2) Partial filling of a prescription drug order for a schedule II (C-II) controlled substance at the request of the prescribing practitioner or patient:
 - (a) A prescription drug order for a schedule II (C-II) controlled substance may be partially filled if all of the following conditions are satisfied:
 - 1. The prescription drug order is written and filled in accordance with State and Federal law;
 - 2. The partial fill is requested by the patient, by one acting on behalf of the patient (parent or legal guardian of a minor patient, or caregiver of an adult patient named in a medical power of attorney), or by the practitioner who wrote the prescription drug order; and
 - 3. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.
 - (b) Non-emergency Prescription Drug Orders. If all the conditions of paragraph (2)(a) of this section are satisfied, and the prescription drug order is partially filled, remaining portions of a partially filled prescription drug order for a schedule II (C-II) controlled substance, if filled, must be filled not later than 30 days, after the date on which the prescription drug order is written; or within such other time as provided by 21 C.F.R. § 1306.13.
 - (c) Emergency Oral Prescription Drug Orders. If all the conditions of paragraph (2)(a) of this section are satisfied, and the prescription drug order is partially filled, remaining portions of a partially filled emergency oral prescription drug order for a schedule II (C-II) controlled substance, if filled, must be filled not later than 72 hours after the prescription is issued.
- (2)(3) A prescription drug order for a schedule II (C-II) controlled substance written for a patient in a Long Term Care Facility (LTCF), a hospice patient, or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities.

- (a) If there is any question whether a patient may be classified as having a terminal illness (TI), the pharmacist must contact the prescribing practitioner prior to partially filling the prescription drug order. The pharmacist must record on the prescription drug order whether the patient is "terminally ill," a "hospice patient," or a "LTCF patient,"
- (b) A prescription drug order may not be partially filled unless it contains the notation "terminally ill,", "hospice patient," or "LTCF patient," or it shall be deemed an unlawful prescription drug order.
- (c) For each partial filling, the dispensing pharmacist shall record on the back of the prescription drug order (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.
- (d) The total quantity of a schedule II (C-II) controlled substance dispensed in all partial fillings may not exceed the total quantity prescribed. Such C-II prescription drug orders may be partially filled for a period not to exceed 60 days from the dispensing date or sooner if the medication is discontinued.
- (3)(4) Information pertaining to current schedule II (C-II) prescription drug orders for patients in a LTCF, a hospice, or for terminally ill patients may also be maintained in a computerized system if this system has the capability to permit the following:
 - (a) Output (display or printout) of the original prescription drug order serial number, date of dispensing, identification by name of the prescribing practitioner, identification by name of the patient, address of the LTCF, hospice, the hospital, or residence of the patient, identification of the medication dispensed to include, dosage, form, strength, and quantity, listing of the partial fillings that have been dispensed under each prescription drug order, and the information required in this rule.
 - (b) Immediate updating of the prescription drug record each time a partial filling is conducted.
 - (c) Retrieval of partially filled C-II prescription drug order information is the same as required by Rule 480-22-.09 for Schedule III and IV prescription refill information.

Authority: O.C.G.A. §§ 16-13-34, 16-13-39, 16-13-41, 26-4-27, 26-4-80, 26-4-83.