

Minutes of the November 9, 2023, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, November 9, 2023, 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
Robert Morgan, MD, 4th District
Morris E. Brown, III, MD, 6th District
William Richmond, MD, 7th District

In attendance by telephone:
Seema Shrivastava-Patel, Chairman

Not in attendance:
Charles M. Joye, II, P.E., 3rd District

Also, in attendance were Dr. Edward Simmer, Director; Ashley Biggers, Acting Board Counsel; M. Denise Crawford, Clerk; Department staff; and members of the public. The meeting was also available via Livestream. (Attachment 0-2)

Dr. Morgan assumed the Chair and 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.

Vice-Chairman Morgan stated that a change had been made to the agenda. Current agenda item number 2 would move up to agenda item 1, and current agenda item number 1 would move to number 2.

Item 1: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-83, Transportation of Radioactive Waste Into or Within South Carolina, Document No. 5226 (Attachment 1-1)

A Public Hearing was conducted concerning the Regulation. Ms. Stacy 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 Regulation 61-83, *Transportation of Radioactive Waste Into and Within South*

Carolina. Legal authority resides in S.C. Code Ann., Sections 13-7-10 et seq., which directs the State to maintain appropriate liaison with agencies of the Federal Government, the United States Congress, certain national foundations and associations, and with other states and regional groups active in nuclear energy affairs.

The Department requires compliance with all applicable provisions and current revisions of Title 10, Part 71 of the Code of Federal Regulations (10 CFR 71), and any disposal facility's radioactive material license requirements and site disposal criteria regarding the packaging, transportation, disposal, storage, or delivery of radioactive materials. The Department proposed amending Regulation 61-83 to incorporate 10 CFR 71 regulations promulgated in 2018, provide clarification for conformance with disposal site criteria, include an exemption allowance for consistency with Regulation 61-63, *Radioactive Materials (Title A)*, and update forms to the current Department documents in use.

The Department had a Notice of Drafting published in the April 28, 2023, *State Register*.

Department staff conducted an internal review of the proposed amendments on July 20, 2023.

The Bureau held a stakeholder meeting on August 2, 2023, to discuss the schedule and implementation process for the proposed amendments.

Upon receiving approval during the August 10, 2023, Board meeting, the Bureau had a Notice of Proposed Regulation published in the August 25, 2023, *State Register*. The Department received no comments by September 25, 2023, close of public comment period.

The Bureau requested the Board find the need and reasonableness of the proposed amendment of Regulation 61-83, *Transportation of Radioactive Waste Into and Within South Carolina*, for submission to the General Assembly.

Acting Board Counsel, Ashley Biggers opened the meeting up for public comments on this matter. No members of the public spoke. The public hearing was closed.

After discussion, Mr. Kinney moved, seconded by Dr. Richmond, that based on the public hearing and documents herein, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-83, *Transportation of Radioactive Waste Into or Within South Carolina*, Document No. 5226, and granted approval for submission to the General Assembly for review. The Board voted and the Motion carried.

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 1-3)

Item 2: Request for a nine-month Board extension of Certificate of Need (CON) SC-20-25, issued to Medical University Hospital Authority d/b/a MUHA Community Hospital, for the construction of a 128-bed general acute hospital in Berkeley County (Attachment 2-1)

Ms. Ashley Grant, Senior Consultant, Certificate of Need Program, presented this item to the Board.

Medical University Hospital Authority d/b/a MUHA Community Hospital requested the Board's approval for the second Board extension of Certificate of Need (CON) SC-20-25, for the Construction of a 128-bed general acute hospital in Berkeley County. Department staff recommended the Board find that MUHA Community Hospital has demonstrated extenuating circumstances beyond its control, which has prevented the Project from advancing, and a 9-month extension of CON SC-20-25 be granted.

After the South Carolina Administrative Law Court's (ALC) affirmation of the Department's approval of the project, CON SC-20-25 was issued to Medical University Hospital Authority d/b/a MUHA Community Hospital on September 29, 2020, for the construction of a 128-bed general acute hospital in Berkeley County at a total project cost of \$325,000,000. The original CON had an expiration date of September 29, 2021.

