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Allen Amsler
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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 September 11, 2014, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, September 11, 2014, 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

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
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.

Item 1: Minutes of August 7 meeting (Attachment 1-1)

Mr. Joye moved, seconded by Dr. Kirol, to approve the minutes as submitted for the August 7 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 four (4) Administrative Orders and sixty-seven (67) Consent Orders had been issued with total penalties of \$128,293.75.

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. Jamie Shuster, Director, Public Health, stated one (1) Administrative Order and two (2) Consent Orders had been issued with total penalties of \$19,900.

The Board accepted this item as information.

Item 4: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II for Controlled Substances (Attachment 4-1)

Ms. Lisa Thomson, Director, 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 this section, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule II substances are listed in Section 44-53-210. 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.

The U.S. Department of Justice, Drug Enforcement Administration (DEA), published on August 22, 2014, a final rule to reschedule hydrocodone combination products (HCPs) from schedule III to schedule II, effective on October 6, 2014. The Administrator of the DEA found HCPs meet the necessary findings on the high potential for abuse, currently accepted medical use in treatment in the U.S., and severe physical or psychological dependence for placement in schedule II.

Hydrocodone is the most frequently prescribed opioid in the United States and was listed in schedule II of the CSA, as well as Section 44-53-210 (Schedule II) of the S.C. Controlled Substances Act, in 1971. However, hydrocodone was listed in schedule III when formulated with specific amounts of an isoquinoline alkaloid of opium or one or more therapeutically active nonnarcotic ingredients. Recently, the U.S. Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services (HHS) conducted scientific and medical evaluations leading to the recommendation that HCPs be rescheduled into schedule II of the CSA based on several findings, including: (1) individuals are taking HCPs in amounts sufficient to create a

hazard to their health or the safety of others; (2) there is significant diversion of HCPs; and (3) individuals are taking HCPs on their own initiative rather than on the basis of medical advice.

The final rule imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule II controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle HCPs beginning October 6, 2014. Board rescheduling document is included as Attachment 4-2.

After discussion, *Mr. Wells moved, seconded by Dr. Kirol, to adopt the final scheduling of the hydrocodone combination products as defined in the Board package and Federal Register Volume 79, Number 163, pp. 49661-49682 and amend Section 44-53-230 of the South Carolina Controlled Substances Act by removing paragraphs (e)(3) and (4) and redesignating paragraphs (e)(5) through (8) as (e)(3) through(6), respectively of the South Carolina Controlled Substances Act. The Board voted and Motion carried.*

Item 5: Public Hearing and Request for Final Approval – Proposed Repeal of Regulation 61-11, Hypodermic Devices and Regulation 61-18, Drugs and Devices, State Register Document No. 4468, Legislative Review is required (Attachment 5-1)

Ms. Thomson presented this item to the Board, also.

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 Sections 44-53-930, 950 and 960 which address retail sales by a pharmacist and penalties. Regulation 61-18 was promulgated pursuant to Title 39, Chapter 23, “Adulterated, Misbranded or New Drugs and Devices.”

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.” Regulation 61-18 is not necessary because the items it regulates are currently addressed in state statute and federal regulation.

A public hearing was conducted; however, no one in attendance spoke. (Attachment 5-2)

After discussion, *Mr. Lutz moved, seconded by Mr. Batts, to find for the need and reasonableness of the Proposed Repeal of Regulation 61-11, Hypodermic Devices, and Regulation 61-18, Drugs and Devices, 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 5-3)

Item 6: Public Hearing and Request for Final Approval – Proposed Amendment of Regulation 61-62, Air Pollution Control Regulations and Standards, and the South Carolina Air Quality Implementation Plan (SIP), State Register Document No. 4465, Legislative Review is not required (Attachment 6-1)

Mr. Robbie Brown, Director, Division of Air Assessment and Regulation, presented this item to the Board.

Pursuant to the Clean Air Act, 42 U.S.C. Sections 7407, 7410, 7413, and 7416, and the South Carolina Pollution Control Act, 1976 Code Section 48-1-10 et seq., the Department must ensure national primary and secondary ambient air quality standards are achieved and maintained in South Carolina. No state may adopt or enforce an emission standard or limitation less stringent than these federal standards or limitations. 42 U.S.C. Section 7416.

