GEORGIA BOARD OF PHARMACY
Conference Call
August 30, 2013
2 Peachtree St., N.W., 36th Floor
Atlanta, GA 30303
9:00 a.m.

The following Board members were present:
Al McConnell, Chairperson
Tony Moye, Vice-Chairperson
Mike Faulk
Chris Jones
Bill Prather
Ronnie Wallace

Staff present:
Tanja Battle, Executive Director
Janet Wray, Senior Assistant Attorney General
Brandi Howell, Business Operations Specialist

Open Session

Chairperson McConnell established that a quorum was present and called the meeting to order at 9:00 a.m.

Bill Prather made a motion to post Rule 480-11-.02 Compounded Drug Preparations. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

480-11-.02 Compounded Drug Preparations

(1) Compounded pharmaceutical preparations-Pharmacist.
(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~~ pharmaceutical order based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, ~~drug~~ pharmaceutical 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. 16-13 and O.C.G.A. 26-3 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 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. 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.~~
(c) Pharmacists shall label all compounded pharmaceutical products that are dispensed pursuant to a prescription in accordance with the provisions of O.C.G.A. 16-13 and O.C.G.A. 26-3 and Board 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.
~~(d) The distribution of compounded prescriptions without a prescriber/patient/pharmacist relationship is considered manufacturing.~~
(d) Pharmacists may compound pharmaceuticals prior to receiving a valid prescription

pharmaceutical order based on a history of receiving valid prescription pharmaceutical 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 pharmaceutical order shall be properly labeled to include the name of compounded pharmaceutical, date of compounding, and beyond-use date. The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.

~~(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.~~

(e) All pharmaceutical products compounded and labeled in accordance with board rules regarding pharmaceutical compounding shall be deemed to meet the labeling requirements of Chapter 13 of Title 16 and Chapters 3 and 4 of this title.

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

(f) The distribution of compounded preparations without a prescriber/patient/pharmacist relationship is considered manufacturing, except as otherwise allowed by the board rule for pharmaceutical compounding.

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

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

(b) A pharmacy receiving an order from a practitioner for a compounded product shall maintain records as provided for in the board rule for Pharmaceutical Compounding.

(c) Pharmacists shall enter into a written agreement with a practitioner for the practitioner's use of a compounded preparation before providing any compounded product to the practitioner. The written agreement shall:

(i) address acceptable standards of practice for a compounding pharmacy and a practitioner that enter into the agreement including a statement that the compounded pharmaceuticals may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity;

(ii) require the practitioner to include on the patient's chart, medication order or medication administration record the lot number and beyond-use date of a compounded medication administered to a patient;

(iii) describe the scope of services to be performed by the pharmacy and practitioner, including a statement for the process for:

(A) a patient to report an adverse reaction or submit a complaint; and

(B) the pharmacy to recall batches of compounded preparations.

(C) Pharmacists shall label all compounded pharmaceutical products distributed to practitioners for administration to their patients with a minimum of: *by purchase order not by Rx

(i) the statement "For Office Use Administration Only - Not for Resale";

(ii) the name of the active ingredients and strengths contained in the compounded medication and the lot or identification number of the compounded medication;

(iii) the pharmacy's name, address, and telephone number

(iv) the initials of the pharmacist verifying the finished product and date verified;

(v) an appropriate beyond-use date, or expiration date, of the compounded product as determined by the pharmacist in compliance with board rules and USP-NF standards for pharmacy compounding;

(vi) quantity, amount, size or weight of the compounded medication in the container; and

(vii) appropriate ancillary instructions, such as storage instructions or cautionary statements,