MUHA requested a first staff extension of the CON on August 27, 2021, which was more than 30 days prior to expiration. MUHA's CON SC-20-25 EXT-1 was valid until June 29, 2022, a period of nine months from original expiration of the CON. On May 3, 2022, the Department received a letter from MUHA requesting a second staff extension of the CON. The Department issued the second staff extension, CON SC-20-25-EXT-2 to MUHA, which was valid until March 29, 2023. MUHA submitted a third extension request to the Department on December 21, 2022, approved by the Board on March 9, 2023. On August 28, 2023, the Department received a letter from MUHA requesting a fourth extension request of the CON. Trident Health appealed the decision of the South Carolina Administrative Law Court (ALC) to the South Carolina Supreme Court. The South Carolina Supreme Court heard the case on October 4, 2023, and the decision is still pending.

Department staff reviewed all relevant information concerning this fourth extension request and found that circumstances beyond the control of MUHA, specifically the delays experienced due to pending litigation, have contributed to the need for further extension of CON SC-20-25.

MUHA provided in its extension request an updated timeline for the project, which Department staff believe is achievable.

Department staff recommended the Board find that MUHA Community Hospital has demonstrated extenuating circumstances beyond its control which have prevented the Project from advancing. The Department staff recommend the Board grant the 9- month extension.

Dr. Richmond stated that due to professional conflicts, he would recuse himself from voting on this agenda item. (Attachment 2-2)

After discussion, **Mr. Kinney moved, seconded by Dr. Brown, to find that Medical University Hospital Authority d/b/a MUHA Community Hospital has demonstrated substantial progress on this project and approves the extension request for CON SC-20-25 issued on September 29, 2020. The Board voted and the Motion carried.**

Item 3: Notice of Proposed Regulation amending Regulation 61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries* (Attachment 3-1)

Ms. Charlene Bell, Director, Division of Hospitals and Professionals, Bureau of Healthcare Systems and Services, Healthcare Quality, presented this item to the Board.

Healthcare Quality proposed the Notice of Proposed Regulation amending R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries* for publication in the November 24, 2023 *South Carolina State Register* (“*State Register*”). Legal authority resides in S.C. Code Sections 44-7-110 through 44-7-394, which requires the Department of Health and Environmental Control (“Department”) to establish and enforce minimum standards for the licensure, maintenance, and operation of hospitals and institutional general infirmaries to ensure the safe and appropriate 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.

Pursuant to S.C. Code Sections 44-7-250 and -260(A)(1), the Department establishes and enforces minimum standards for the licensure, maintenance, and operation of hospitals to ensure the safe and appropriate treatment of persons served in this state. The Department proposed amending Regulation 61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*, to ensure alignment with current state laws and to update and revise definitions, license requirements and fees, staff and training, reporting, disaster management, accommodations for patients, patient care and services, design and construction, fire protection, prevention and life safety, and policies and procedures.

The Department had a Notice of Drafting published in the July 28, 2023 *State Register*. This notice supersedes the Notice of Drafting that was published in South Carolina State Register Volume 47, Issue 3 on March 24, 2023. The Department received public comments from 27 parties by August 28, 2023, close of the public comment period.

Department staff conducted Stakeholder Meetings on August 22, 2023, and October 25, 2023, to discuss the proposed amendments and/or to receive comments on the proposed amendments.

Department staff conducted an internal review of the proposed amendments on October 9, 2023.

Healthcare Quality requested the Board grant approval of the Notice of Proposed Regulation for publication in the November 24, 2023 *State Register*.

After discussion, Dr. Brown moved, seconded by Dr. Richmond, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*, 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 4: Notice of Proposed Regulation Amending R.61-91, *Standards for Licensing Ambulatory Surgical Facilities* (Attachment 4-1)

Ms. Kristen Juarez Kollu, Director, Division of Medical Services, Bureau of Healthcare Systems and Services, Healthcare Quality, presented this item to the Board.

