

BOARD:
Allen Amsler
Chairman
Mark S. Lutz
Vice Chairman
Ann B. Kirol, DDS
Secretary



Catherine E. Heigel, Director

Promoting and protecting the health of the public and the environment

BOARD:
R. Kenyon Wells
Charles M. Joye II, P.E.
L. Clarence Batts, Jr.
John O. Hutto, Sr., MD
William Lee Hewitt, III

*South Carolina Board of Health and Environmental Control
2600 Bull Street, Columbia, South Carolina 29201 · Telephone: (803) 898-3309 · Facsimile: (803) 898-3393 lucaslm@dhec.sc.gov*

South Carolina Board of Health and Environmental Control

May 12, 2016

The South Carolina Board of Health and Environmental Control met on Thursday, May 12, 2016, at 10:00 a.m. in the Board Room of 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, Chairman, Member-at-Large
Charles M. Joye, II, P.E., 3rd District
John O. Hutto, Sr., MD, 6th District

In attendance via phone:
Mark S. Lutz, Vice-Chairman, 1st District
L. Clarence Batts, 4th District
William Lee Hewitt, III, 7th District

Absent:
Ann B. Kirol, DDS, Secretary, 5th District
R. Kenyon Wells, 2nd District

Also in attendance were Catherine E. Heigel, Director; W. Marshall Taylor, Jr., General Counsel; Lisa L. Longshore, Clerk; Department staff and members of the public. (Attachment 0-2)

Chairman 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.

Chairman Amsler welcomed Mr. Hewitt back to the Board after a leave of absence.

Item 1: Minutes of March 10, 2016 meeting (Attachment 1-1)

Dr. Hutto moved, seconded by Mr. Joye, to approve the minutes as presented for the March 10, 2016 meeting. The Board voted and Motion carried.

Item 2: Administrative and Consent Orders issued by Environmental Affairs (Attachment 2-1)

Ms. Robin Stephens, Compliance Assistance and Enforcement, Environmental Affairs, stated seven (7) Administrative Orders and one hundred twenty-two (122) Consent Orders had been issued with total penalties of \$374,896.

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

Item 3: Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation (Attachment 3-1)

Ms. Shelly Kelly, Deputy Director of Health Regulation, stated one (1) Administrative Order and thirteen (13) Consent Orders had been issued with total penalties of \$74,850.

The Board accepted this item as information.

Item 4: Public Hearing and Request for Final Approval - Proposed Amendment of Regulation 61-79, Hazardous Waste Management Regulations, State Register Document No. 4646, Legislative Review is not required (Attachment 4-1)

Mr. David Scaturro, Director, Division of Hazardous Waste Management, presented this item to the Board.

The Department proposed to amend S.C. Regulation 61-79, Hazardous Waste Management Regulations, to adopt four final rules published in the Federal Register by the United States Environmental Protection Agency (EPA).

The Department is proposing to amend R.61-79 as follows:

- to adopt the “Hazardous Waste Electronic Manifest System; Final Rule,” published on February 7, 2014 at 79 FR 7518-7563;
- to adopt the “Revisions to the Export Provisions of the Cathode Ray Tube (CRT) Rule,” published on June 26, 2014 at 79 FR 36220-36231;
- to adopt the “Revisions to the Definition of Solid Waste,” published on January 13, 2015 at 80 FR 1694-1814;
- to adopt the “Vacatur of the Comparable Fuels Rule and the Gasification Rule,” published on April 8, 2015 at 80 FR 18777-18780.

Adoption of these federal amendments is required to comply with Federal law and will bring R.61-79 into conformity with the Federal regulation.

A public hearing was conducted and no one requested the opportunity to speak. (Attachment 4-2)

After discussion, *Dr. Hutto moved, seconded by Mr. Batts, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-79, Hazardous Waste*

Management Regulations and approve it for publication in the State Register as final. The Board voted and Motion carried.

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 4-3)

Item 5: Placement of AH-7921 into Schedule I for Controlled Substances (Attachment 5-1)

Ms. Rachel Richmon, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of laws. Section 44-53-160 is titled "Manner in which changes in schedule of controlled substances shall be made." Pursuant to § 44-53-160, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule I substances are listed in § 44-53-190. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate a substance as a controlled substance if the federal government has so designated.

§ 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairman of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

The U.S. Department of Justice, Drug Enforcement Administration (DEA), published on April 14, 2016, its final order scheduling the substance AH-7921 (Systematic IUPAC Name: 3,4-dichloro-N[(1dimethylamino)cyclohexylmethyl]benzamide), including its Isomers, esters, ethers, salts, and salts of isomers, esters and ethers, into schedule I of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of these synthetic opioids into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety.

