Minutes of the February 8, 2018, meeting of the
South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, February 8, 2018, 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:
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

Not in attendance:
Ann B. Kirol, DDS, Vice-Chair, 5th District.

The 1st District, 7th District and Member-at-Large 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)

Mr. Batts, Secretary, served as Chair in the absence of Ann Kirol, vice-chairman.

Mr. Batts 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 January 4, 2017, meeting (Attachment 1-1)

Dr. Gillespie moved, seconded by Mr. Wells, to approve the minutes of the January 4 meeting 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 two (2) Emergency Suspension Orders had been issued with no assessed penalties.

The Board accepted this item as information.

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

Ms. Myra Reece, Deputy Director of Environmental Affairs, stated two (2) Administrative Orders and sixty-four (64) Consent Orders had been issued with total penalties of $154,499.

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

Item 4: Public Hearing for Notice of Final Regulation for Regulation 61-78, Standards for Licensing Hospices, State Register Document No. 4800, General Assembly review is required (Attachment 4-1)

Ms. Gwen Thompson, Chief, Bureau of Health Facilities Licensing, presented this item to the Board.

The proposed amendments incorporate 2017 Act No. 61, which comprises amendments to the Hospice Licensure Act. The proposes regulatory amendments include requirements to register multiple locations and updated requirements for medication disposal to comply with the new statutory changes.

A public hearing was conducted with no one present wishing to speak. (Attachment 4-2)

After discussion, ***Dr. Gillespie moved, seconded by Mr. Joye, that based on the public hearing and documents herein, to find for the need and reasonableness of the Department's Notice of Final Regulation for Regulation 61-78, Standards for Licensing Hospices, and grant approval for submission to the General Assembly for review. The Board voted and Motion carried.***

A verbatim transcript of these proceedings is included as part of the public record. (Attachment 4-3)

Item 5: Public Hearing for Notice of Final Regulation amending R.61-63, Radioactive Materials, (Title A), State Register Document No. 4791, General Assembly review is not required (Attachment 5-1)

Mr. Aaron Gantt, Chief, Bureau of Radiological Health, presented this item to the Board.

The Federal Atomic Energy Act of 1954 enables the United States Nuclear Regulatory Commission to enter into agreements with state governors allowing for state regulation of byproduct, source and special nuclear materials. The Commission enters into such agreements if it finds the state regulatory program is in compliance with applicable federal regulations. *Id.* To renew South Carolina's ongoing agreement with the Commission, the Bureau requests final approval to amend Regulation 61-63, ensuring state standards comply with the Commission's regulatory updates. The amendments add clarification or corrections to arts II, V, VII, and XII of the regulation. Additionally, for Part II, the amendments enable specific licensees to install and service generally licensed devices. For XII, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, the amendments enable individuals receiving security-related information to protect it from public disclosure.

A public hearing was conducted with no one present wishing to speak. (Attachment 5-2)

After discussion, ***Mr. Joye moved, seconded by Dr. Gillespie, that based on the public hearing and documents herein, to find for the need and reasonableness of the Department's Notice of Final Regulation amending R.61-63, Radioactive Materials, (Title A), and grant approval for submission to the General Assembly as final. The Board voted and Motion carried.***

A verbatim transcript of these proceedings is included as part of the public record. (Attachment 5-3)

Item 6: Notice of Proposed Regulation amending Regulation 30-14, Administrative Procedures, General Assembly review is required

Ms. Elizabeth VonKolnitz, Director, Office of Ocean and Coastal Resource Management, presented this item to the Board.

The Office of Ocean and Coastal Resource Management ("OCRM") proposed to amend Regulation 30-14, *Administrative Procedures* which requires the Department to establish and review the position of the state's beachfront jurisdictional setback lines, baselines, and erosion rates once every seven (7) to ten (10) years.

