BOARD:
Allen Amsler
Chairman

Mark S. Lutz
Vice Chairman

Ann B. Kirol, DDS
Secretary

Catherine B. Templeton, 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

Minutes of the July 10, 2014, meeting of the
South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, July 10, 2014, at 10:00 a.m. in the Board Room at the South Carolina Department of Health and Environmental Control building, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance:

Allen Amsler, Chairman
Member-At-Large

Mark Lutz, Vice-Chairman
1st District

Ann B. Kirol, DDS, Secretary
5th District

R. Kenyon Wells
2nd District

Charles M. Joye, II, P.E.
3rd District

L. Clarence Batts by telephone
4th District

John O. Hutto, Sr., MD
6th District

William Lee Hewitt, III
7th District

Also in attendance were Catherine B. Templeton, 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 introduced Harrison Kirol as a special guest of the Board. Harrison is working to obtain his Boy Scouts Citizenship Badge which requires him to attend a meeting of a public body.

Item 1: Minutes of June 12 meeting (Attachment 1-1)

Mr. Hewitt moved, seconded by Mr. Batts, to approve the minutes as submitted for the June 12 meeting. The Board voted and Motion carried.

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

Ms. Robin Stephens, Assistant to the Deputy Director, EQC, stated one (1) Administrative Order and thirty-eight (38) Consent Orders had been issued with total penalties of $95,360.

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. Melinda Bradshaw, Health Regulation Liaison, stated one (1) Administrative Order and one (1) Consent Order had been issued with total penalties of $10,000.

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

Item 4: Placement of Tramadol Into Schedule IV for Controlled Substances (Attachment 4-1)

Ms. Stefanie Corbett, Director, Health Regulation, 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 Pursuant to § 44-53-160, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule IV substances are listed in § 44-53-250. 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 July 2, 2014, a final order to schedule tramadol, 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol (tramadol), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act (CSA), effective on August 18, 2014.

The Assistant Secretary of the Department of Health and Human Services and the Administrator of the DEA found tramadol meets the necessary findings on the potential for abuse, currently accepted medical use, and physical or psychological dependence for placement in schedule IV.

Tramadol is a centrally acting opioid analgesic that produces its primary opioid-like action through an active metabolite, referred to as the "M1" metabolite (O-desmethyltramadol). Tramadol was first approved for use in the United States by the U.S. Food and Drug Administration (FDA) in 1995 under the trade name ULTRAM®. Subsequently, the FDA approved generic, combination, and extended release tramadol products. Tramadol is manufactured and distributed in various forms which include tablets, capsules and liquid.

The abuse of tramadol products has increased over the last several years and it is used as a substitute for other opioids such as hydrocodone. The final rule imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle tramadol beginning August 18, 2014.

Ms. Cheryl Bullard, legal counsel for Bureau of Drug Control, answered questions of the Board.

After discussion, ***Mr. Wells moved, seconded by Dr. Kirol, to adopt the final scheduling of tramadol as defined in the Board package and Federal Register Volume 79, Number 127, pp. 37623-37630 and amend Section 44-53-250 by adding and designating the same substance(s) into Schedule IV of the South Carolina Controlled Substances Act. The Board voted and the Motion carried.***

Board Designation for Placement of tramadol Into Schedule IV for Controlled Substances. (Attachment 4-2)

Item 5: Proposed Repeal of Regulation 61-11, Hypodermic Devices, and Regulation 61-18, Drugs and Devices, Legislative Review is required (Attachment 5-1)

Ms. Corbett presented this item to the Board.

Regulation 61-11 was promulgated pursuant to Article 7, Title 44, Chapter 53, "Hypodermic Needles and Syringes," which was repealed by 2002 Act No. 365, Section 5, effective September 26, 2002, with the exception of Section 44-53-950. Regulation 61-18 was promulgated pursuant to Title 39, Chapter 23, "Adulterated, Misbranded or New Drugs and Devices." R.61-18 is not necessary because the items it regulates are currently addressed in state statute and federal regulation.

The proposed repeals would provide for consistency with state and federal laws. For example, the authority for Regulation 61-11 was repealed in 2002. Also, Regulation 61-18 regulation incorporates by reference those rules and regulations issued by the Food and Drug Administration, U.S. Department of Health, Education and Welfare which are contained in 21 CFR 1 through 21 CFR 129, that pertain to drugs and devices, as defined by S.C. Code Ann. Section 39-23-10 et seq., "The South Carolina Drug Act." R.61-18 is not necessary because the items it regulates are currently addressed in state statute and federal regulation.

Ms. Cheryl Bullard, legal counsel for Bureau of Drug Control, answered questions of the Board

After discussion, ***Mr. Lutz moved seconded by Dr. Kirol, to grant approval to publish a Notice of Proposed Repeal of Regulation 61-11, Hypodermic Devices, and R.61-18, Drugs and Devices, 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: Proposed Amendment of Regulation 61-58, State Primary Drinking Water Regulations, Legislative review is not required (Attachment 6-1)

Mr. Doug Kinard, Director, Division of Drinking Water Protection, presented this item to the Board.

R.61-58, State Primary Drinking Water Regulations, was promulgated to protect public health by ensuring that all public water systems in the state are properly constructed, operated, and maintained.

