NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES
CHAPTER 480-11, RULE 480-11-.02 COMPOUNDED DRUG PREPARATIONS 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 amendments to the Georgia Board of Pharmacy Rules, Rule 480-11-.02 COMPOUNDED DRUG PREPARATIONS. (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 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 December 11, 2013 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, GA 30303 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 may be received prior to December 4, 2013. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, Atlanta, Georgia 30303 FAX: 678-717-6694. You may email your comments to tbattle@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 9:05 AM on December 11, 2013 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, GA 30303. 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. §§ 26-4-4, 26-4-5, 26-4-27, 26-4-28, 26-4-80, and 26-4-86.

At its meeting on October 16, 2013, 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 October 16, 2013, 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

these amendments 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 30th day of October, 2013

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: October 30, 2013

SYNOPSIS OF PROPOSED AMENDMENTS OF THE GEORGIA STATE BOARD OF PHARMACY RULES CHAPTER 480-11, RULE 480-11-.02 COMPOUNDED DRUG PREPARATIONS

Purpose of Rule: The purpose of this rule is to provide legal limitations on production and distribution of compounded drugs.

Main Features: The main feature of this rule is to permit production and distribution of compounded drugs, subject to clear restrictions.

DIFFERENCES OF THE PROPOSED AMENDMENTS FOR THE GEORGIA STATE BOARD OF PHARMACY RULES CHAPTER 480-11, RULE 480-11-.02 COMPOUNDED DRUG PREPARATIONS

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

RULE 480-11-.02 COMPOUNDED DRUG PREPARATIONS

(1) Compounded drug preparations –Pharmacist/Patient/Prescriber Relationship.
(a) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order or in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug preparations that are ~~commercially or~~ not commercially available in the marketplace. Dispensing of pharmaceutical products shall be consistent with the provisions of O.C.G.A. T. 16, Ch. 13 and T. 26, Ch. 4 relating to the issuance of prescriptions and the dispensing of drugs.
(b) Pharmacists shall receive, store, or use ~~drugs~~ pharmaceuticals that have been made in a FDA-approved facility. Pharmacists shall also receive, store, or use ~~drugs~~ pharmaceuticals in compounding prescriptions that meet official compendia requirements. If neither of these requirements can be met, pharmacists shall use their professional judgment to procure alternatives.
(c) Pharmacists may compound ~~drugs~~ pharmaceuticals prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such preparations compounded at the pharmacy. Pharmaceuticals compounded in anticipation of a valid prescription drug order shall be properly labeled to include the name of the compounded pharmaceutical, date of compounding, and beyond-use date. The distribution of compounded products, for office use by a practitioner, shall not exceed 5% of production of compounded product in a calendar year by that pharmacy. Amounts produced greater than 5% shall be considered manufacturing and will require separate licensure as a manufacturer. Pharmacists must maintain a separate compounding log for each product that includes the quantity and amount of each product that is compounded. ~~The compounding of inordinate amounts of drugs, relative to the practice site, in anticipation of receiving prescriptions without any historical basis is considered manufacturing which requires a manufacturer's license.~~
(d) ~~The distribution of compounded preparations without a prescriber/patient/pharmacist relationship is considered manufacturing.~~ Pharmacists shall label all compounded pharmaceutical products that are dispensed pursuant to a prescription in accordance with the provisions of O.C.G.A. T. 16, Ch. 13 and O.C.G.A. T. 26, Chs. 3 and 4, and Board rules and regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

(e) ~~Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order, pharmacists may compound, in reasonable quantities, drug products that are commercially or not commercially available in the marketplace.~~ All pharmaceutical products compounded and labeled in accordance with Board rules and regulations regarding pharmaceutical compounding shall be deemed to meet the labeling requirements of O.C.G.A. T. 16, Ch. 13, and T. 26, Chs. 3 and 4.

~~(f) Pharmacists shall not offer compounded drugs to other state-licensed persons or commercial entities for subsequent resale.~~

~~(g) Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable state laws and rules regulating the practice of pharmacy.~~

(2) Compounded drug preparations –Pharmacist for Distribution to Practitioner

(a) Only a pharmacy licensed or registered by the Board may distribute compounded products to practitioners licensed in this state for administration to their patients in the course of their professional practice, either personally or by an authorized person under their direct and immediate supervision.

(b) A practitioner shall make a request to the pharmacy for a compounded pharmaceutical in the same manner as ordering pharmaceuticals from a wholesale pharmaceutical distributor or manufacturer and not by using a prescription drug order.

(c) A pharmacy receiving an order from a practitioner for a compounded pharmaceutical shall maintain such order with its compounding rules as required in Rule 480-11-.08 and other rules and regulations of the Board.

(d) Pharmacists shall label all compounded pharmaceutical products distributed to practitioners for administration to their patients with the following:

1. "By purchase order, Not by prescription",
2. "For Office Use Administration Only – Not for resale",
3. The name of the active ingredients and strengths contained in the compounded pharmaceutical,
4. The lot number or identification of the compounded pharmaceutical,
5. The pharmacy's name, address and telephone number,
6. The initials of the pharmacist verifying the finished product and the date verified,
7. The quantity, amount, size, or weight of the compounded pharmaceutical in the container,
8. An appropriate beyond-use (expiration) date of the compounded pharmaceutical as determined by the pharmacist in compliance with Board rule and USP-NF standards for pharmacy compounding, and
9. Appropriate ancillary instructions such as storage instructions or cautionary statements, and where appropriate, hazardous drug warning labels.