The United States Environmental Protection Agency (“EPA”) promulgated amendments to national air quality standards in 2013. The recent federal amendments include clarification, guidance and technical revisions to state implementation plan (“SIP”) requirements promulgated pursuant to 42 U.S.C. Sections 7410 & 7413, New Source Performance Standards (“NSPS”) mandated by 42 U.S.C. Section 7411, and federal National Emission Standards for Hazardous Air Pollutants (“NESHAP”) for Source Categories.

The Department is amending Regulation 61-62.5, Standard No. 2, *Ambient Air Quality Standards* to codify recent federal amendments to the National Ambient Air Quality Standards for Fine Particulate Matter (“PM_{2.5}”), Sulfur Dioxide (“SO₂”), and Nitrogen Dioxide (“NO₂”) set forth in 40 C. F. R. Part 50.

Additionally, the Department proposed to amend Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards* and Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (“NESHAP”) for Source Categories* to adopt federal amendments to these standards promulgated from January 1, 2013 through December 31, 2013.

South Carolina industries are already subject to these national air quality standards as a matter of federal law. Thus, there will be no increased cost to the State or its political subdivisions resulting from codification of these amendments to federal law. The State of South Carolina is already reaping the environmental benefits of these amendments.

In accordance with 1976 Code Section 1-23-120(H), legislative review is not required because the Department proposes promulgating the amendments to maintain compliance with federal law. As such, neither a preliminary assessment report nor a preliminary fiscal impact statement is required.

A public hearing was conducted; however, no one in attendance spoke. (Attachment 6-2)

After discussion, *Mr. Batts moved, seconded by Mr. Hewitt, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-62, Air Pollution Control*

Regulations and Standards, and the South Carolina Air Quality Implementation Plan (SIP), and approve for publication as final in the State Register. The Board voted and Motion carried.

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 6-3)

Item 12: Proposed Amendment of Regulation 61-62, Air Pollution Control Regulations and Standards, and the South Carolina Air Quality Implementation Plan (SIP), Legislative Review is required (Attachment 12-1)

Mr. Brown presented this item to the Board, also.

Pursuant to the Clean Air Act, 42 U.S.C. Section 7401 et seq., and the South Carolina Pollution Control Act, 1976 Code Section 48-1-10 et seq., the South Carolina Department of Health and Environmental Control (“Department”) proposes to amend South Carolina Regulation 61-62, *Air Pollution Control Regulations and Standards*, and the State Implementation Plan (“SIP”).

The Department also proposes to amend Regulation 61-62.5, Standard No. 1, *Emissions from Fuel Burning Operations* to exempt owners or operators of propane fired units from having to maintain a startup and shutdown log in order to be consistent with the same exemption already allowed for owners or operators of natural gas fired units.

The Department also proposes to amend Regulation 61-62.5, Standard No. 2, *Ambient Air Quality Standards* to remove from the list of pollutants Gaseous Fluorides (as hydrogen fluoride (HF)). HF is a federal Hazardous Air Pollutant or HAP. It has no primary or secondary national ambient air quality standard and, therefore, is more appropriately regulated under Regulation 61-62.5, Standard No. 8, *Toxic Air Pollutants* rather than Standard No. 2.

The Department also proposes to repeal Regulation 61-62.5, Standard No. 5.1, *Best Available Control Technology (BACT)/Lowest Achievable Emission Rate (LAER) Applicable to Volatile Organic Compounds*. Because other regulations such as Regulation 61-62.5, Standard No. 5, *Volatile Organic Compounds*; Regulation 61-62.5, Standard No. 7, *Prevention of Significant Deterioration*; and Regulation 61-62.5, Standard No. 7.1, *Nonattainment New Source Review* are available to limit VOC emissions, the Department finds that Regulation 61-62.5, Standard No. 5.1 is no longer necessary.

The Department also proposes to amend Regulation 61-62.5, Standard No. 7, *Prevention of Significant Deterioration* to modify the criteria for creditability of an increase or decrease in actual emissions and modify various text to create consistency with 40 Code of Federal Regulations (CFR) 52.21, *Prevention of Significant Deterioration of Air Quality*.

The Department also proposes to amend Regulation 61-62.5, Standard No. 7.1, *Nonattainment New Source Review (NSR)* to add timing flexibility language to the section of the regulation governing the calculation of emission offsets. Because of public notice requirements, the Department was unable to submit these revisions for approval as part of the “2013 General

Assembly Package” but agreed the changes would be submitted for approval as part of the current set of revisions (2014 General Assembly Package).

