NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-25-.01 DEFINITIONS. AMENDED., 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 480-25-.01 DEFINITIONS. AMENDED. (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 11:00 AM on March 18, 2015 at the Mercer University College of Pharmacy, 3001 Mercer University Drive, Atlanta, GA 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 must be received prior to March 11, 2015. 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 11:05 AM on 3/18/2015 at the Mercer University College of Pharmacy, 3001 Mercer University Drive, Atlanta, GA 30341. 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. §§ 26-4-27, 26-4-28, 26-4-110, 26-4-130, 26-4-171, and 26-5-178.

At its meeting on January 21, 2015, 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.

At its meeting on 1/21/2015, the Board also 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 13th day of February, 2015.

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: February 13, 2015

SYNOPSIS OF GEORGIA STATE BOARD OF PHARMACY RULE
480-25-.01 DEFINITIONS. AMENDED.

Purpose of Rule: The purpose of this rule is to define significant terms used in Chapter 480-25 of the Georgia Board of Pharmacy Rules.

Main Features: The main feature of this rule is the clarification of language used in the rules that follow.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-25-.01 DEFINITIONS. AMENDED.

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

480-25-.01 Definitions. Amended.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:
(a) "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.
(b) "Board" means the State Board of Pharmacy.
(c) "Compounding of radiopharmaceuticals" means the addition of a radioactive substance to nonradioactive substances or the use of a radioactive substance in preparation for single or multidose dispensation upon the prescription order of a physician who is licensed to use radioactive materials. Compounding of radiopharmaceuticals may include: loading and eluting of radionuclide generators; using manufactured reagents; preparing reagent kits; aliquoting reagents; formulation and quality assurance testing of radiochemicals for use as radiopharmaceuticals, and radiolabeling of compounds or products, including biological products, for use as radiopharmaceuticals.
(d) "Department" means the Department of ~~Human~~Natural Resources.
(e) "Governing Body" or "Management" means the board of directors, trustees, partnership, corporation, association, person or group of persons who maintain and control the operation of the nuclear pharmacy, and who are legally responsible for its operation.
(f) "Internal Test Assessment" means, but is not limited to conducting those tests of a quality assurance necessary to ensure the integrity of the test.
(g) "Licensed Nuclear Pharmacist" means an authorization granted by the Board to a pharmacist to practice as a nuclear pharmacist.
(h) "Manufacturing of radiopharmaceuticals" means the preparation, derivation, or production of a product to which a radioactive substance is or will be added to provide a radiopharmaceutical for sale, resale, redistribution, or reconstitution.
(i) "Nuclear pharmacist" means a pharmacist who compounds and dispenses radiopharmaceuticals in the course of his/her pharmacy practice.
(j) "Nuclear Pharmacy" means a pharmacy providing radiopharmaceutical services.
(k) "Nuclear Pharmacy Permit" means an authorization granted by the Board to the governing body of a facility to operate a nuclear pharmacy.

(l) "Pharmacist" means an individual who is currently licensed to practice pharmacy under the provisions of O.C.G.A. Title 26, Chapter 4, Article 3.
(m) "Pharmacy Intern" means an individual who is currently licensed to practice as a pharmacy intern under the provisions of O.C.G.A. Title 26, Chapter 4, Article 3.
(n) "Physician" means an individual who is currently licensed to practice medicine under the provisions of O.C.G.A. Title 43, Chapter 34.
(o) "Radiopharmaceutical" means radioactive drugs and chemical products used for diagnostic and therapeutic purposes and includes the terms radioactive pharmaceuticals, radioisotopes, and radioactive tracers.
(p) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on radiopharmaceuticals and their component materials and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.
(q) "Radiopharmaceutical service" means, but is not limited to, the compounding, dispensing, labeling, and delivering of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization review; the
maintenance of radiopharmaceutical quality assurance; and the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy.
(r) "Unit dose transport container" (a/k/a "lead pig") means a lead lined container designed to transport doses of radiopharmaceutical agents and prevent the emission of radiation or radioactive materials during the process. The terms "unit dose transport container" and "lead pig" may be used interchangeably.

Authority: O.C.G.A. Sections 26-4-27, 26-4-28, 26-4-110, 26-4-130, 26-4-171, and 26-5-178