



Allen Amsler, *Chairman*
Ann B. Kirol, DDS, *Vice Chair*
L. Clarence Batts, Jr., *Secretary*

Board:
R. Kenyon Wells
Charles M. Joye II, P.E.
David W. Gillespie, MD

Minutes of the November 9, 2017 meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, November 9, 2017, at 10:00 a.m. in the Board Room at the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance:

Allen Amsler, Member-at-Large
Ann B. Kirol, DDS, Vice Chair, 5th District
L. Clarence Batts, Secretary, 4th District
R. Kenyon Wells, 2nd District
Charles M. Joye, II, P.E., 3rd District
David W. Gillespie, MD, 6th District

1st District and 7th District seats are currently vacant.

Also in attendance were David E. Wilson, Acting Director; W. Marshall Taylor, Legal Counsel; Lisa Lucas Longshore, Clerk; Department staff and members of the public. (Attachment 0-2) The meeting was live streamed on the internet.

Chairman Allen Amsler called the meeting to order and stated notice of this meeting had been provided to all persons, organizations and news media, which have requested notification, as required by Section 30-4-80(e) of the South Carolina Code of Laws.

Item 1: Minutes of the October 12 meeting (Attachment 1-1)

Mr. Joye moved, seconded by Mr. Batts, to approve the minutes for October 12 as presented. The Board voted and Motion carried.

Item 2: Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation (Attachment 2-1)

Mr. Thomas Bowen, Senior Consultant, Health Regulation Policy and Communications, stated four (4) Consent Orders, three (3) Emergency Suspension Orders and one (1) License Suspension had been issued with total assessed penalties of \$5,850.

After discussion, ***the Board accepted this item as information.***

Item 3: Administrative Orders and Consent Orders issued by Environmental Affairs
(Attachment 3-1)

Ms. Robin Stephens, Compliance Assistance and Enforcement, Environmental Affairs, stated five (5) Administrative Orders, three (3) Consent Agreements and ninety-four (94) Consent Orders had been issued with total penalties of \$181,050.

After discussion, ***the Board accepted this item as information.***

Item #4: Request for a nine-month extension by the Board of Certificate of Need (CON) SC-15-26 issued to Medical University Hospital Authority d/b/a Medical University of South Carolina (MUSC) for renovation of existing facility for the addition of fifty-two (52) acute hospital beds for a total of six hundred fifty-six (656) acute hospital beds, the purchase of a Siemens Artist Q Biplane, and the renovation of the existing inpatient pharmacy (Attachment 4-1)

Mr. Louis Eubank, Director, Certificate of Need Office, presented this item to the Board.

CON SC-15-26 was issued to MUSC on June 30, 2015, for the referenced project. The original CON had an expiration date of June 30, 2016. The Department staff issued two extension requests for this project with the second extension set to expire on January 1, 2018.

In accordance with R. 61-15, Section 601, MUSC submitted a third extension request to the Department on August 4, 2017, which is more than 90 days prior to expiration.

Department staff have reviewed all relevant information concerning this third extension request and find that construction timelines beyond the control of MUSC have contributed to the need for further extension of CON SC- 15-26. While parts of the project have been implemented in accordance with the CON, there are several approved beds which cannot be implemented until MUSC's new children's hospital and women's pavilion is complete and licensed,

After discussion, ***Mr. Wells moved, seconded by Dr. Gillespie, to find that MUSC has demonstrated substantial progress on this project and approves the extension request for CON SC-15-26 issued to Medical University Hospital Authority d/b/a Medical University of South Carolina through October 1, 2018. The Board voted and Motion carried.***

Item #5: Notice of Proposed Regulation amending Regulation 61-78. Standards for Licensing Hospices (Attachment 5-1)

Mr. Terry English, Director, Division of Health Facilities Oversight, presented this item to the Board.

The S.C. Department of Health and Environmental Control is required to promulgate regulations for standards of care, treatment, health, safety, welfare, and comfort of patients and their families serviced by hospices and for the maintenance and operation of hospices. General Assembly review is required.

The Department proposed amending Regulation 61-78 to incorporate newly passed amendments to the Hospice Licensure Act, S.C. Code Sections 44-71-10 et seq. The proposed regulatory

amendments include requirements to register multiple locations and updated requirements for medication disposal to comply with the recent statutory changes. The statutory changes also expanded Joint Annual Report requirements to outpatient Hospices, however, existing wording of Regulation 61-78 adequately executes those requirements.

After discussion, ***Dr. Gillespie moved, seconded by Mr. Batts, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-78, Standards for Licensing Hospices, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted and Motion carried.***

Item 6: Placement of ortho-Fluorofentanyl, Tetrahydrofuranyl Fentanyl, and Methoxyacetyl Fentanyl into Schedule I for S.C. Controlled Substances (Attachment 6-1)

Ms. Heather Lukshis, Bureau of Drug Control, presented this item to the Board.

On October 26, 2017, the Administrator of the Drug Enforcement Administration issued a temporary scheduling order to schedule the synthetic opioids, N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl) propionamide (ortho-fluorofentanyl or 2-fluorofentanyl), N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (tetrahydrofuranyl fentanyl), and 2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (methoxyacetyl fentanyl), into Schedule I. This action was based on a finding by the Administrator that the placement of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I of the Controlled Substances Act was necessary to avoid an imminent hazard to the public safety. The federal temporary scheduling order became effective October 26, 2017.

