

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

The following Board members were present:

Chris Jones, President
Bob Warnock, Vice-President
Jim Bracewell
Mike Faulk
Lisa Harris
Laird Miller
Bill Prather

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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(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.

