NOTICE OF INTENT TO AMEND RULE OF THE GEORGIA STATE BOARD OF PHARMACY RULES
CHAPTER 480-11, RULE 480-11-.01 DEFINITIONS. 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-.01 DEFINITIONS (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 proposed amendments, and a synopsis of 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 January 22, 2014 at the Mercer University of College of Pharmacy, 3001 Mercer University Drive, Atlanta, Georgia 30341 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 January 15, 2014. 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 rule will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:05 AM on January 22, 2014 at the Mercer University of College of Pharmacy, 3001 Mercer University Drive, Atlanta, Georgia 30341. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed rule pursuant to authority contained in O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-37, 26-4-80, 26-4-86.

At its meeting on November 13, 2013, the Board voted that the formulation and adoption of this rule do 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 O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22.

Also, at its meeting on November 13, 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 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.

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 25th day of November 2013

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: November 25, 2013

SYNOPSIS OF PROPOSED RULE OF THE
GEORGIA STATE BOARD OF PHARMACY RULES
RULE 480-11-.01 DEFINITIONS

Purpose of Rule: The purpose of this rule is to define the terms used in Chapter 480-11 of the Georgia Board of Pharmacy Rules.

Main Features: The main feature of this rule is to provide clear definitions of terms used in the following Rules.

PROPOSED RULE FOR THE GEORGIA STATE BOARD OF PHARMACY RULES
RULE 480-11-.01 DEFINITIONS

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

480-11-.01 Definitions.
(1) "Administer" or "administration" means the provision of a unit dose and/or doses of medication to an individual patient as a result of the order of an authorized practitioner of the healing arts.
(2) "Barrier Isolator" means an isolator specifically designed for compounding pharmaceutical ingredients or preparations in an aseptic environment.
(3) "Biological safety cabinet" means a ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.
(4) "Board of Pharmacy" or "Board" means the Georgia State Board of Pharmacy.
(5) "Class 100 Environment" or "ISO Class 5" means an atmospheric environment which contains fewer than 100 particles 0.5 microns or larger in diameter per cubic meter of air.
(6) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or de vice as the result of a practitioner's prescription drug order or initiative based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine and regularly observed prescribing patterns. Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.
(7) "Component" means any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.
(8) "Cytotoxic" means a pharmaceutical that has the capability of killing living cells.
(9) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.
(10) "Device" means an instrument, apparatus, contrivance, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: federal or state law requires dispensing by or on the order of a physician" or "Rx Only."

(11) "Dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient, patient's caregiver, or patient's agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by a patient.
(12) "Distribute" means the delivery of a drug or device other than by administering or dispensing.
(13) "Drug" means:
(a) Articles recognized as drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
(c) Articles, other than food, intended to affect the structure or any function of the body of humans or animals; and
(d) Articles intended for use as a component of any articles specified in subparagraph (a), (b), or (c) of this paragraph but does not include devices.
(14) Drug regimen review includes but is not limited to the following activities:
(a) Evaluation of any prescription drug order and patient record for:
1. Known allergies;
2. Rational therapy-contraindications;
3. Reasonable dose and route of administration; and
4. Reasonable directions for use.
(b) Evaluation of any prescription drug order and patient record for duplication of therapy;
(c) Evaluation of any prescription drug order and patient record for the following interactions:
1. Drug-drug;
2. Drug-food;
3. Drug-disease; and
4. Adverse drug reactions.
(d) Evaluation of any prescription drug order and patient record for proper utilization, including over utilization or under utilization, and optimum therapeutic outcomes.
(15) "Enteral" means within or by way of the intestine.
(16) "FDA" means the United States Food and Drug Administration.
~~(16)~~(17) "GDNA" means the Georgia Drugs and Narcotics Agency.
~~(17)~~(18) "Labeling" means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or rule.
~~(18)~~(19) "Nonprescription drug" means a drug which may be sold without a prescription drug order and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and/or the federal government.
~~(19)~~(20) "Parenteral" means an injectable sterile preparation of drugs for administration by any other means than through the gastrointestinal tract.
~~(20)~~(21) "Patient counseling" means the oral communication by the pharmacist of information, as defined in the law and the rules of the Board, to the patient, patient's caregiver, or patient's agent, in order to improve therapy by ensuring proper use of drugs and devices.
(22) "Pharmaceutical" means a compound to be used as a medicinal drug.

~~(21)~~(23) "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy. This recognizes a pharmacist as a learned professional who is authorized to provide patient services and pharmacy care.
~~(22)~~(24) "Pharmacist in charge" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of such pharmacy and personnel.
~~(23)~~(25) "Pharmacy" means any place licensed in accordance with the laws and rules of this state wherein the possessing, displaying, compounding, dispensing, or selling of drugs may be conducted, including any and all portions of the building or structure leased, used, or controlled by the licensee in the conduct of the business or profession licensed by the Board at the address for which the license was issued.
(26) "Practitioner" or "practitioner of the healing arts" means a physician, dentist, podiatrist, or veterinarian and shall include any other person licensed under the laws of this state to use, mix, prepare, dispense, prescribe, and administer drugs in connection with medical treatment to the extent provided by the laws of this state.
~~(24)~~(27) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient.
~~(25)~~(28) "Prospective drug use review" means a review of the patient's drug therapy and prescription drug order, as defined in the law and the rules of the Board, prior to dispensing the drug as part of a drug regimen review.
~~(26)~~(29) "Sterile pharmaceutical" means any dosage form devoid of viable microorganisms, or any other contaminant including, but not limited to, parenterals, injectables, and ophthalmics.
~~(27)~~(30) "Sterile Preparations" are those as defined by USP 797.
(31) "USP-NF" means the United States Pharmacopeia and National Formulary.

Authority: O.C.G.A. Secs. 26-4-5, 26-4-27, 26-4-28, 26-4-37, 26-4-80, 26-4-86.