(e) Pharmacists shall enter into a written agreement with a practitioner for the practitioner's use of the compounded pharmaceutical before providing any compounded pharmaceutical to the practitioner. The written agreement shall provide the following information:

1. The name and address of the practitioner, license number and contact information.
2. An agreement by the practitioner that the compounded pharmaceutical may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity.
3. An agreement by the practitioner to include on the patient's chart, or medication administration record the lot number and beyond-use date of the compounded pharmaceutical administered to the patient.
4. The procedures for a patient to report an adverse reaction or to submit a complaint about a compounded pharmaceutical.
5. The procedure to be used when the pharmacy has to recall a batch of compounded pharmaceuticals.

(f) When pharmacists are compounding sterile pharmaceuticals to be provided to practitioners for use in patient care or when pharmacists are altering or repackaging such pharmaceuticals for practitioners to use in patient care in the practitioner's office, the sterile compounding shall be conducted as allowed by applicable federal law and Board rules and shall be in compliance with USP-NF standards for sterile compounding.
(g) Sterile compounded pharmaceuticals may be dispensed to practitioners in quantities no more than 100 individual dosage containers and must have a beyond-use date no less than one week.
(h) Pharmacist may not compound Schedule II, III, IV or V controlled substances, as defined in Article 2 of Chapter 13 of Title 16 without a patient specific prescription drug order.
(i) Prior to any pharmacy engaging in the practice of compounding pharmaceuticals for use in the practitioner's office, the pharmacy must notify the Georgia Drugs and Narcotic Agency ("GDNA") of its practice, and must maintain on file the written acknowledgement of receipt of the notice from GDNA.
(j) Nothing in this paragraph shall be construed to apply to pharmacies owned or operated by institutions or to pharmacists or practitioners employed by an institution or its affiliated entities; provided, however, pharmacies owned or operated by institutions and pharmacists and practitioners within or employed by institutions or affiliated entities shall remain subject to the other rules and regulations of the Board governing the compounding of pharmaceuticals.
(3) Pharmacists must maintain documentation of proof that the beyond-use date on compounded pharmaceuticals is valid.
(4) Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final verification check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.
(5) Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.
(6) Pharmacists may use prescription bulk substances in compounding when such bulk substances:
(a) Comply with the standards of an applicable USP-NF monograph, if such monograph exists, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-91) and the Board rules on pharmaceutical compounding; or are substances that are components of pharmaceuticals approved by the FDA for use in the United States; or otherwise approved by the FDA;
(b) Are manufactured by an establishment that is registered by the FDA; and
(c) Are distributed by a wholesale distributor licensed by the Board and are distributed by a supplier approved by the FDA to distribute bulk substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.
(7) Pharmacists shall maintain records of all compounded pharmaceutical products. Pharmacist shall maintain a complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail when such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.
(8) Pharmacists engaged in the compounding of pharmaceuticals shall operate in conformance with USP 795 and applicable state laws regarding the practice of pharmacy. ~~(2)~~ If low or ~~,~~ medium risk preparations are being compounded, they must be compounded in accordance with USP 795 and applicable laws and rules. If ~~, and/or~~ high risk sterile preparations are being compounded, they must be in accordance with USP 797 and~~/or~~ Georgia laws and regulations.
~~(3)~~(9) Radiopharmaceuticals. If radiopharmaceuticals are being compounded, conditions set forth in the Board's rules for nuclear pharmacists and pharmacies must be followed.

~~(4)~~(10) Special precaution preparations. If drug preparations with special precautions for contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.
~~(5)~~(11) Cytotoxic drugs. In addition to the minimum requirements for a pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved.
(a) All cytotoxic drugs should be compounded in a vertical flow, Class II, biological safety cabinet or an appropriate barrier isolator. Other preparations should not be compounded in this cabinet.
(b) Personnel compounding cytotoxic drugs shall wear protective apparel as outlined in the National Institute of Occupation Hazards (NIOSH.) in addition to appropriate compounding attire as described in USP 797.
(c) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations.
(d) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.
(e) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual.
(f) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and delivered in a manner to minimize the risk of accidental rupture of the primary container.
(g) Disposal of cytotoxic and/or hazardous wastes. The pharmacist-in-charge is responsible for assuring that there is a system for the disposal of cytotoxic and/or infectious waste in a manner so as not to endanger the public health.
(12) Pharmacists shall not engage in the following:
(a) The compounding for human use of a pharmaceutical product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe.
(b) The compounding of any pharmaceutical products that are essentially copies of commercially available pharmaceutical products. However, this prohibition shall not include:
1. The compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient,
2. The compounding of a commercially available manufactured pharmaceutical during times when the product is not available from the manufacturer or wholesale distributor,
3. The compounding of a commercially manufactured pharmaceutical whose manufacturer has notified the FDA that the pharmaceutical is unavailable due to a current drug shortage,
4. The compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or
5. The mixing of two or more commercially available products of which the end product is a commercially available product.
(13) Practitioners who may lawfully compound pharmaceuticals for administering or dispensing to their own patients pursuant to O.C.G.A. Section 26-4-130 shall comply with all the provisions of this rule and other applicable Board laws, rules and regulations.

Authority: O.C.G.A. §§ 26-4-4, 26-4-5, 26-4-27, 26-4-28, 26-4-80, and 26-4-86.