The population likely to abuse ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl overlaps with the population abusing prescription opioid analgesics, heroin, fentanyl, and other fentanyl-related substances. This is evidenced by the routes of drug administration and drug use history documented in ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl fatal overdose cases and encounters of the substance by law enforcement officials. Because abusers of these substances are likely to obtain them through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (i.e. use a drug for the first time) the substance abuse are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (e.g., fentanyl, morphine, etc.).

As DEA has determined the placement of ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into schedule I of the federal CSA is necessary, the Department recommends the permanent placement of ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I for Controlled Substances in South Carolina and amend S.C. Code Section 44-53-190(B) to include:

N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl) propionamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: ortho-fluorofentanyl, 2-fluorofentanyl) N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: tetrahydrofuranyl fentanyl) 2-methoxy-N-(1-

phenethylpiperidin-4-yl)-N-phenylacetamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: methoxyacetyl fentanyl).

After discussion, **Mr. Batts moved, seconded by Dr. Kirol, to designate the additional substances as named in the DEA Final Rule published in the Federal Register on October 26, 2017, and amend Section 44-53-190 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.** Board Designation (Attachment 6-2)

Item 7: Placement of the synthetic cannabinoid, methyl 2-(1-(4-fluorobenzyl)-1 Hindazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMBFUBINACA, AMB-FUBINACA], and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I (Attachment 7-1)

Ms. Heather Lukshis, Bureau of Drug Control, presented this item to the Board.

The South Carolina Board of Health and Environmental Control has scheduled a similar compound on February 27, 2014. In order to assure there is no question as to the placement of synthetic cannabinoid, methyl 2-(1-(4-fluorobenzyl)-1 H-indazole-3carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA], and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I, the Bureau of Drug Control provides this information as background to the current DEA action.

Available data and information for FUB-AMB, summarized below, indicate that this synthetic cannabinoid (SC) has a high potential for abuse. no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

The illicit use of the synthetic cannabinoid (SC) methyl 2-(1-(4-fluorobenzyl)-1 Hindazole-3-carboxamido)-3-methylbutanoate (Street names: FUB-AMB, MMBFUBINACA, AMB-FUBINACA) has dramatically increased over the past 12 months posing an imminent threat to public safety. FUB-AMB has no accepted medical use in the United States. Use of this specific SC has been reported to result in adverse effects in humans. Use of other SCs has resulted in signs of addiction and withdrawal and based on the similar pharmacological profile of FUB-AMB, it is believed that there will be similar observed adverse effects.

SCs including FUB-AMB continue to be encountered on the illicit market regardless of scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Novel substances are encountered each month, differing only by small modifications intended to avoid prosecution while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products.

Any activity involving FUB-AMB not authorized by, or in violation of the CSA, occurring as of November 3, 2017, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

For the reasons set forth above, the Department recommends the Board designate methyl2-(1-(4-fluorobenzyl)-1 H-indazole-3carboxamido)-3-methylbutanoate, its optical, positional, and geometric

isomers, salts and salts of isomers (Other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) and place into Schedule I of the SC Controlled Substances Act.

After discussion, **Mr. Batts moved, seconded by Dr. Gillespie, to designate the additional substances as named in the DEA Final Rule published in the Federal Register on November 3, 2017, and amend Section 44-53-190 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.** Board Designation (Attachment 7-2)

Item 8: Agency Affairs

Acting Director Wilson briefed the Board on the following agency accomplishments:

- 2017 Environmental Assistance Awards “DHEC and Industry: Going Beyond the Fenceline Together” with over 250 attendees from the regulated community; Myra Reece received the first Community Star Award, which highlights what happens when DHEC, environmental community and business work collaboratively.
- International Association of Business Communicators Awards - DHEC Communications Team received awards for the following submissions: Palmetto Award of Excellence for “Rebranding DHEC from the Inside Out” and a Palmetto Award of Merit for Hurricane Matthew communications.
- Spirit of Caring Award – DHEC recognized 13 partner facilities with Best Practice Awards.

The Board accepted this as information.

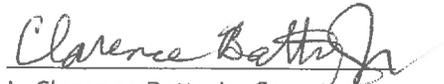
Chairman Amsler asked for a Motion for an Executive Session for the legal advice on the Jurisdictional Beachlines. **Mr. Joye moved, seconded by Mr. Wells, to go into Executive Session. The Board voted and Motion carried.**

Chairman Amsler announced the Board was back in public session and while in Executive Session, no actions were taken.

Being no further business, Chairman Amsler adjourned the meeting.

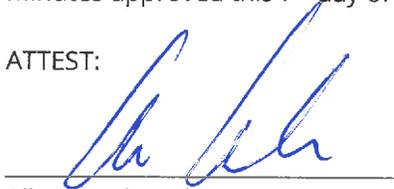
All referenced attachments are made a permanent part of these minutes.

Respectfully submitted,


L. Clarence Batts, Jr., Secretary

Minutes approved this 7th day of December 2017.

ATTEST:


Allen Amsler, Chairman

Attachments

- 0-1 Agenda
- 0-2 Attendance Roster
- 1-1 Minutes of October 12, 2017
- 2-1 Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation
- 3-1 Administrative Orders and Consent Orders issued by Environmental Affairs
- 4-1 Request for nine-month extension of CON SC-15-26 issued to MUSC
- 5-1 Notice of Proposed Regulation, R.61-78, Standards for Licensing Hospices
- 6-1 Placement of ortho-Fluorofentanyl, Tetrahydrofuranyl Fentanyl, and Methoxyacetyl Fentanyl into Schedule I for S.C. Controlled Substances
- 6-2 Board Designation
- 7-1 Placement of the synthetic cannabinoid, methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMBFUBINACA, AMB-FUBINACA], and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I
- 7-2 Board Designation