OCRM proposed amending R.30-14 with respect to the review process for revising beachfront jurisdictional lines and erosion rates affecting beachfront properties. S.C. Code Section 48-39-280 required the Department to establish and review the position of jurisdictional setback lines, baselines, and erosions rates of beachfront jurisdiction once every seven (7) to ten (10) years. Existing Coastal Division Regulation 30-14.F provides that a landowner may request a review of the jurisdictional lines or erosion rate affecting his or her property within one (1) year of adoption. However, statutory changes under Act No. 387 of 2006 limit the review of a Department decision to fifteen (15) calendar days. This proposed regulatory amendment would clarify the review process to allow sufficient time for affected landowners to understand the Department's methodology in setting jurisdictional lines and erosion rates, and bring any substantiating evidence to the attention of OCRM for staff determination. The amendment will provide landowners a timely review and would comply with Act No. 387 of 2006.

The Department published proposed revisions to the state's beachfront jurisdictional setback lines, baselines and erosions rates on October 6, 2017. Based on comments received from landowners, community leaders, the conservation community and others during the initial 30-day public comment period, the Department extended the public comment period until April 6, 2018. Existing jurisdictional lines will remain in place until final revised lines are adopted.

After discussion, ***Mr. Wells moved, seconded by Mr. Joye, to grant approval to publish the Notice of Proposed Regulation amending Regulation 30-14, Administrative Procedures, 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 7: Placement of Seven Fentanyl related Substances in Schedule I for Controlled Substances (Attachment 7-1)

Ms. Anne Marie Ravenna, Bureau of Drug Control, presented this item to the Board.

Pursuant to S.C. Code Section 44-53-160(C), the South Carolina Board of Health and Environmental Control (Board) is authorized to add a substance as a controlled substance if the Federal government has so designated.

On February 1, 2018, the Administrator of the Drug Enforcement Administration issued a temporary scheduling order to schedule the synthetic opioids N-(1- phenethylpiperidin-4-yl)-Nphenylpentanamide (valeryl fentanyl), N-(4-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)butyramide (para-fluorobutyryl fentanyl), N-(4- methoxyphenyl)-N-(1- phenethylpiperidin-4-yl)butyramide (para-methoxybutyryl fentanyl), N-(4- chlorophenyl)-N-(1-phenethylpiperidin4-yl)isobutyramide (parachloroisobutyryl fentanyl), N-(1-phenethylpiperidin-4-yl)-Nphenylisobutyramide (isobutyryl fentanyl), N-(1-phenethylpiperidin-4- yl)-N-phenylcyclopentanecarboxamide (cyclopentyl fentanyl), and N-(2- fluorophenyl)-2-methoxy-N-(1-

phenethylpiperidin-4-yl)acetamide (ocfentanil), and their isomers, esters, ethers, salts and salts of isomers, esters and ethers in schedule I. Federal Register, Volume 83, Number 22, pp. 4580-4585.

Substances listed in Schedule I are those that have a high potential for abuse, no currently acceptable medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA conducted its own review and determined that valeryl fentanyl, para-fluorobutyryl fentanyl, para-methoxybutyryl fentanyl, parachloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil met the criteria for placement in schedule I of the federal CSA because a review of available data showed it had a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use in treatment under medical supervision.

Although there is no legitimate medical use in the United States, valeryl fentanyl, parafluorobutyryl fentanyl, paramethoxybutyryl fentanyl, parachloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil have emerged on the illicit drug market. Substances within this chemical structural class have demonstrated pharmacological profiles like that of fentanyl and other mopioid receptor agonists (see DEA 3- Factor Analysis). The abuse of these fentanyl-related substances poses significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone.

The toxic effects of substances within this structural class in humans are demonstrated by overdose fatalities described in previous scheduling actions. Based on information received by the DEA, the misuse and abuse of valeryl fentanyl, para-fluorobutyryl fentanyl, para-methoxybutyryl fentanyl, parachloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil lead to, at least, the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. As with any non-medically approved opioid, the health and safety risks for users are high. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

After discussion, ***Mr. Wells moved, seconded by Dr. Gillespie, to designate the additional substances as named in the DEA Interim Final Rule as published in the Federal Register on February 1, 2018, 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 Order (Attachment 7-2)

Item 8: Placement of Fentanyl Related Substances in Schedule I for Controlled Substances (Attachment 8-1)

Ms. Anne Marie Ravenna, Bureau of Drug Control, presented this item to the Board.

Pursuant to S.C. Code Section 44-53-160(C), the South Carolina Board of Health and Environmental Control (Board) is authorized to add a substance as a controlled substance if the Federal government has so designated.