The Department also proposes to amend Regulation 61-62.5, Standard No. 8, *Toxic Air Pollutants* to add maximum allowable concentration time frame of “24-Hour Average” to table and add Hydrogen Fluoride (HF) as a pollutant (See item 4 for justification).

The Department also proposes to amend Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards* to correct an error in punctuation.

The Department also proposes to amend Regulation 61-62.70, *Title V Operating Permit Program* to make a change to Section 62.70.5(c) to correct a unit of measurement error.

The Department also proposes to amend Regulation 61-62 to include corrections for consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of Regulation 61-62 as necessary.

Mr. Brown provided an Addendum to the Board package correcting Attachment F of the package. (Attachment 12-2)

After discussion, *Mr. Lutz moved, seconded by Dr. Kirol, to grant approval to publish a Notice of Proposed Amendment of Regulation 61-62, Air Pollution Control Regulations and Standards and the South Carolina Air Quality Implementation Plan (SIP), 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 the Motion carried.*

Item 7: Public Hearing and Request for Final Approval – Proposed Amendment of Regulation 61-58, State Primary Drinking Water Regulations, Document No. 4469, Legislative Review is not required (Attachment 7-1)

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. Since the changes presented in this package 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). Neither a fiscal impact statement nor assessment report are required.

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

After discussion, *Mr. Hewitt moved, seconded by Dr. Hutto, find for the need and reasonableness of the Proposed Amendment of Regulation 61-58, State Primary Drinking Water Regulations, and approve for publication as final in the State Register. 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: Proposed Amendment of Regulation 61-47, Shellfish, Legislative Review is required
(Attachment 8-1)

Mr. Chuck Gorman, Director, Division of Water Monitoring, Assessment and Protection, presented this item to the Board.

Pursuant to S.C. Code Section 44-1-140, the Department is authorized to promulgate and enforce rules and regulations for public health for the classification of waters and for the safety and sanitation in the harvesting, storing, processing, handling and transportation of mollusks, fin fish and crustaceans. Regulation 61-47, Shellfish, prescribes requirements for producers, processors, harvesters, and transporters of shellfish and is intended to protect the health of consumers of molluscan shellfish (oysters and clams).

The Department proposed to amend R.61-47, Shellfish, to update the regulation to be consistent with the latest version of the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (2013, currently being finalized for publication) and improve the regulation. The amendments include changes to certain control measures intended to limit the growth of pathogens after the harvest of shellfish, a simplification of the retagging requirements for certified reshippers, a requirement for certified shippers to receive annual training for the safe and sanitary handling of shellfish, and stylistic changes to correct for spelling, clarity, readability, grammar, and codification for overall improvement of the text of the regulation.

After discussion, *Dr. Kirol moved, seconded by Mr. Lutz, to grant approval to publish a Notice of Proposed Amendment of Regulation 61-47, Shellfish, 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 the Motion carried.*

Item 9: Proposed Amendment of Regulation 61-67, Standards for Wastewater Facility Construction, Legislative Review is required (Attachment 9-1)

Mr. Jeff DeBessonnet, Director, Division of Water Facilities Permitting, presented this item to the Board.

Pursuant to S.C. Code Sections 48-1-50 and 48-1-110, the Department proposes to amend R.61-67, *Standards for Wastewater Facility Construction*. The purpose of this amendment is to reduce unit loading flows in Appendix A by 25 percent based on the knowledge of water savings fixtures and improved designs of sewer collection systems. For ease of implementation, the loading was rounded to the nearest whole number. The proposed revisions also include having a service connection definition similar to the definition for a drinking water service connection, reducing the number of plans and other documents that need to be submitted, revisions to streamline industrial pump and haul operations and allowing issuance of a treatment plant permit coincident with a discharge permit.

After discussion, *Mr. Joye moved, seconded by Mr. Wells, to grant approval to publish a Notice of Proposed Amendment of Regulation 61-67, Standards for Wastewater Facility Construction, 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 the Motion carried.*

Item 10: Proposed Amendment of Regulation 61-65, Particle Accelerators (Title C), Legislative Review is required (Attachment 10-1)

Mr. Charles Ditmer, Director, Division of Electronic Products, presented this item to the Board.

