NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-34-.06 HYDROCODONE COMBINATION PRODUCTS, 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 480-34-.06 HYDROCODONE COMBINATION PRODUCTS (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 11:30 AM on January 21, 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 January 14, 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 11:35 AM on 1/21/2015 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. §§ 16-13-22, 26-4-28, and 50-13-4.

At its meeting on November 19, 2014, 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 11/19/2014, 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 19th day of December, 2014.

Tanja D. Battle

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: December 19th, 2014

SYNOPSIS OF GEORGIA STATE BOARD OF PHARMACY RULE 480-34-.06 HYDROCODONE COMBINATION PRODUCTS

Purpose of Rule: The purpose of this rule is to remove hydrocodone combination products from Schedule III of the Georgia Controlled Substances Act.

Main Features: The main feature of this rule is to set effective dates for the removal of hydrocodone combination products from Schedule III of the Georgia Controlled Substances Act.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-34-.06 HYDROCODONE COMBINATION PRODUCTS

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

480-34-.06 Hydrocodone Combination Products.

(1) Effective October 6, 2014, Official Code of Georgia Annotated (O.C.G.A.) §§16-13-27(4)(C), 16-13-27(4)(D) are hereby removed from Schedule III of the Georgia Controlled Substances Act, O.C.G.A. 16-13-25, et. seq. The following language shall be deleted from O.C.G.A. §§16-13-27(4): "(C) Not more than 300 milligrams of dihydrocodeinone (hydrocodone), or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium; (D) Not more than 300 milligrams of dihydrocodeinone (hydrocodone), or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts."
(2) Effective October 6, 2014, all Hydrocodone Combination Products (HCPs) in the State of Georgia are Schedule II controlled substances.
(a) Each registrant possessing HCPs must make an actual count inventory of all HCPs as of October 6, 2014 and maintain it with the registrant's biennial DEA inventory.
(b) All HCPs products must be treated as any other Schedule II controlled substance. There can be no oral prescriptions except in the case of an emergency, and all hard-copy HCP prescriptions must be issued on security paper.
(c) For any HCP prescription written and filled before October 6, 2014 with authorized refills, the prescription can be refilled only for the authorized number of refills prior to ~~February 1~~April 8, 2015.
(3) This rule is based on the following findings of the Board:
(a) that as Schedule III controlled substances, HCPs have an extremely high potential for abuse;
(b) that scientific evidence and scientific knowledge of the pharmacological effects of HCPs demonstrate that the public is at extreme risk if HCPs are not regulated as Schedule II controlled substances;
(c) that the history and pattern of abuse of HCPs as a Schedule III controlled substance and the scope and significance of that abuse support stricter regulation;
(d) that as a Schedule III controlled substance, there exists an imminent peril to the public health and welfare with regard to the abuse of HCPs;
(e) that HCPs have the same risk to the public health of citizens of the State of Georgia as other Schedule II controlled substances already contained in the Georgia Controlled Substances Act;

(f) that as of October 6, 2014, the U.S. Drug Enforcement Administration has removed all reference to HCPs from Schedule III of 21 CFR 1308.13, which places all HCPs under Schedule II of 21 CFR 1308.12.

Authority: O.C.G.A. §§16-13-22, 26-4-28, and 50-13-4.