NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-24-.04 DRUG DISTRIBUTION, 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 480-24-.04 DRUG DISTRIBUTION (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 9, 2025 at South University, School of Pharmacy, 709 Mall Blvd., Savannah, GA 31406 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 8, 2025. 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 9, 2025 at South University, School of Pharmacy, 709 Mall Blvd., Savannah, GA 31406. 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, 16-13-35, 16-13-39, 16-13-72, 26-3-16, 26-4-27, 26-4-28, 26-4-80, 26-4-110, and 43-1-25.

At its meeting on December 18, 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 December 18, 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 5th day of March, 2025.

J. Clinton Joiner, II
Executive Director
Georgia State Board of Pharmacy

Posted: March 5, 2025.

SYNOPSIS OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-24-.04 DRUG DISTRIBUTION

Purpose: To provide for the recognition of Chart Orders as lawful prescription drug orders, where such orders contain specified information. To clarify rule language and requirements hereunder.

Main Features: This amendment recognizes Chart Orders as a lawful prescription drug order and specifies the minimum requirements for same. This amendment provides for the delivery of drug orders by electronic chart order. This amendment provides clarification of duties and recordkeeping responsibilities relative to emergency drug kits. This amendment requires Vendor Pharmacies to establish certain policies and procedures relative to drug distribution, use and control.

TEXT OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-24-.04 DRUG DISTRIBUTION

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 480-24-.04. Drug Distribution

(1) ~~Dispensing~~ Dispensing of ~~of all~~ drugs to the facility shall be pursuant to ~~a legal~~ lawful prescription drug orders for ~~an~~ individual patients~~.~~: ~~S~~standing medication orders shall not be allowed. ~~Policies may be established by the vendor pharmacist in conjunction with the appropriate committee of the facility.~~

(a) Chart Orders shall be considered lawful prescription drug orders, provided such Order includes the following:

1. Date of issue;
2. Name of the patient;
3. Address of the patient, or the location of the patient in an institutional facility;
4. Patient's date of birth or medical record number;
5. Name of the ~~prescribing~~ ordering practitioner;
6. Name, strength and dosage form of the drug ordered ~~prescribed~~;
7. Directions for use by the facility; and
8. Any cautionary statements as may be required or necessary.

~~(1)~~(2) All drugs supplied to the facility must be obtained from a pharmacy having a retail pharmacy permit.

~~(2)~~(3) For use inside the facility, all drugs dispensed shall be dispensed in appropriate containers, as defined by the Food and Drug Administration and the Consumer Protection Agency, and adequately labeled with the following information:

(a) Name, address, and telephone number of the pharmacy;
(b) Date of issuance and identifying serial number;
(c) Full name of patient;
(d) Brand and/or generic name of drug, strength, and quantity dispensed;
(e) Directions for use, which may be placed on the container label or on a Medication Administration Record available and consulted at the time of the administration of each dose, provided, however, that both methods may be utilized inside a single facility;
(f) Name of ~~physician prescribing~~ordering practitioner;
(g) Required precautionary information regarding controlled substances;
(h) Such other and further accessory cautionary information as may be required or desirable for proper use and absolute safety to the patient; and
(i) Expiration date.

~~(3) If a unit dose drug distribution system is utilized, the above information shall be readily available on the patient medication profile. A drug distribution system in a long term care facility may be regarded as a unit dose drug distribution system if:~~

~~(a) The pharmacist maintains medication profiles on each patient and refers to these files each time a medication is filled;~~

~~(b) Doses of solid oral medications dispensed are pharmacy-prepared or manufacturer-prepared in individually packaged and sealed doses which are identifiable and properly labeled to include, at a minimum:~~

~~1. Brand and/or generic name of the drug;~~
~~2. Strength;~~
~~3. Lot number; and~~

~~4. Expiration date.~~

~~(c) Doses of medication for individual patients are placed into individual patient containers, bins, compartments, or drawers and whenever possible, are subdivided by dose and administration time and not to exceed a 72-hour supply. Drug distribution systems which exceed a 72-hour supply must follow labeling requirements of 480-24-.04(2).~~

~~(4) Partial filling of Schedule II drugs will be allowed but limited to 60 days only.~~

~~(5) Drugs added to parenteral, enteral, or irrigation solutions. Whenever any drugs are added to such solutions, whether within or outside the direct and personal supervision of a registered pharmacist, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time if applicable, and identity of the person so adding.~~

~~(6)~~(4) Prescription drug orders and Chart Orders.

(a) Drugs may be dispensed or administered only upon orders of an authorized prescriber. For schedule II drugs refer to the Georgia Controlled Substances Act, Code Section 16-13-41, and Chapter 480-22 of the Board rules and regulations. For other drugs orders may be received by the pharmacy by fax or delivery of:

1. A direct copy of a prescription drug order;

~~1.~~2. A direct copy of a chart order;

~~2.~~3. Obtaining a signed prescription drug order from the ~~prescriber~~ ordering practitioner; or

4. A verbal or telephone order from ~~an authorized prescriber~~ the authorized practitioner or duly authorized agent.

~~3.~~5. An electronically prescribed chart order from an institutional patient's chart.