On May 8, 2015, the Secretary General of the United Nations advised the U.S. Secretary of State that AH-7921 was added to schedule I of the Single Convention on Narcotic Drugs, 1961, during the 58th session of the Commission on Narcotic Drugs. As a signatory Member State to the Single Convention on Narcotic Drugs, the United States is obligated to control AH-7921 under its national drug control legislation.

AH-7921 is an N-substituted cyclohexylmethyl benzamide developed in 1962 by a pharmaceutical company in the United Kingdom. AH-7921 is a u-opioid receptor agonist with analgesic activity similar to that of morphine with the potential for abuse. There have been several reports of overdoses and deaths from AH-7921 worldwide and at least one death in the United States.

According to its final order, the DEA has determined AH-7921 has no currently accepted medical use in treatment in the United States and, to meet the obligations of the Single Convention on Narcotic Drugs, 1961, should be placed in schedule I of the Controlled Substances Act effective May 16, 2016.

After discussion, Mr. Batts moved, seconded by Mr. Lutz, to designate the additional substances as named in the DEA notice published in the Federal Register on April 14, 2016, 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 Scheduling Document to General Assembly (Attachment 5-2)

Item 6: Placement of Butyryl Fentanyl and Beta-Hydroxythiofentanyl into Schedule I for Controlled Substances (Attachment 6-1)

Ms. Rachel Richmon, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of Laws. Section 44-53-160 is titled “Manner in which changes in schedule of controlled substances shall be made.” Pursuant to Section 44-53-160, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule I substances are listed in § 44-53-190. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate a substance as a controlled substance if the federal government has so designated.

§ 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant

to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairman of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

The U.S. Department of Justice, Drug Enforcement Administration (DEA), published on March 23, 2016, its notice to temporarily schedule the synthetic opioids, N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide (butyryl fentanyl) and N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide (beta-hydroxythiofentanyl), into schedule I pursuant to the scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of these synthetic opioids into schedule I of the Controlled Substances Act (CSA) is necessary to avoid an imminent hazard to the public safety. <https://www.gpo.gov/fdsys/pkg/FR-2016-03-23/pdf/2016-06468.pdf>. On May 12, 2016, the DEA published its Final Order to temporarily schedule butyryl fentanyl and beta-hydroxythiofentanyl into schedule I of the CSA, effective immediately.

The DEA is currently aware of at least 40 confirmed fatalities associated with butyryl fentanyl and 7 confirmed fatalities associated with beta-hydroxythiofentanyl.

Based on the documented case reports of overdose fatalities, the abuse of butyryl fentanyl and beta-hydroxythiofentanyl leads to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. 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.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3). A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have 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. 21 U.S.C. 812(b)(1). Available data and information for butyryl fentanyl and beta-hydroxythiofentanyl, indicates that these synthetic opioid substances have 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.

Dr. Hutto moved, seconded by Mr. Batts, to designate the additional substances as named in the DEA notice published in the Federal Register on May 12, 2016, 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 Scheduling Document to General Assembly (Attachment 6-2)

Item 7: Agency Affairs

Director Catherine Heigel reported on the following topics:

- Zika Preparedness
- Dam Program
- Budget
- Director's Awards.

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

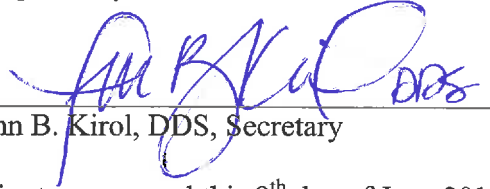
Item 8: Legal Report

Mr. Taylor responded to requests from the Board members on the status of regulations and provided a verbal report of the number of governing statutes and regulations for the agency.

Meeting adjourned.

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

Respectfully submitted,



Ann B. Kirol, DDS, Secretary

Minutes approved this 9th day of June 2016.

ATTEST:



Allen Amsler, Chairman

Attachments

- 0-1 Agenda
- 0-2 Attendance Roster
- 1-1 March 10, 2016 minutes
- 2-1 Administrative and Consent Orders issued by Environmental Affairs
- 3-1 Administrative Orders, Consent Orders and Sanctions issued by Health Regulation
- 4-1 Public Hearing Proposed Amendment of R.61-79, Hazardous Waste Management Regulations
- 4-2 Public Hearing Sign-in Sheet
- 4-3 Verbatim Transcript of Public Hearing
- 5-1 Placement of AH-7921 into Schedule I for Controlled Substances
- 5-2 Board Designation Document
- 6-1 Placement of Butyryl Fentanyl and Beta-Hydroxythiofentanyl into Schedule I for Controlled Substance
- 6-2 Board Designation Document