

**NOTICE OF INTENT TO ADOPT PROPOSED RULE TO THE GEORGIA STATE BOARD
OF PHARMACY RULES,
RULE 480-34-.12 SYNTHETIC FENTANYL, 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 a new Rule to the Georgia Board of Pharmacy Rules: Rule 480-34-.12 SYNTHETIC FENTANYL (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 9:00 AM on November 8, 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 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 November 1, 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: 678-717-6694. 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 November 8, 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 rule pursuant to authority contained in O.C.G.A. §§ 16-13-22, 16-13-25, 26-4-28, and 50-13-4.

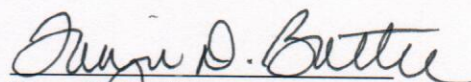
At its meeting on June 29, 2017, the Board voted that the formulation and adoption of this rule do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A. §§ 26-4-27, 26-4-28, 16-13-22.

Also, at its meeting on June 29, 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 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 3rd day of Oct, 2017.



Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: Oct 3, 2017

**SYNOPSIS OF PROPOSED RULE OF THE
GEORGIA STATE BOARD OF PHARMACY RULES
RULE 480-34-.12 SYNTHETIC FENTANYL**

Purpose of Rule: The purpose of this rule is to protect the health, safety, and welfare of the public.

Main Features: The main feature of this rule is to identify new compounds of Synthetic Fentanyl as Schedule I substances under the Georgia Controlled Substances Act.

**PROPOSED RULE FOR THE GEORGIA STATE BOARD OF PHARMACY RULES
RULE 480-34-.12 SYNTHETIC FENTANYL**

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

480-34-.12 Synthetic Fentanyl.

(a) This rule was adopted to protect the health, safety, and welfare of the public. This rule places newly identified compounds, including any derivatives, their salts, isomers, or salts of isomers, unless specifically utilized as part of the manufacturing process by a commercial industry of a substance or material not intended for human ingestion or consumption, as a prescription administered under medical supervision, or for research at a recognized institution, whenever the existence of these salts, isomers, or salts of isomers is possible within the specific chemical designation or unless specifically excepted or listed in this or another schedule, structurally derived from fentanyl, and whether or not further modified in any of the following ways under Schedule I of the Georgia Controlled Substances Act, Section 16-13-25(13) as follows: (H) Tetrahydrofuran fentanyl (N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide)

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

- (1) That synthetic fentanyls have an extremely high potential for abuse;
- (2) That scientific evidence and scientific knowledge of the pharmacological effects of these compounds demonstrate that the public is at extreme risk if they are not regulated as controlled substances;
- (3) That the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;
- (4) That there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;
- (5) That these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule I under the Controlled Substances Act; and
- (6) That these compounds have no known precursor already scheduled under the Act.

Authority: O.C.G.A. §§ 16-13-22, 16-13-25, 26-4-28, and 50-13-4.