



Mark R. Elam, Chairman
Jim P. Creel, Jr., Vice-Chairman
Charles M. Joye, II, P.E., Secretary
J.B. (Sonny) Kinney

Board:
Seema Shrivastava-Patel
Richard V. Lee, Jr.
Alex A. Singleton

Minutes of the November 12, 2020, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, November 12, 2020, at 10:00 a.m. in the Boardroom (#3420) 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:

J.B. (Sonny) Kinney, 1st District
Seema Shrivastava-Patel, 2nd District
Robert Morgan, MD, 4th District
Richard V. Lee, Jr., 5th District

In attendance via telephone
Jim P. Creel, Jr., Vice-Chairman
Charles M. Joye, II, P.E., 3rd District
Alex A. Singleton, 6th District

In attendance later in the meeting
Mark Elam, Chairman

Also, in attendance were W. Marshall Taylor, Acting Director, Rupinderjit S. Grewal, Legal Counsel; M. Denise Crawford, Clerk; Department staff; and members of the public. The meeting was also available via Livestream.

Chairman Elam was absent, and Vice Chairman Creel attended by telephone, and Mr. Lee assumed the Chair to conduct the meeting. Mr. Lee 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 October 8, 2020 meeting (Attachment 1-1)

Mr. Kinney moved, seconded by Dr. Morgan, to approve the minutes as presented. The Board voted and Motion carried.

Item 2: Agency Affairs

W. Marshall Taylor, Jr., Acting Director, recognized LA Williams for almost fifty years of service and contribution to public health and environmental protection.

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

Dr. Brannon Traxler, Acting Director of Public Health, provided an update on the COVID 19 (Coronavirus).

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

Stephen White, Director of Division of Immunization, provided an update on the COVID 19 (Coronavirus) vaccine.

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

Item 3: Administrative Orders and Consent Orders issued by Healthcare Quality (Attachment 3-1)

Ms. Bentley White, Director of Policy and Communications, Healthcare Quality, stated that for this reporting period, five (5) Consent Orders with assessed civil penalties totaling \$11,650.00 have been issued.

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

Item 4: Administrative Orders and Consent Orders issued by Environmental Affairs (Attachment 4-1)

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, eighty-two (82) Consent Orders with assessed civil penalties totaling \$115,830.00 and three (3) Administrative Orders with no assessed civil penalties have been issued.

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

Item 5: Placement of Oliceridine in Schedule II for Controlled Substances (Attachment 5-1)

Ms. Christie Frick, Director, Prescription Monitoring Program, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule II substances are listed in Section 44-53-210 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina Section 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 Chairmen 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 United States Food and Drug Administration ("FDA") approved a new drug application for oliceridine for intravenous use on August 7, 2020. Oliceridine is chemically known as N-[(3-methoxythiophen-2-yl)methyl] (2- [(9R)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl)amine fumarate. The Department of Health and Human Services ("HHS") provided the Drug Enforcement Administration ("DEA") with a scheduling recommendation to place oliceridine in schedule II of the Controlled Substances Act ("federal CSA"). In accordance with the federal CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, the DEA issued an interim final rule placing oliceridine, including its salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule II of the CSA, effective October 30, 2020 in *Federal Register*, Volume 85, Number 211, pages 68749-68753; <https://www.govinfo.gov/content/pkg/FR-2020-10-30/pdf/2020-22762.pdf>.

Oliceridine, chemically known as N-[(3- methoxythiophen-2-yl)methyl] (2- [(9R)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl)amine fumarate, is a new molecular entity with Central Nervous System ("CNS") depressant properties. On November 2, 2017, Trevena, Inc. ("Sponsor") submitted an initial new drug application ("NDA") for oliceridine that was subsequently resubmitted on February 7, 2020. On August 7, 2020, FDA approved the NDA for oliceridine for medical use as an intravenous drug for the management of acute pain severe enough to require an intravenous opioid analgesic and for patients for whom alternative treatments are inadequate.