On February 6, 2018, the Administrator of the Drug Enforcement Administration (DEA) issued a temporary scheduling order to schedule fentanyl-related substances that are not currently listed in any schedule of the Controlled Substances Act (CSA) and their isomers, esters, ethers, salts and salts of isomers, esters, and ethers in schedule I. These substances include any substance, not otherwise controlled in any schedule (i.e., not included under any other Administration Controlled Substance Code Number), that is structurally related to fentanyl by one or more of the following modifications:

(A) Replacement of the phenyl portion of the phenethyl group by any monocycle, if further substituted in or on the monocycle;
(B) substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino or nitro groups;
(C) substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;
(D) replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or
(E) replacement of the N-propionyl group by another acyl group.

Substances listed in Schedule I are those that have a high potential for abuse, no currently acceptable medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Information provided by the Assistant Secretary of HHS indicates that these fentanyl-related substances, as defined, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision; and

Fentanyl is often mixed with heroin and other substances (such as cocaine and methamphetamine) or used in counterfeit pharmaceutical prescription drugs. As a consequence, users who buy these substances on the illicit market are often unaware of the specific substance they are actually consuming and the associated risk. According to the Centers for Disease Control and Prevention (CDC), drug overdose deaths involving synthetic opioids (excluding methadone), such as fentanyl and tramadol, increased from 5,544 in 2014 to 9,580 in 2015. According to provisional data released in August 2017 by the CDC, National Center for Health Statistics, an estimated 55 Americans are dying every day from overdoses of synthetic opioids (excluding methadone). Drug overdose deaths involving synthetic opioids excluding methadone for the 12-month period ending in January of 2017 (20,145 deaths) more than doubled from the corresponding data for the period ending in January of 2016 (9,945 deaths).

According to the DEA, it is well known that deaths associated with the abuse of substances structurally related to fentanyl in the United States are on the rise and have already reached alarming levels. While many factors appear to be contributing to this public health crisis, chief among the causes is the sharp increase in recent years in the availability of illicitly produced, potent substances structurally related to fentanyl. Fentanyl is approximately 100 times more potent than morphine, and the substances structurally related to fentanyl that DEA is temporarily controlling also tend to be potent substances. Typically, these substances are manufactured outside the United States by clandestine manufacturers and then smuggled into the United States.

After discussion, ***Dr. Gillespie moved, seconded by Mr. Wells, to designate the additional substances as named in the DEA Interim Final Rule published in the Federal Register on February 6, 2018, and amend Section 44-53-190 of the S.C. Controlled Substances Act for consistency with the Federal scheduling***. Board Order (Attachment 8-2)

Item 9: Agency Affairs

Acting Director Wilson introduced Dr. Lillian Peake, Deputy Director for Public Health, who gave an update on influenza in S.C.

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

Mr. Batts asked for a Motion for an Executive Session for discussion of a personnel matter. ***Mr. Joye moved, seconded by Mr. Wells, to go into Executive Session. The Board voted and Motion carried.***

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

Being no further business, Mr. Batts adjourned the meeting.

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

Respectfully submitted,

L. Clarence Batts, Jr.

L. Clarence Batts, Jr., Secretary

Minutes approved this 27th day of March 2018.

ATTEST:

David W. Gillespie, M.D.

Attachments

0-1	Agenda
0-2	Attendance Roster
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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	Public Hearing for Notice of Final Regulation for R.61-78, Standards for Licensing Hospices
4-2	Public Hearing Sign-in Sheet
4-3	Verbatim Transcript for Public Hearing on R.61-78
5-1	Public Hearing for Notice of Final Regulation amending R.61-63, Radioactive Materials (Title A)
5-2	Public Hearing Sign-in Sheet
5-3	Verbatim Transcript for Public Hearing on R.61-63
6-1	Notice of Proposed Regulation amending Regulation 30-14, Administrative Procedures Act
7-1	Placement of Seven Fentanyl related Substances into Schedule I for Controlled Substances
7-2	Board Scheduling Order
8-1	Placement of Fentanyl Related Substances into Schedule I for Controlled Substances
8-2	Board Scheduling Order