Regulation 61-65, *Particle Accelerators (Title C)* is authorized by the Atomic Energy and Radiation Control Act at S.C. Code Ann. Section 13-7-10 *et seq.* and was last amended on July 27, 1984. This regulation provides for radiation control and applies to all persons who receive, possess, use, transfer, own, or acquire any particle accelerator producing device. The cost of running the program to implement the provisions of this regulation is funded by the collection of fees from the regulated community as mandated by the Act.

As a result of the 2012, statutory five-year review of this regulation and due to advancing technologies, the Department has determined it necessary to substantially amend Regulation 61-65. Proposed changes will strengthen equipment performance standards. Language changes are being proposed that will result in clarifying many sections of the regulation by making them more specific, better organized, and the intent of the regulation more clear. In addition, revisions may result in amending the fee structure in accordance with the governing statute.

After discussion, *Mr. Lutz moved, seconded by Mr. Batts, to grant approval to publish a Notice of Proposed Amendment of Regulation 61-65, Particle Accelerators (Title C), 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 the Motion carried.*

Item 11: Proposed Revision of Regulation 61-84, Standards for Licensing Community Residential Care Facilities, Legislative Review is required (Attachment 11-1)

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

Statutory authority for Regulation 61-84, *Standards for Licensing Community Residential Care Facilities* resides in 1976 Code Sections 44-7-260. Community residential care facilities are facilities that offer room and board and unlike a boarding house, provide/coordinate a degree of personal care. These facilities are designed to accommodate residents' changing needs and preferences, maximize residents' dignity, autonomy, privacy, independence, and safety, and encourage family and community involvement. The proposed new amendments herein include the Department's Bureau of Health Facilities Licensing's effort to incorporate provisions relating to statutory mandates, medication management, meal service, emergency procedures, design and construction, fire and life safety, and overall licensing requirements for community residential care facilities. In addition, corrections have been made for clarity and readability, grammar, references, codification and overall improvement to the text of the regulation.

After discussion, *Mr. Batts moved, seconded by Dr. Kirol, to grant approval to publish a Notice of Proposed Amendment of Regulation 61-84, Standards for Licensing Community Residential Care Facilities, 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 the Motion carried.*

Item 13: Agency Affairs

No Report.

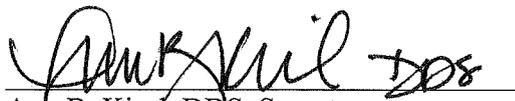
Item 14: Legal Report

No report.

Chairman Amsler adjourned the meeting.

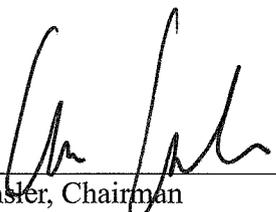
All referenced attachments are made a permanent part of these minutes.

Respectfully submitted,


Ann B. Kirol, DDS, Secretary

Minutes approved this 9th day of October 2014.

ATTEST:


Allen Amster, Chairman

Attachments

- 0-1 Agenda
- 0-2 Attendance Roster
- 1-1 Minutes of August 7 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 Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II for Controlled Substances
- 4-2 Scheduling by Board of Health and Environmental Control
- 5-1 Public Hearing – Proposed Repeal of Regulation 61-11, Hypodermic Devices and Regulation 61-18, Drugs and Devices, Document No. 4468
- 5-2 Sign-in Sheet for Public Hearing
- 5-3 Verbatim Transcript of Public Hearing
- 6-1 Public Hearing – Proposed Amendment of Regulation 61-62, Air Pollution Control Regulations and Standards, and SC SIP, Document No. 4465
- 6-2 Sign-in Sheet for Public Hearing
- 6-3 Verbatim Transcript of Public Hearing
- 7-1 Public Hearing – Proposed Amendment of Regulation 61-58, State Primary Drinking Water Regulations, Document No. 4469
- 7-2 Sign-in Sheet for Public Hearing
- 7-3 Verbatim Transcript of Public Hearing
- 8-1 Proposed Amendment of Regulation 61-47, Shellfish
- 9-1 Proposed Amendment of Regulation 61-67, Standards for Wastewater Facility Construction
- 10-1 Proposed Amendment of Regulation 61-65, Particle Accelerators (Title C)
- 11-1 Proposed Amendment of Regulation 61-84, Standards for Licensing Community Residential Care Facilities
- 12-1 Proposed Amendment of Regulation 61-62, Air Pollution Control Regulations and Standards, and SC SIP
- 12-2 Addendum to Board Package Attachment F