On July 27, 2020, DEA received from HHS a scientific and medical evaluation entitled "Basis for the Recommendation to Control Oliceridine and its Salts in Schedule II of the Controlled Substances Act" and a scheduling recommendation. This document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of oliceridine, along with a recommendation from HHS to control oliceridine and its salts under schedule II of the CSA. DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that oliceridine meets the 21 U.S.C. 812(b)(2) criteria for placement in schedule II of the CSA.

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and

recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 812(b)(2), finds that:

1) Oliceridine Has a High Potential for Abuse.

Oliceridine is a mu-opioid receptor agonist and produces behavioral effects that are similar to those of morphine, a schedule II opioid substance, in animals and humans. A self-administration study in animals demonstrated that oliceridine produced self-administration that was comparable to morphine. Additionally, a drug discrimination study in animals demonstrated that oliceridine generalized to morphine, indicating that it has mu-opioid receptor agonist properties. Results from a human abuse potential ("HAP") study showed that oliceridine produces positive subjective effects as well as adverse events such as euphoria, similar to that of morphine, a schedule II substance with a high potential for abuse. Lastly, clinical studies in healthy individuals indicate that oliceridine produces abuse-related adverse events such as euphoria and sedation. These data collectively indicate that oliceridine has a high potential for abuse similar to the schedule II substance morphine.

2) Oliceridine Has a Currently Accepted Medical Use in the United States.

FDA recently approved a NDA for oliceridine for the management of acute pain severe enough to require an intravenous opioid analgesic and for patients for whom alternative treatments are inadequate. Thus, oliceridine has a currently accepted medical use in treatment in the United States.

3) Abuse of Oliceridine May Lead to Severe Physical Dependence or Psychological Dependence.

Chronic administration of oliceridine in rats followed by drug discontinuation produced classic opioid withdrawal signs, similar to that of schedule II drug morphine. This study would indicate oliceridine's potential to cause physical dependence similar to that of morphine. Oliceridine also produces self-administration in rats and positive subjective responses in a HAP study. These results parallel those produced by morphine and suggest that oliceridine can also produce psychological dependence. These data collectively suggest that oliceridine abuse may lead to psychological and physical dependence similar to that of schedule II opioids.

The Acting Administrator of the Drug Enforcement Administration has concluded that oliceridine, including its salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, warrants control in schedule II of the CSA.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommended the addition of oliceridine to Schedule II for controlled substances in South Carolina and the amendment of Section 44-53-210 of the South Carolina Code of Laws to include:

() Oliceridine N-[(3- methoxythiophen-2-yl)methyl] (2- [(9R)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl)amine fumarate.

After discussion, **Ms. Shrivastava-Patel moved, seconded by Dr. Morgan, to designate the additional substances names in the DEA Notice published in the Federal Register**

on October 30, 2020, and amend Section 44-53-210 of the S.C. Controlled Substances Act for consistency with the Federal scheduling.

Item 6: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-56, Onsite Wastewater Systems; Proposed Repeal of Regulation 61-55, Septic Tank Site Evaluation Fees; Proposed Repeal of Regulation 61-56.1, License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets; and Proposed Repeal of Regulation 61-56.2, Licensing of Onsite Wastewater Systems Master Contractors, Document No. 4979 (Attachment 6-1)

A Public Hearing was conducted concerning the Regulation. Mr. David Vaughan, Director, Division of Onsite Wastewater, Environmental Affairs, presented this item to the Board.

The Bureau of Environmental Health Services ("Bureau") proposed the Notice of Final Regulation amending R.61-56, *Onsite Wastewater Systems*; and repealing R.61-55, *Septic Tank Site Evaluation Fees*; R.61-56.1, *License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets*; and R.61-56.2, *Licensing of Onsite Wastewater Systems Master Contractors*, and merging these regulations' requirements, as amended, into R.61-56. Legal authority resides in S.C. Code Sections 44-1-140(11), 44-1-150, 44-55-825, 44-55-827, and 48-1-10 *et seq.*, which enable the Department of Health and Environmental Control ("Department") to promulgate regulations related to the disposal of sewage. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these amendments.

Pursuant to R.61-56, the Department provides oversight for safe treatment and disposal of domestic wastewater to protect the health of families and communities. In accordance with R.61-55, R.61-56, R.61-56.1, and R.61-56.2, the Department issues onsite wastewater contractor licenses, permits to construct, and approvals to operate for individual onsite wastewater treatment systems (septic systems).

