# GEORGIA BOARD OF PHARMACY Conference Call 2 Peachtree Street, NW, 6<sup>th</sup> Floor Atlanta, GA 30303 June 29, 2017 1:00 p.m.

### Staff present:

Tanja Battle, Executive Director Rick Allen, Director, GDNA Janet Wray, Senior Assistant Attorney General Max Changus, Assistant Attorney General Anil Foreman, Attorney Brandi Howell, Business Support Analyst I

#### **Open Session**

President Jones established that a quorum was present and called the meeting to order at 1:00 p.m.

Lisa Harris made a motion to adopt Emergency Rule 480-34-0.34-.12 Synthetic Fentanyl. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

### Rule 480-34-0.34-.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.

A motion was made by Bill Prather, seconded by Mike Faulk, and the Board voted that pursuant to O.C.G.A. Section 26-4-28(a)(9), the Board has the right to seize any drugs and devices found by the Board to constitute an imminent danger to public health and welfare. Pursuant to O.C.G.A. Section 26-3-

4(a), any duly authorized agent of the Board who finds or has probable cause to believe any drug is adulterated or misbranded as to be dangerous or fraudulent may tag the article to detain or embargo the article. If the article is unsound or unsafe, O.C.G.A. Section 26-3-4(d) authorizes the Board or its authorized agents to condemn or destroy the article. The agents of the Georgia Drugs and Narcotics Agency ("GDNA") are authorized agents of the Board. O.C.G.A. Section 26-4-29(b)(5) authorizes agents of GDNA to seize and take possession of all articles of contraband. O.C.G.A. Section 26-4-29(b)(7) provides that the GDNA shall perform such other duties as the Board may direct.

In consideration of these Code sections and the danger to public health, safety and welfare, the Board is directing GDNA to take the lead in enforcement of Emergency Rule 480-34-0.34.-12, and is directing that GDNA designate, on behalf of the Board, POST certified officers who are members of state and local law enforcement agencies to act as Board agents to: (1) seize drugs, compounds and/or articles identified in Emergency Rule 480-34-0.34.-12 on behalf of the Board and to maintain such seized drugs, compounds and/or articles within their evidence rooms, or (2) tag adulterated or misbranded drugs identified in Emergency Rule 480-34-0.34.-12 to detain or embargo such drugs. Any law enforcement agencies operating on behalf of the Board in enforcing Emergency Rule 480-34-0.34.-12 shall provide GDNA with notification of any seizure, detention or embargo. Finally, GDNA is authorized to utilize in enforcing Emergency Rule 480-34-0.34.-12 any state agency identified in O.C.G.A. Section 26-3-18.

Lisa Harris made a motion to post Rule 480-34-.12 Synthetic Fentanyl. Laird Miller seconded and the Board voted unanimously in favor of the motion.

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(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.

A motion was made by Mike Faulk, seconded by Bill Prather, and the Board voted that the formulation and adoption of this rule does 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 the relevant code sections. In the same motion, the Board also voted that it is not legal or feasible to meet the objectives of the relevant code sections 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.

Lisa Harris made a motion and Bill Prather seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2) and §43-1-2(k) to deliberate and to receive the Assistant Attorney General's report. Voting in favor of the motion were those present who included Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

### **Executive Session**

### Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders:

- E.U.I.L.
- G.C.P.I.

The Board received legal advice regarding a recent media inquiry.

No votes were taken in Executive Session. President Jones declared the meeting back in Open Session.

### **Open Session**

In regards to a recent media inquiry about pharmacy shopping, Bill Prather made a motion to direct staff to draft a statement to include information regarding PDMP and complaint/disciplinary process, and allow Vice-President Warnock, Mr. Bracewell, and Ms. Wray review the statement. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Mike Faulk made a motion for the Board to take the following actions:

### <u> Attorney General's Report – Max Changus</u>

Mr. Changus presented the following consent orders:

E.U.I.L. Private Consent Order to be accepted and signed with express permission upon receipt of the original
Global Care Pharmacy, Inc. Public Consent Order to be accepted and signed with express permission upon receipt of the original

Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 1:20 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, July 12, 2017 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 5<sup>th</sup> Floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I Minutes edited by Tanja D. Battle, Executive Director