Healthcare Quality proposed the Notice of Proposed Regulation amending Regulation 61-91, *Standards for Licensing Ambulatory Surgical Facilities*, for publication in the November 24, 2023, *South Carolina State Register* (“*State Register*”). Legal authority resides in S.C. Code Sections 44-7-250 and 44-7-260(A)(4), which requires the Department of Health and Environmental Control (“Department”) to establish and enforce the minimum standards for the licensure, maintenance, and operation of ambulatory surgical facilities to ensure the safe and appropriate 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.

In accordance with 2023 Act No. 20 (S.164), the Department proposed amending Regulation 61-91 to promulgate regulations concerning the provision of uncompensated indigent/charity care required pursuant to S.C. Code Section 44-7-266(C), including related definitions, licensure requirements, reporting requirements, and enforcement. Additionally, the Department proposed amending the regulation to address the required quality of care, services, and treatment provided by facilities and to prescribe the manner and method of fee payments.

The Department had a Notice of Drafting published in the August 25, 2023 *State Register*. The Department received public comments from eight parties by September 25, 2023, the close of the public comment period.

Department staff conducted a virtual stakeholder meeting on September 13, 2023, to receive comments on the proposed amendments. No comments were offered during the meeting.

Department staff conducted an internal review of the proposed amendments on October 17, 2023.

Healthcare Quality requested the Board grant approval of the Notice of Proposed Regulation for publication in the November 24, 2023 *State Register*.

After discussion, Dr. Brown moved, seconded by Mr. Kinney, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-91, *Standards for Licensing Ambulatory Surgical 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 5: Request for Placement of Zuranolone in Schedule IV for Controlled Substances in South Carolina (Attachment 5-1)

Mr. Ben McKeever, Drug Control Upstate Agent, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act, Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule IV substances are listed in Section 44-53-250 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.

On August 4, 2023, the United States Food and Drug Administration (“FDA”) approved a new drug application (“NDA”) for ZURZUVAE (Zuranolone) capsules for the treatment of post-partum depression. The Department of Health and Human Services (“HHS”) provided the Drug Enforcement Administration (“DEA”) with a scheduling recommendation to place zuranolone and its salts in schedule IV of the Controlled Substances Act. In accordance with the federal Controlled Substances Act (“CSA”), as amended by the Improving Regulatory Transparency for New Medical Therapies Act, the DEA issued an interim final rule placing zuranolone, including its salts, in schedule IV of the federal CSA. This action facilitates the public availability of zuranolone as a schedule IV controlled substance. This rule has an effective date of October 31, 2023, Federal Register, Volume 88, Number 209, pages 74347-74352; [https:// www.govinfo.gov/content/pkg/FR-2023-10-31/pdf/2023-23982.pdf](https://www.govinfo.gov/content/pkg/FR-2023-10-31/pdf/2023-23982.pdf).

Zuranolone is a new molecular entity that has not been marketed in the United States or any country. Thus, evidence regarding its diversion, illicit manufacturing, or deliberate ingestion is currently lacking. DEA notes that there are no reports of law enforcement encounters of zuranolone in the National Forensic Laboratory Information System (“NFLIS”) Drug database. Zuranolone has sedative effects and is likely to have abuse potential, similar to schedule IV sedatives such as alprazolam. Thus, it is reasonable to assume that zuranolone may be diverted from legitimate channels, used contrary to or without medical advice, and capable of creating hazards to the users and to the safety of the community. In human abuse potential studies, zuranolone produced positive subjective responses that are similar to those produced by alprazolam (schedule IV). Zuranolone produces rewarding effects that are comparable to those produced by schedule IV sedatives; therefore, zuranolone is likely to be abused for its sedative effects contrary to medical advice.

On July 12, 2023, DEA received from HHS a scientific and medical evaluation entitled “Basis for the Recommendation to Control Zuranolone and its Salts in Schedule IV of the Controlled Substances Act” and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eightfactor analysis of the abuse potential, legitimate medical use, and dependence liability of zuranolone, along with HHS’s recommendation to control zuranolone and its salts under schedule IV of the federal CSA. In response, 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 zuranolone meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the CSA. Pursuant to subsection 811(j), and based on HHS’ scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA’s determination, DEA issued an interim final rule to schedule zuranolone as a schedule IV controlled substance under the federal CSA.