The Department is amending R.61-56, *Onsite Wastewater Systems*, to add new system standards, clarify and amend definitions, and clarify and update selected sections. The amendments will modernize the regulation and streamline permitting procedures to address needed updates in administering the Onsite Wastewater program.

The Department is also amending provisions of R.61-56.1 and R.61-56.2 and merging R.61-56.1 and R.61-56.2 into R.61-56 to improve efficiency and clarity for regulated entities and the public. This will entail repealing R.61-56.1 and R.61-56.2 and simultaneously adding their provisions, as amended, to R.61-56. The amendments include changes to licensing requirements for pumpers and haulers currently under R.61-56.1. The amendments will revise provisions currently contained in R.61-56.2 to implement a tiered licensing program to establish improved competency of onsite wastewater system contractors/installers. This approach includes new requirements for examination and continuing education. In addition, because R.61-56.1 and R.61-56.2 are being combined with R.61-56, previously separate enforcement provisions will also be consolidated and updated for clarity and to improve administration of the Onsite Wastewater program.

The revisions will expand existing site evaluation options and allow more streamlined permit processing by allowing an applicant to submit a proposed system layout from a licensed

Professional Soil Classifier ("PSC") or other licensed person qualified by statute to practice professional soil classifying. Under this regulation, applicants desiring to install systems for a subdivision will be required to submit third-party soils work from a PSC or other licensed person qualified by statute to practice professional soil classifying. That person would then have the option to either submit a proposed system layout under one of the system standards established within R.61-56 or give the soils report to a Registered Professional Engineer to design a specialized septic system through the 610 Standard. Outside of the subdivision context, applicants for conventional systems will retain the option to use a qualified third party or allow the Department to conduct a soil evaluation and prepare a system layout. The expanded options and enhanced involvement of third-party contractors will serve to streamline and expedite the permit process for the Department and the regulated community.

In the interest of efficiency, the Department is repealing R.61-55 and adding its provisions to R.61-56. The amendments related to R.61-55 include amendments to definitions and other changes as necessary to facilitate merging this regulation into R.61-56.

The Department has also made other corrections for clarity and readability, grammar, punctuation, codification, and regulation text improvement.

The Department had a Notice of Drafting published in the March 27, 2020, *State Register*.

The Bureau held twenty-two (22) stakeholder engagement meetings between August 2, 2017, and July 1, 2020, to solicit input, including open-invitation public meetings, in person and virtually, and individual interest group discussions. A total of three hundred and seventy-five (375) stakeholders attended. The Bureau utilized the Department's website and agency calendar to advertise these meetings, as well as mailed invitation cards and emailed invitations to identified stakeholders. The Bureau received favorable feedback from these meetings.

Department staff conducted an internal review of the amendments on July 8, 2020.

The Department had a Notice of Proposed Regulation published in the August 28, 2020, *State Register*. The Department received public comments from 16 people by the September 28, 2020, close of the public comment period. One comment also included a petition with a list of signatories in support of the comment. A summary of these public comments received and Department responses were provided to the Board.

After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board in the August 13, 2020, Board meeting and published in the August 28, 2020, *State Register*. Descriptions of the changes and a Summary of Public Comments and Department Responses were presented to the Board.

The Bureau of Environmental Health Services requested the Board find need and reasonableness of the amendment of R.61-56, *Onsite Wastewater Systems*; and the repeals of R.61-55, *Septic Tank Site Evaluation Fees*; R.61-56.1, *License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets*; and R.61-56.2, *Licensing of Onsite Wastewater Systems Master Contractors*, for submission to the General Assembly.

Mr. Vaughn provided revised language for the proposed amendment based on public comments received. (Attachment 6-3)

Mr. Grewal opened the meeting up for public comments on this matter, the board. No comments were received and the public hearing was closed.

