

**NOTICE OF INTENT TO ADOPT PROPOSED RULE TO THE GEORGIA STATE BOARD
OF PHARMACY RULES
RULE 480-34-.15 ADDITIONAL COMPOUNDS UNDER SCHEDULE V**

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 Rule to the Georgia Board of Pharmacy Rules: Rule 480-34-.15 ADDITIONAL COMPOUNDS UNDER SCHEDULE V (hereinafter "proposed rule").

This notice, together with an exact copy of the proposed rule and a synopsis of the proposed rule, 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 rule, and a synopsis of the proposed rule 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 9:30 AM on December 12, 2018 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th Floor, Atlanta, Georgia 30303 to provide the public an opportunity to comment upon and provide input into the proposed rule. 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 December 5, 2018. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, 6th Floor, Atlanta, Georgia 30303. 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 9:35 AM on December 12, 2018 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th 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 rule pursuant to authority contained in O.C.G.A. §§ 16-13-22, 26-4-28, and 50-13-4.


At its meeting on October 31, 2018, 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 October 31, 2018, 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 7th day of Nov., 2018.



Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: November 7, 2018

**SYNOPSIS OF PROPOSED RULE OF THE
GEORGIA STATE BOARD OF PHARMACY RULES
RULE 480-34-.15 ADDITIONAL COMPOUNDS UNDER SCHEDULE V**

Purpose of Rule: The purpose of this rule is to place the drug product Epidiolex, as defined below, under Schedule V of the Georgia Controlled Substances Act, Section 16-13-29. Currently, Epidiolex has been moved to Schedule V under Emergency Rule 480-34-0.35-.12 which became effective on November 5, 2018.

Main Features: The main feature of this rule is to place the drug product Epidiolex, as defined below, under Schedule V of the Georgia Controlled Substances Act, Section 16-13-29.

**PROPOSED RULE FOR THE GEORGIA STATE BOARD OF PHARMACY RULES
RULE 480-34-.15 ADDITIONAL COMPOUNDS UNDER SCHEDULE V**

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

Rule 480-34-.15 Additional Compounds under Schedule V

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places an additional compound as specifically identified here under Schedule V of the Georgia Controlled Substances Act, Section 16-13-29 as follows:

(1.5) Epidiolex: A drug product in finished dosage formulation in its original container that has been approved by and labelled in compliance with the U.S. Food and Drug Administration (FDA) that contains cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

(2) This rule is based on the following findings of the Board:

(a) that the FDA approved the drug Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex is an oral solution that contains CBD extracted from the cannabis plant.

(b) that the U.S. Drug Enforcement Administration (DEA) did seek a medical and scientific evaluation or scheduling recommendation from the U.S. Department of Health and Human Services (HHS) with respect to the Epidiolex formulation. In responding to that request, HHS advised DEA that it found the Epidiolex formulation to have a very low potential for abuse and therefore, recommended that if DEA concluded that control of the drug was required under the Single Convention, Epidiolex should be placed in Schedule V of the Federal Controlled Substance Act (CSA).

(c) that the Board has considered, based on available information, the potential for abuse; scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; and the potential of the drug to produce psychic or physiological dependence liability.

Authority: 16-13-22, 26-4-28, and 50-13-4.