

GEORGIA BOARD OF PHARMACY
Conference Call
2 Peachtree St., N.W., 6th Floor
Atlanta, GA 30303
July 20, 2015
1:00 p.m.

The following Board members were present:

Laird Miller, Chairperson
Mike Faulk, Vice-Chairperson
Vicki Arnold
Jim Bracewell
Chris Jones
Tony Moye
Bill Prather
Bob Warnock

Staff present:

Eric Lacefield, Deputy Executive Director
Rick Allen, GDNA
Janet Wray, Senior Assistant Attorney General
Anil Foreman, Legal Officer
Brandi Howell, Business Operations Specialist

Open Session

Chairperson Miller established that a quorum was present and called the meeting to order at 1:01 p.m.

Jim Bracewell made a motion to adopt emergency Rule 480-34.0.26-.07 Hallucinogens. Bill Prather seconded and the Board voted unanimously in favor of the motion.

480-34-0.26-.07 Hallucinogens.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places additional newly identified compounds, including any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers (whether optical, position, or geometrics), and salts of isomers under Schedule I of the Georgia Controlled Substances Act, Section 16-13-25(3) as follows:

(EEEE) 1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (SDB-006)

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

(a) that hallucinogens have an extremely high potential for abuse;

(b) 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;

(c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(e) 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

(f) that these compounds have no known precursor already scheduled under the Act.

Bob Warnock made a motion to adopt emergency Rule 480-34-0.27-.09 Additional Compounds Under Schedule IV. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

480-34-0.27-.09 Additional Compounds Under Schedule IV.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places additional newly identified compounds, including any material, compound, mixture, or preparation which contains any quantity of the following substances, their salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specified chemical designation, including as having a stimulant or depressant effect on the central nervous system or a hallucinogenic effect, under Schedule IV of the Georgia Controlled Substances Act, Section 16-13-28 as follows:

(14.3) Flubromazepam

(30.07) Pyrazolam

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

(a) that benzodiazepines have a high potential for abuse;

(b) 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;

(c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(e) 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 IV under the Controlled Substances Act; and

(f) that these compounds have no known precursor already scheduled under the Act.

A motion was made by Jim Bracewell, seconded by Chris Jones, 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 Rules 480-34-0.26-.07 and 480-34-0.27-.09 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 Rules 480-34-0.26-.07 and 480-34-0.27-.09 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 Rules 480-34-0.26-.07 and 480-34-0.27-.09 to detain or embargo such drugs. Any law enforcement agencies operating on behalf in the Board in enforcing Emergency Rules 480-34-0.26-.07 and 480-34-0.27-.09 shall provide GDNA with notification of any seizure, detention or embargo. Finally, GDNA is authorized to utilize in enforcing Emergency Rules 480-34-0.26-.07 and 480-34-0.27-.09 any state agency identified in O.C.G.A. Section 26-3-18.

Bill Prather made a motion to post Rule 480-34-.07 Hallucinogens. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

480-34-.07 Hallucinogens.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places additional newly identified compounds, including any material, compound, mixture, or preparation which contains any quantity of the following substances, their salts, isomers (whether optical, position, or geometrics), and salts of isomers under Schedule I of the Georgia Controlled Substances Act, Section 16-13-25(3) as follows:

(BBBB) Methoxyphencyclidine (MeO-PCP)

(CCCC) 4-hydroxy-N-methyl-N-isopropyltryptamine (4-OH-MiPT)

(DDDD) N, α -dimethyl-5-benzofuranethanamine (5-MAPB)

(EEEE) 1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (SDB-006)

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

(a) that hallucinogens have an extremely high potential for abuse;

(b) 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;

(c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(e) 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

(f) that these compounds have no known precursor already scheduled under the Act.

Chris Jones made a motion to post Rule 480-34-.09 Additional Compounds Under Schedule IV. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

480-34-.09 Additional Compounds Under Schedule IV

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places additional newly identified compounds, including any material, compound, mixture, or preparation which contains any quantity of the following substances, their salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specified chemical designation, including as having a stimulant or depressant effect on the central nervous system or a hallucinogenic effect, under Schedule IV of the Georgia Controlled Substances Act, Section 16-13-28 as follows:

(14.3) Flubromazepam

(30.07) Pyrazolam

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

(a) that benzodiazepines have a high potential for abuse;

(b) 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;

(c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(e) 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 IV under the Controlled Substances Act; and

(f) that these compounds have no known precursor already scheduled under the Act.

A motion was made by Chris Jones, seconded by Bill Prather, and the Board voted that the formulation and adoption of these rules does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rules cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

In the same motion, the Board 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 these rules will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

The Board discussed amendments to the letter to Governor Nathan Deal regarding the forthcoming Memorandum of Understanding (MOU) by the Food and Drug Administration. Jim Bracewell made a motion to send the MOU with the proposed amendments to Governor Deal. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Mike Faulk made a motion and Jim Bracewell 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 information on applications. Voting in favor of the motion were those present who included Vicki Arnold, Jim Bracewell, Mike Faulk, Chris Jones, Laird Miller, Tony Moye, Bill Prather and Bob Warnock.

Executive Session

Applications

- S.A.D.
- J.B.H.
- H.L.L.
- A.K.C.
- L.D.A.
- C.J.M.
- C.A.H.
- C.M.F.
- D.A.S.
- D.C.D.
- C.H.F.
- G.N.J.
- N.M.B.
- A.M.R.
- Z.F.D.

No votes were taken in Executive Session. Chairperson Miller declared the meeting back in Open Session.

Open Session

Bill Prather made a motion for the Board to take the following actions:

Applications

- | | | |
|--------------------|---------------------|--|
| • S.A.D. | Pharmacy Technician | Overturn denial and approve for registration |
| • Jeremy B. Hamm | Pharmacy Technician | Approved renewal |
| • Heather L. Lewis | Pharmacy Technician | Approved renewal |
| • A.K.C. | Pharmacy Technician | Approved renewal with letter stating the Board is not waiving its right to take disciplinary action should the final disposition result in a conviction. |
| • L.D.A. | Pharmacy Technician | Refer to the Attorney General's office for discipline |
| • C.J.M. | Pharmacy Technician | Table renewal pending receipt of additional information |
| • C.A.H. | Pharmacy Technician | Revoke technician registration |
| • C.M.F. | Pharmacy Technician | Schedule for investigative interview |
| • D.A.S. | Pharmacy Technician | Schedule for investigative interview |
| • D.C.D. | Pharmacy Technician | Table renewal pending receipt of additional information |
| • C.H.F. | Pharmacy Technician | Refer to the Attorney General's office |
| • G.N.J. | Pharmacy Technician | Approved renewal with letter stating the Board is not waiving its right to take disciplinary action should the final disposition result in a conviction. |
| • N.M.B. | Pharmacy Technician | Approved renewal with letter stating the Board is not waiving its right to take disciplinary action should the final disposition result in a conviction. |
| • A.M.R. | Pharmacy Technician | Table renewal pending receipt of additional information |
| • Z.F.D. | Pharmacy Technician | Table renewal pending receipt of additional information |

No votes were taken in Executive Session. Chairperson Miller declared the meeting back in Open Session.

There being no further business to discuss, the meeting was adjourned at 1:31 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, August 5, 2015 at 9:00 a.m. at Philadelphia College of Osteopathic Medicine (PCOM), 625 Old Peachtree Rd., NW, Suwanee, GA 30024.

Minutes recorded by Brandi P. Howell, Business Operations Specialist

Minutes edited by Eric Lacefield, Deputy Executive Director