After discussion, **Mr. Singleton moved, seconded by Dr. Morgan, that based on the public hearing and documents herein, move to find for the need and reasonableness of the Proposed Amendment of Regulation 61-56, Onsite Wastewater Systems; Proposed Repeal of Regulation 61-55, Septic Tank Site Evaluation Fees; Proposed Repeal of Regulation 61-56.1, License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets; and Proposed Repeal of Regulation 61-56.2, Licensing of Onsite Wastewater Systems Master Contractors, Document No. 4979, and grant approval for submission to the General Assembly for review. The Board voted and Motion did not carry.**

After further discussion, **Mr. Kinney moved, seconded by Ms. Shrivastava-Patel that based on the public hearing and documents herein, move to find for the need and reasonableness of the Proposed Amendment of Regulation 61-56, Onsite Wastewater Systems; Proposed Repeal of Regulation 61-55, Septic Tank Site Evaluation Fees; Proposed Repeal of Regulation 61-56.1, License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets; and Proposed Repeal of Regulation 61-56.2, Licensing of Onsite Wastewater Systems Master Contractors, Document No. 4979, and grant approval for submission to the General Assembly for review with the revisions that were raised, considered, or discussed by public comment as provided by staff. The Board voted and Motion carried.**

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 6-4)

Item 7: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-79, Hazardous Waste Management Regulations, Document No. 4976, Exempt from General Assembly Review (Attachment 7-1)

A Public Hearing was conducted concerning the Regulation. Ms. Stacey French, Director, Division of Waste Management, Environmental Affairs, presented this item to the Board.

The Bureau of Land and Waste Management ("Bureau") proposed the Notice of Final Regulation amending R.61-79, *Hazardous Waste Management Regulations*, for publication in the November 27, 2020, *South Carolina State Register* ("State Register"). Legal authority resides in the South Carolina Hazardous Waste Management Act, S.C. Code Ann. §§ 44-56-10 *et seq.*, which authorizes the Department of Health and Environmental Control ("Department") to promulgate hazardous waste management regulations, procedures, or standards as may be necessary to protect human health and the environment. The Administrative Procedures Act, S.C. Code Ann. §1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department promulgates these amendments for compliance with federal law. These amendments will take legal effect as of the November 27, 2020, after publication in the *State Register*.

Pursuant to the South Carolina Hazardous Waste Management Act, S.C. Code Ann. §§ 44-56-10 *et seq.*, the Department is authorized to promulgate hazardous waste management

regulations, procedures, or standards as may be necessary to protect human and environmental health.

The Bureau proposed amending R.61-79, *Hazardous Waste Management Regulations*, to adopt the Environmental Protection Agency ("EPA") final rule "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine," published on February 22, 2019, at 84 FR 5816-5950. This rule creates new standards for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors in lieu of the existing generator regulations and reduces regulatory burdens for over-the-counter Food and Drug Administration-approved nicotine replacement therapies. Adoption of this rule is required to comply with federal law and will bring R.61-79 into conformity with the federal regulations.

The Bureau had a Notice of Drafting published in the April 24, 2020, *State Register*. The Bureau received no comments during the public comment period.

The Bureau published a summary of the proposed amendments on the Department's Regulation Development Update webpage. The Bureau provided notice to stakeholders via an email list on April 24, 2020. The Bureau maintains a website (<https://www.scdhec.gov/about-dhec/laws-regulationsregulatory-updates/hazardous-waste-management-regulations-update-status>) which provides more detail on the proposed amendments.

Appropriate Department staff conducted an internal review of the proposed rule on June 3, 2020.

The Department had a Notice of Proposed Regulation published in the August 28, 2020, *State Register*. The Department received no public comments by the September 28, 2020, close of the public comment period.

The Bureau requested the Board to find need and reasonableness of the proposed amendments of R.61-79, *Hazardous Waste Management Regulations*, for legal effect as of the November 27, 2020, publication in the *State Register*.

Mr. Grewal opened the meeting up for public comments on this matter, but no one wished to speak. (Attachment 7-2) No comments were received, and the public hearing was closed.