The United States Environmental Protection Agency (USEPA) promulgated a final rule in the Federal Register at 40 CFR Parts 141 and 142 on February 13, 2013 known as Revisions to the Total Coliform Rule. Under the new rule, there is no longer a monthly maximum contaminant level (MCL) violation for total coliform detections. Instead, the revisions require systems that have an indication of coliform contamination in the distribution system to assess the problem and take corrective action. As required by Section 1413 of the federal Safe Drinking Water Act, states must revise its public drinking water program to include regulations that are no less stringent than the federal requirements in order to retain primary enforcement responsibility for the drinking water supervision program.

4. Since the changes presented in this item are required by changes to the National Primary Drinking Water Regulations, they do not require legislative review pursuant to S.C. Section 1-23-120(H)(1).

After discussion, ***Mr. Joye moved, seconded by Mr. Lutz, to grant approval to publish a Notice of Proposed Amendment of Regulation 61-58, State Primary Drinking Water Regulations, 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: Public Hearing and Request for Final Approval – Proposed Revision of Regulation 61-93, Standards for Licensing Facilities that Treat Individuals for Pschoactive Substance Abuse and Dependence, Document No. 4464, Legislative review is required (Attachment 7-1)

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

Statutory authority for Regulation 61-93, Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence can be found in 1976 Code Section 44-7-260. The Department substantively amended the regulation May 25, 2001. The purpose of the regulation is to provide a set of minimum licensing standards for facilities that treat individuals for psychoactive substance abuse or dependence. Psychoactive substance abuse or dependence facilities provide specialized structured psychoactive substance abuse/dependence care/treatment, including outpatient services such as narcotic and methadone treatment programs, and inpatient services such as residential treatment and/or detoxification.

After a review of the regulation as required by 1976 Code Ann Section 1-23-120(J), the Department proposes the revision to ensure compliance with current construction requirements. The proposed new amendments herein also include the Department's Bureau of Health Facilities Licensing's effort to incorporate current urine testing, emergency procedures, design, and fire and life safety sections of the regulation.

A public hearing was conducted, however, no one in attendance spoke. (Attachment 7-2)

After discussion, ***Dr. Hutto moved, seconded by Mr. Lutz, to find for the need and reasonableness of the Proposed Regulation 61-93, Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse and Dependence, and approve it for submission to the Legislature for review. The Board voted and Motion carried.***

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 7-3)

Item 8: Public Hearing and Request for Final Approval – Proposed Revision of Regulation 61-16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries (Perinatal Provisions only), Document No. 4461, Legislative review is required (Attachment 8-1)

Ms. Thompson presented this item to the Board.

The Department received approval from the Board to submit proposed amendments for the entire Regulation 61-16 on January 9, 2014. This amendment revises Section 1300, Perinatal Services, of State Register Document 4430 at http://www.scstatehouse.gov/regs/4430.docx that completed legislative review May 17, 2014. Document 4430 is effective by publication in the State Register on June 27, 2014. The proposed new amendments herein include the Department's Bureau of Health Facilities Licensing's effort to amend the Perinatal Care Sections to account for evolving practices and improve overall quality and effectiveness.

A public hearing was conducted and several persons in attendance spoke on this regulation amendment. (Attachment 8-2) The written comments that were provided to the Clerk by the speakers at the public hearing are included in the permanent record. (Attachment 8-3)

After discussion, ***Dr. Hutto moved, seconded by Dr. Kirol, to go into Executive Session for the purpose receiving legal advice pertaining to proposed amendment of R.61-16. 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.

After further discussion, ***Dr. Hutto moved, seconded by Mr. Batts, to find for the need and reasonableness of the Proposed Regulation 61-16, Minimum Standards for Licensing Hospitals and General Infirmaries (Perinatal Provisions only), and approve for submission to the Legislature for review with the following revisions that were raised, considered, or discussed by public comment: a. change Board Certified to Board Eligible or Board Certified in 61-16.1306.C. The Board voted and the Motion carried.***

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 8-4)

Item 9: Agency Affairs

Director Templeton reported on agency tracking systems and the re-instatement of the Certificate of Need Program.

Item 10: Legal Report

No report.

Dr. Hutto moved, seconded by Dr. Kirol, to go into Executive Session for the purpose of discussing the reinstatement of the CON Program under the attorney-client privilege. 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.

Chairman Amsler adjourned the meeting.

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

Respectfully submitted,

Ann B. Kirol, DDS, Secretary

Minutes approved this 7th day of August 2014.

ATTEST:

Mark Lutz, Vice-Chairman

Attachments

0-1 Agenda
0-2 Attendance Roster
1-1 Minutes of June 12 meeting
2-1 Administrative Orders, Consent Orders issued by Environmental Affairs
3-1 Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation
4-1 Placement of tramadol Into Schedule IV for Controlled Substances
5-1 Proposed Repeal of R.61-11, Hypodermic Devices and 61-18, Drugs and Devices
6-1 Proposed Amendment of R.61-58, Primary Drinking Water Regulations
7-1 Public Hearing – Proposed Revision of R.61-93, Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse and Dependence
7-2 Public Hearing Sign-in Sheet
7-3 Verbatim Transcript of Public Hearing
8-1 Public Hearing – Proposed Amendment of R.61-16, Minimum Standards for Licensing Hospitals and General Infirmaries (Perinatal Provisions only)
8-2 Public Hearing Sign-in Sheet
8-3 Written Statement from Public Hearing
8-4 Verbatim Transcript of Public Hearing