including hazardous drug warning labels where appropriate.
(d) In regards to pharmacists compounding sterile pharmaceuticals to be provided to practitioners to use in patient care or altering or repackaging such pharmaceuticals for practitioners to use in patient care in the practitioner's office, such as sterile compounding shall be conducted as allowed by applicable federal law and board rule for pharmaceutical compounding using USP-NF standards for sterile compounding.
(i) Such sterile pharmaceuticals may be compounded only in quantities determined by board rule or policy following consultation with the Georgia Composite Medical Board.
(ii) In order for the two boards to consider allowing any quantity of a sterile pharmaceutical to be compounded for distribution to a practitioner to use in the patient care in the practitioner's office, a pharmacy must first file a petition with the board of pharmacy to consider along with the medical board to set a quantity for each sterile drug to be compounded; with each petition to include the pharmaceutical and quantity requested, accompanied by a copy of the procedures demonstrating how the pharmacy's final sterile compounded drug product will meet USP-NF standards and be properly labeled as required by the board rule for pharmaceutical compounding.
(iii) No Schedule II, III, IV, or V controlled substance, as defined in Article 2 of Chapter 13 of Title 16, shall be eligible for such designation.
(e) Prior to any pharmacy engaging in this manner of compounding for use in a practitioner's office, it must first notify the Georgia Drugs and Narcotics Agency in writing and maintain a copy of a GDNA acknowledging receipt of the notification.
(f) Nothing in this subsection shall be construed to apply to pharmacies owned or operated by institutions or to pharmacists or practitioners employed by an institution or affiliated entity; provided, however, that pharmacies owned or operated by institutions and pharmacists and practitioners within or employed by institutions or affiliated entities shall remain subject to other rules and regulations established by the board governing the compounding of pharmaceuticals.
(3) 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.
(4) Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.
(5) Pharmacists may use 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. 104-191) and the board rule on Pharmaceutical Compounding; or are substances that are components of pharmaceuticals approved by the FDA for use in the United States; or are otherwise approved by the FDA;
(b) Are manufactured by an establishment that is registered by the FDA; or
(c) Are distributed by a wholesale distributor or nonresident wholesale distributor licensed with the board, or are distributed by a supplier otherwise 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.
(6) 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:
(i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient,
(ii) the compounding of a commercially manufactured pharmaceutical during times when the product is not available from the manufacturer or supplier,

(iii) the compounding of a commercially manufactured pharmaceutical whose manufacturer has notified the FDA that the pharmaceutical is unavailable due to a current drug shortage,
(iv) 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
(v) the mixing of two or more commercially available products of which the end product is a commercially available product.
(c) The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such case shall constitute manufacturing of pharmaceuticals.
(7) Pharmacists shall maintain records of all compounded pharmaceutical products according to the board rule for Pharmaceutical Compounding.
(a) A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where 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) Practitioners who may lawfully compound pharmaceuticals for administering or dispensing to their own patients pursuant to O.C.G.A. 24-6-130 shall comply with all provisions of this section and the relevant Board rules and regulations.
(9) Pharmacists engaged in the compounding of pharmaceuticals shall operate in conformance with USP 795 and applicable state laws regulating the practice of pharmacy.
(10) If low or medium risk preparations are being compounded, they must be in accordance with USP 795 and Georgia regulations. Compounded high risk preparations must be done in accordance with USP 797 and Georgia regulations.
(11) Radiopharmaceuticals. If radiopharmaceuticals are being compounded, conditions set forth in the Board's rules for nuclear pharmacists and pharmacies must be followed.
(12) 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.
(13) 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 Occupational Hazards (NIOSH) in addition to appropriate compounding attire as described in USP 797. Such protective apparel must include but is not limited to gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and appropriate gloving.
(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.
~~(g) Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable state laws and rules regulating the practice of pharmacy.~~
~~(2) If low, medium, and/or high risk sterile preparations are being compounded, they must be in accordance with USP 797 and/or Georgia regulations.~~
~~(3) Radiopharmaceuticals. If radiopharmaceuticals are being compounded, conditions set forth in the Board's rules for nuclear pharmacists and pharmacies must be followed.~~
~~(4) 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 crosscontamination.~~
~~(5) 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.~~
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A motion was made by Mike Faulk, seconded by Chris Jones, and the Board voted that the formulation and adoption of this amendment does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

In the same motion, the Board voted that it is not legal or feasible to meet the objectives of the relevant code sections 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 rule will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Ms. Wray discussed the rule talking about inordinate amounts. She stated that this is too vague and the Board should really consider giving a percentage instead of using the term "inordinate amounts".

Ms. Wray stated that the Board may want to authorize Ms. Battle to set up a meeting with a committee of the Pharmacy Board and a committee of the Medical Board to discuss what quantities should be considered. Chairperson McConnell appointed Mike Faulk, Laird Miller and Rick Allen to the committee.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, September 18, 2013, at 9:30 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

The Board meeting adjourned at 9:14 a.m..

Minutes recorded by Brandi P. Howell, Business Operations Specialist
Minutes edited by Tanja D. Battle, Executive Director