After discussion, **Ms. Shrivastava-Patel moved, seconded by Dr. Morgan, that based on the public hearing and documents herein, moved to find for the need and reasonableness of the proposed amendment of Regulation 61-79, *Hazardous Waste Management Regulations*, Document 4976, and grant approval to public the Notice of Final Regulation for legal effect as of the November 27, 2020, publication in the State Register. The Board voted and Motion carried.**

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 7-3)

Item 8: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-79, *Hazardous Waste Management Regulations*, Document No. 4975 (Attachment 8-1)

A Public Hearing was conducted concerning the Regulation. Ms. Stacey French, Director, Division of Waste Management, Environmental Affairs, presented this item to the Board.

The Bureau of Land and Waste Management ("Bureau") proposed the Notice of Final Regulation amending R.61-79, *Hazardous Waste Management Regulations*. Legal authority resides in the South Carolina Hazardous Waste Management Act, S.C. Code Ann. § 44-56-10 *et seq.*, which authorizes the Department of Health and Environmental Control ("Department") to promulgate hazardous waste management regulations, procedures, or standards as may be necessary to protect human health and the environment. The Administrative Procedures Act, S.C. Code Ann. § 1-23-120(A), requires General Assembly review of these proposed amendments.

Pursuant to the South Carolina Hazardous Waste Management Act, S.C. Code Ann. §§ 44-56-10 *et seq.*, the Department is authorized to promulgate hazardous waste management regulations, procedures, or standards as may be necessary to protect human and environmental health.

The Bureau proposed amending R.61-79, *Hazardous Waste Management Regulations*, to adopt Environmental Protection Agency ("EPA") interim final rule "Safe Management of Recalled Airbags," published on November 30, 2018, at 83 FR 61552-61563. This rule provides a conditional exemption from the Resource Conservation and Recovery Act ("RCRA") hazardous waste requirements for entities, including but not limited to, automobile dealerships, automotive salvage and scrap yards, independent repair facilities, and collision centers that collect airbag modules and inflators ("airbag waste") from automobiles as long as certain conditions are met. This rule enables expedited removal of defective airbag inflators.

The Bureau also proposed amending R.61-79, *Hazardous Waste Management Regulations*, to adopt EPA final rule "Universal Waste Regulations: Addition of Aerosol Cans," published on December 9, 2019, at 84 FR 67202-67220. This rule adds hazardous waste aerosol cans to the universal waste program under the federal RCRA regulations. Adopting the rule will reduce regulatory burdens on retail stores and other establishments that generate, manage, and dispose of aerosol cans by providing a clear, protective system for handling waste aerosol cans. This will promote the collection and recycling of aerosol cans and encourage the development of municipal and commercial programs to reduce the amount of aerosol can waste going to municipal solid waste landfills or combustors.

The Bureau had a Notice of Drafting published in the April 24, 2020, *State Register*. The Bureau received no comments during the public comment period.

The Bureau published a summary of the proposed amendments on the Department's Regulation Development Update webpage. The Bureau provided notice to stakeholders via an email list on April 24, 2020. The Bureau maintains a website (<https://www.scdhec.gov/about-dhec/laws-regulations-regulatory-updates/hazardous-waste-management-regulations-update-status>) which provides more detail on the amendments.

Appropriate Department staff conducted an internal review of the proposed amendments on June 3, 2020.

The Department had a Notice of Proposed Regulation published in the August 28, 2020, *State Register*. The Department received public comments from one (1) person by the September 28, 2020, close of the public comment period.

The Bureau requested the Board to find need and reasonableness of the attached proposed amendments of R.61-79, *Hazardous Waste Management Regulations*, for submission to the General Assembly.

Mr. Grewal opened the meeting up for public comments on this matter, but no one wished to speak. (Attachment 8-2) No comments were received, and the public hearing was closed.

After discussion, **Ms. Shrivastava-Patel moved, seconded by Mr. Kinney, that based on the public hearing and documents, moved to find for the need and reasonableness of the proposed amendment of Regulation 61-79, *Hazardous Waste Management Regulations*, Document 4975, 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 official record. (Attachment 8-3)

Item 9: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-75, Standards for Licensing Day Care Facilities for Adults, Document No. 4977 (Attachment 9-1)

A Public Hearing was conducted concerning the Regulation. Mr. Russ Morrison, Office of Policy and Communications, Healthcare Quality, presented this item to the Board.

