NOTICE OF INTENT TO ADOPT PROPOSED CHAPTER OF THE GEORGIA STATE BOARD OF PHARMACY RULES
CHAPTER 480-51 INTERCHANGEABLE BIOLOGICAL PRODUCTS

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 a new chapter to the Georgia Board of Pharmacy Rules: Chapter 480-51 INTERCHANGEABLE BIOLOGICAL PRODUCTS (hereinafter "proposed chapter").

This notice, together with an exact copy of the proposed chapter and a synopsis of the proposed chapter, 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 chapter, and a synopsis of the proposed chapter 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 12:30 PM on April 12, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, Georgia 30303 to provide the public an opportunity to comment upon and provide input into the proposed chapter. 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 5, 2017. 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: 678-717-6435. You may email your comments to tbattle@dch.ga.gov.

The proposed chapter will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 12:35 PM on April 12, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, Georgia 30303. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed chapter pursuant to authority contained in O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-81.

At its meeting on January 11, 2017, the Board voted that the formulation and adoption of this chapter do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed chapter 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 January 11, 2017, 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 6th day of March, 2017.

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: March 6, 2017

SYNOPSIS OF PROPOSED CHAPTER OF THE GEORGIA STATE BOARD OF PHARMACY RULES CHAPTER 480-51 INTERCHANGEABLE BIOLOGICAL PRODUCTS

Purpose of Chapter: The purpose of this chapter is to permit the substitution of interchangeable biological products.

Main Features: The main feature of this chapter is to set forth the requirements for substitution of interchangeable biological products.

PROPOSED CHAPTER OF THE GEORGIA STATE BOARD OF PHARMACY RULES CHAPTER 480-51 INTERCHANGEABLE BIOLOGICAL PRODUCTS

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

480-51-.01 Definitions.

(1) "Biological product" means a biological product as defined in subsection (i) of section 351 of the Public Health Service Act, 42 U.S.C. Section 262.
(2) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in subsection (k)(4) of 42 U.S.C. 262 or has been deemed therapeutically equivalent by the federal Food and Drug Administration.
(3) "Substitution" means to dispense pharmaceutically equivalent and therapeutically equivalent drug products as regulated by the board in place of the drug prescribed.

Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-81.

480-51-.02 Substituting Interchangeable Biological Products.

(1) If a practitioner of the healing arts prescribes a biological product by its nonproprietary name, the pharmacist may substitute the biological product with an interchangeable biological product, but shall dispense the lowest retail-priced interchangeable biological product, which is in stock.
(2) Substitutions as provided in this rule are authorized for the express purpose of making available to the consumer the lowest retail priced interchangeable biological product which is in stock.
(3) Whenever a substitution is made:
(a) The pharmacist shall record on the original prescription the fact that there has been a substitution and the identity of the dispensed interchangeable biological product and its manufacturer. Such prescription shall be maintained for two years and shall be available for inspection by the board or its representative.
(b) The pharmacist shall affix to the prescription label or container or an auxiliary label, the name of the interchangeable biological product, with an explanation of "interchangeable biological product for (insert name of prescribed biological product)" or similar language to indicate substitution has occurred, unless the prescribing practitioner indicated that the name of the biological product may not appear upon the prescription label.

1. This labeling requirement does not apply to biological products dispensed for in-patient hospital services, to hospital-administered biological products for outpatients, or to biological products in specialty packaging for dosing purposes. This labeling requirement does apply to hospital retail pharmacies and to any biological products dispensed by a hospital for a patient's use or administration at home.
(4) The substitution of any biological product by a registered pharmacist pursuant to this rule section does not constitute the practice of medicine.
(5) A patient for whom a prescription biological product order is intended may instruct a pharmacist not to substitute an interchangeable biological product in lieu of a prescribed biological product.
(6) A practitioner of the healing arts may instruct the pharmacist not to substitute an interchangeable biological product in lieu of a prescribed biological product by including the words "brand necessary" in the body of the prescription.
(a) When a prescription is a hard copy biological product order, such indication of brand necessary must be in the practitioner's own handwriting and shall not be printed, applied by rubber stamp, or any such similar means.
(b) When the prescription is an electronic prescription drug or biological product order, the words "brand necessary" are not required to be in the practitioner's own handwriting and may be included on the prescription in any manner or by any method.
(c) When a practitioner has designated "brand necessary" on an electronic biological product order or interchangeable biological product shall not be substituted without the practitioner's express consent, which shall be documented by the pharmacist on the prescription and by the practitioner in the patient's medical record.
(7) Within forty-eight (48) hours, excluding weekends and holidays, following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the biological product and the manufacturer.
(a) The communication shall be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber by using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:
1. There is no interchangeable biological product approved by the federal Food and Drug Administration for the prescribed product; or
2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription.
(8) A link for the current list of all biological products determined by the federal Food and Drug Administration to be interchangeable with a specific biological products is available on the Board's website.

Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-81.