The federal 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 Administrator of DEA (“Administrator”), pursuant to 21 U.S.C. 812(b)(4), found that:

- 1) Zuranolone has a potential for abuse similar to drugs or other substances in schedule IV.
- 2) Zuranolone has a currently accepted medical use in treatment in the United States.
- 3) Abuse of zuranolone may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III but similar to other substances in schedule IV.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommended placement of zuranolone and its salts in schedule IV and the amendment of Section 44-53-250 of the South Carolina Controlled Substances Act.

After discussion, Dr. Brown moved, seconded by Mr. Kinney, to designate Zuranolone and the additional substances named in the DEA Notice published in the Federal Register on October 31, 2023, and amend Section 44-53-250 of the South Carolina Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the Motion carried.

Item 6: Minutes of October 12, 2023 meeting (Attachment 6-1)

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

Item 7: Minutes of October 25, 2023 meeting (Attachment 7-1)

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

Item 8: Administrative Orders and Consent Orders issued by Healthcare Quality (Attachment 8-1)

Mr. Vito Wicevic, Director, Healthcare Quality Office of Public Information and Regulatory Affairs, stated that for this reporting period, six (6) Consent Orders with assessed monetary penalties totaling \$9,600.00 were issued.

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

Item 9: Administrative Orders and Consent Orders issued by Environmental Affairs (Attachment 9-1)

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, fifty-seven (57) Consent Orders with assessed civil penalties totaling \$249,270.00 and ten (10) Administrative Orders with assessed civil penalties totaling \$11,035.85 were issued.

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

Item 10: Administrative Orders and Consent Orders issued by Public Health
(Attachment 10-1)

Ms. Bentley White, Public Health Policy Director, Public Health, stated that for this reporting period, forty-five (45) Consent Orders with assessed monetary penalties totaling \$54,100.00 were issued.

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

Item 11. Agency Affairs

Dr. Edward Simmer, Director, updated the Board on:

- Receiving Environmental Justice Grant
- Hiring Veterans
- Honoring DHEC Veterans
- Preparing for the Holidays


Dr. Simmer presented Employee Appreciation Coins to the following Department staff:

- Dr. Karla Buru, Chief of Staff
- Ms. Jervelle Fort, Community Engagement Manager – East

Being no further business, Vice-Chairman Morgan adjourned the meeting.

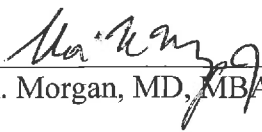
All referenced attachments are made a permanent part of these minutes.

Respectfully submitted,


J.B. (Sonny) Kinney, 1st District
Acting Secretary

Minutes approved this 4th day of January, 2024.

ATTEST:



Robert R. Morgan, MD, MBA, Vice-Chairman

Attachments

- 0-1 Agenda
- 0-2 Sign in Sheet
- 1-1 Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-83, *Transportation of Radioactive Waste Into or Within South Carolina*, Document No. 5226
- 1-2 Public Hearing Sign in Sheet
- 1-3 Verbatim Transcript of Public Hearing
- 1-4 Board Order
- 2-1 Request for a nine-month Board extension of Certificate of Need (CON) SC-20-25, issued to Medical University Hospital Authority d/b/a MUHA Community Hospital, for the construction of a 128-bed general acute hospital in Berkeley County
- 2-2 Recusal Statement
- 3-1 Notice of Proposed Regulation amending Regulation 61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*
- 4-1 Notice of Proposed Regulation Amending R.61-91, *Standards for Licensing Ambulatory Surgical Facilities*
- 5-1 Request for Placement of Zuranolone in Schedule IV for Controlled Substances in South Carolina
- 5-2 Board Order
- 6-1 Minutes of October 12, 2023 meeting
- 7-1 Minutes of October 25, 2023 meeting
- 8-1 Administrative Orders and Consent Orders issued by Healthcare Quality
- 9-1 Administrative Orders and Consent Orders issued by Environmental Affairs
- 10-1 Administrative Order and Consent Orders issued by Public Health