The Bureau of Facilities Oversight ("Bureau") proposed the Notice of Final Regulation amending R.61-75, *Standards for Licensing Day Care Facilities for Adults*. Legal authority resides in S.C. Code Section 44-7-260, which requires the Department of Health and Environmental Control ("Department") to establish and enforce basic standards for the licensure, maintenance, and operation of health facilities and services in order to ensure the safe and adequate treatment of persons served in this state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Bureau proposed amending R.61-75 to update provisions in accordance with current practices and standards. Proposed amendments incorporate and revise provisions relating to statutory mandates, update definitions to conform to terminology widely used and understood within the provider community, and revise requirements for incident reporting, staffing and training, medication management, patient care and services, infection control, meal service, emergency procedures, design and construction, fire and life safety, and licensure. The proposed amendments also update the structure of the regulation throughout for consistency with other Department regulations.

The Department had a Notice of Drafting published in the February 28, 2020, *State Register*.

The Bureau held a stakeholder meeting on March 12, 2020. The Bureau considered stakeholder feedback in formulating the proposed amendments herein.

Department staff conducted an internal review of the proposed amendments on June 29, 2020.

The Department had a Notice of Proposed Regulation published in the August 28, 2020, *State Register*. The Department received public comments from three (3) people by the September 28, 2020, close of the public comment period. A summary of the public comments received and Department responses were provided to the Board.

The Bureau held another stakeholder meeting on September 16, 2020. The Bureau considered stakeholder feedback in formulating the proposed amendments herein.

After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board in the August 13, 2020, Board meeting and published in the August 28, 2020, *State Register*. Descriptions of the changes, Summary of Public Comments and Department Responses was provided to the Board.

The Bureau of Facilities Oversight requested the Board find need and reasonableness of the proposed amendment of R.61-75, *Standards for Licensing Day Care Facilities for Adults*, for submission to the General Assembly.

Mr. Grewal opened the meeting up for public comments on this matter, but no one wished to speak. (Attachment 9-2) No comments were received, and the public hearing was closed.

After discussion, **Ms. Shrivastava-Patel moved, seconded by Mr. Kinney, that based on the public hearing and documents, moved to find for the need and reasonableness of the proposed amendment of Regulation 61-75, *Standards for Licensing Day Care Facilities for Adults*, Document 4977, 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 official record. (Attachment 9-3)

Item 10: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-24, *Licensed Midwives*, Document No. 4974 (Attachment 10-1)

A Public Hearing was conducted concerning the Regulation. Mr. Russ Morrison, Office of Policy and Communications, Healthcare Quality, presented this item to the Board.

The Bureau of Facilities Oversight ("Bureau") proposed the Notice of Final Regulation amending R.61-24, *Licensed Midwives*. Legal authority resides in South Carolina Code Sections 44-1-140 et seq., which requires the Department of Health and Environmental Control ("Department") to establish and enforce basic standards for the licensure of midwives and midwifery services to ensure the safe and adequate treatment of persons served in this state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department proposed amending R.61-24 to update provisions in accordance with current practices and standards. Proposed amendments incorporate and revise provisions relating to statutory mandates, update definitions to conform to the terminology widely used and understood within the provider community, and revise requirements for scope of practice, incident reporting, continuing education training requirements, prescription medication

administration, client and neonate care and services, infection control, monetary penalties, and other requirements for licensure.

The Department had a Notice of Drafting published in the February 28, 2020, *State Register*.

The Bureau held a stakeholder meeting on March 17, 2020. The Bureau considered stakeholder feedback in formulating the proposed amendments herein.

Department staff conducted an internal review of the proposed amendments on July 10, 2020.

The Midwifery Advisory Council reviewed the proposed amendments, and on July 21, 2020, the Department received the Council's comments. A summary of the comments received and Department responses was provided to the Board.

The Department had a Notice of Proposed Regulation published in the August 28, 2020, *State Register*. The Department received public comments from 107 people by the September 28, 2020, close of the public comment period. A summary of these public comments received and Department responses were provided to the Board.

The Bureau held another stakeholder meeting on September 14, 2020. The Bureau considered stakeholder feedback in formulating the proposed amendments herein.