~~(b) The consultant pharmacist will verify orders as required by current state and federal laws, rules and regulations.~~

~~(c)~~(b) For purposes of recordkeeping under this chapter, all original prescriptions, those hard copies written by a practitioner, telephoned to the pharmacist by a practitioner and reduced to writing, or sent via facsimile machine or other electronic means must be retained as a permanent record for two years in the retail pharmacy and must be filed by the usually consecutively serial numbered prescription file or by patient name or by any other means that assures a complete, retrievable and accurate record. Any refill information subsequently authorized by a practitioner must be maintained in the manner required by O.C.G.A. § 26-4-80(3).

~~(7)~~(5) Emergency kits. Emergency kits may be placed in licensed nursing homes by the pharmacy of the consultant or vendor pharmacist provided the following guidelines are met:

(a) A record of the drugs to be kept in an emergency drug kit be kept in the nursing home and the ~~provider~~ Vendor Pharmacy~~pharmacy~~;

(b) Drugs shall not be accessed for use from the emergency drug kit in an emergency situation without a new prescription drug order from a licensed practitioner. A valid, signed prescription drug order or chart order for any such drug must be issued to the vendor pharmacy, supplying the emergency drug kit, within 72 hours of the drug being taken from the kit.

(c) Emergency drug kits shall be stored in limited access areas and sealed to prevent unauthorized access and to insure a proper environment for preservation of the drugs therein. The provider pharmacy shall develop a method to readily determine if an emergency drug kit has been accessed without authorization;

(d) An emergency drug kit must be inventoried at least once a month by a pharmacist from the ~~provider~~ Vendor ~~pharmacy~~Pharmacy ~~and sign a card attached to the kit indicating the date it was inspected~~, and a record of the dates of each such inventory shall be kept with the kit. Nothing herein, shall prohibit the inventory record from being maintained electronically, provided the electronic record is immediately retrievable for inspection by GDNA. The ~~provider pharmacy~~Vendor Pharmacy must maintain an adequate record of such inspections.

(e) Special Agents of the GDNA shall have the authority to check emergency drug kits as well as the records in the provider pharmacy to determine that drugs and records are ~~accurate~~accurate, and the emergency drug kit is being properly used;

(f) The ~~provider pharmacy~~Vendor Pharmacy must apply on an individual basis to the Board, in care of the GDNA Director, for approval to place an emergency drug kit in each individual nursing home and a copy of this approval will be kept on file in both the nursing home and the provider pharmacy. Upon recommendation by the GDNA Director, the Board may revoke the approval for an emergency drug kit in any nursing home where abuse or misuse of drugs from the emergency drug kit is used for any purpose other than emergency purposes;

(g) The Board shall have the authority to approve on an individual basis the drugs and the amounts of each individual drug allowed to be kept in an emergency drug kit. Any change in the drugs and amounts kept in a kit must be submitted in writing to the GDNA Director who shall make recommendations to the Board. After Board approval, a copy of this approval will be maintained in the GDNA provider pharmacy file and by the nursing home. Any emergency drug kit approval becomes null and void once the approved pharmacy ceases to provide that kit.

(h) Each solid oral dosage form placed in an emergency drug kit must be individually labeled with the name and strength of the drug, lot number, expiration date, and other appropriate cautionary information; and

(i) The exterior of an emergency drug kit shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for "EMERGENCY USE ONLY~~", and the label shall be physically signed and dated by the pharmacist who sealed the kit.~~." The name of the pharmacist and the dates of inventory should be readily available on or within the kit. This information may be provided electronically. In addition, a listing of the drugs contained therein, including the name, address, and telephone number(s) of the provider pharmacy shall be attached to both the exterior and the interior of an emergency drug kit.

~~(8)~~(6) Accountability of scheduled drugs and other specified drugs.

(a) Proof of use. Proof of use of Schedule II, III, IV and V controlled substances and such other drugs as may be specified by the appropriate committee of the facility, shall be

~~upon proof of use forms~~provided to the Vendor Pharmacy. Proof of use may be provided by written or electronic means and ~~which~~ shall specify at a minimum:

1. Name and strength of the drug;
2. Dose and route of administration for the drug;
3. Name of ordering prescriber;
4. Name of patient;
5. Date and time of administration to patient;
6. Signature and title of individual administering, the medication; and
~~6.~~7.7. Documentation of destruction of all unused portions of single doses shall include signature verifications of two licensed authorized personnel.

(b) Container requirement. Any medication that has to be counted and accounted for ~~with~~ by proof of use ~~forms~~ must be dispensed in a container that allows verification of individual doses. Containers for solid oral doses must allow identification of individual doses and individual accountability.

(7) Medications brought by patients. When patients bring drugs into the facility, such drugs shall be sent to the vendor pharmacist who shall handle these drugs in accordance with guidelines established by the appropriate committee within the facility.

(8) The vendor pharmacy shall establish policies and procedures for safe and effective drug therapy, distribution, use, and control. At a minimum, the pharmacist shall:

(a) Make periodic inspections, which shall occur at least every 30 days of drugs and medication records kept within the facility. A written report of inspection shall be maintained at the facility; and,

~~(c)~~(b) Remove for proper disposal any drugs or narcotics which are in a deteriorated condition, expired, discontinued for use, or the patient for whom they are ordered is no longer a patient These drugs shall be the responsibility of the vendor pharmacy.

Authority: O.C.G.A. §§ 16-13-21(23), 16-13-34, 16-13-35, 16-13-39, 16-13-41, 16-13-45, 16-13-72, 16-13-77, 26-3-8, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-80, and 26-4-110.