After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board in the August 13, 2020, Board meeting and published in the August 28, 2020, *State Register*. Descriptions of the changes, Summary of Public Comments and Department Responses, were provided to the Board.

The Bureau of Facilities Oversight requested the Board to find need and reasonableness of the attached proposed amendments of R.61-24, *Licensed Midwives*, for submission to the General Assembly.

Mr. Grewal opened the meeting up for public comments on this matter. The board received a large number of public comments. (Attachment 10-2) The public comment portion of the public hearing was concluded.

At the conclusion of the public comments, **Dr. Morgan made a motion that the Board go into Executive Session pursuant to SC Code Section 30-4-70(A)(1) and (A)(2) to obtain legal advice. Ms. Seema Shrivastava-Patel seconded the motion and the motion carried unanimously.**

Mr. Lee stated the Board was back in public session and while in Executive Session no actions were taken.

Mr. Lee recognized that Chairman Mark Elam had joined the meeting and was listening to the comments in the public hearing.

After discussion, **Mr. Kinney moved, seconded by Chairman Elam, to continue the public hearing on proposed amended to Regulation 61-24, *Licensed Midwives*, Document No. 4974, until the December 10th, 2020 board meeting, at which time staff are asked to provide additional information and revisions to the proposed regulation as it relates to use of Lidocaine, use of anti-hemorrhagic, mandatory 911**

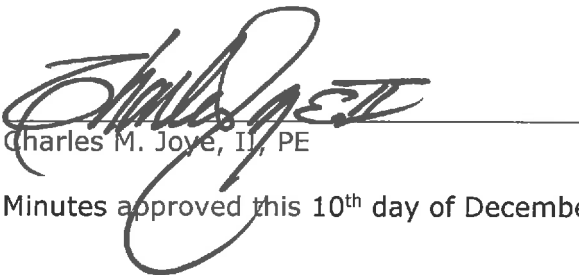
transport, physician sign off on high risk birth, and any items received in comments. The Board voted and Motion carried.

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 10-3)

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

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

Respectfully submitted,



Charles M. Joye, II, PE

Minutes approved this 10th day of December 2020.

ATTEST:



Mark R. Elam, Chairman

Attachments

- 0-1 Agenda
- 0-2 Sign in Sheet
- 1-1 Minutes of October 8, 2020 meeting
- 3-1 Administrative Orders and Consent Orders issued by Healthcare Quality
- 4-1 Administrative Orders and Consent Orders issued by Environmental Affairs
- 5-1 Placement of Oliceridine in Schedule II for Controlled Substances
- 6-1 Request for Final Approval, Proposed Amendment of Regulation 61-56; *Onsite Wastewater Systems*; Proposed Repeal of Regulation 61-55, *Septic Tank Site Evaluation Fees*; Proposed Repeal of Regulation 61-56.1, *License to Construct or Clean Onsite Sewage Treatment and Disposal Systems and Self-Contained Toilets*; and Proposed Repeal of Regulation 61-56.2, *Licensing of Onsite Wastewater Systems Master Contractors*, Document No. 4979
- 6-2 Public Hearing Sign in Sheet
- 6-3 Regulation Revisions
- 6-4 Verbatim Transcript
- 7-1 Request for Final Approval, Proposed Amendment of Regulation 61-79, *Hazardous Waste Management Regulations*, Document No. 4976, Exempt from General Assembly Review
- 7-2 Public Hearing Sign in Sheet
- 7-3 Verbatim Transcript
- 8-1 Request for Final Approval, Proposed Amendment of Regulation 61-79, *Hazardous Waste Management Regulations*, Document No. 4975
- 8-2 Public Hearing Sign in Sheet
- 8-3 Verbatim Transcript
- 9-1 Request for Final Approval, Proposed Amendment of Regulation 61-75, *Standards for Licensing Day Care Facilities for Adults*, Document No. 4977
- 9-2 Public Hearing Sign in Sheet
- 9-3 Verbatim Transcript
- 10-1 Request for Final Approval, Proposed Amendment of Regulation 61-24, *Licensed Midwives*
- 10-2 Public Hearing Sign in Sheet
- 10-3 Verbatim Transcript