



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 January 7, 2021, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, January 7, 2021, 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:

Mark Elam, Chairman
J.B. (Sonny) Kinney, 1st District
Robert Morgan, MD, 4th District

In attendance virtually
Charles M. Joye, II, P.E., 3rd District
Seema Shrivastava-Patel, 2nd District
Richard V. Lee, Jr., 5th District
Alex A. Singleton, 6th District

Not in attendance
Jim P. Creel, Jr., Vice-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 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 December 1, 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: Minutes of December 10, 2020 meeting (Attachment 2-1)

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

Item 3: Minutes of December 17, 2020 meeting (Attachment 3-1)

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

Item 4: Minutes of December 22, 2020 meeting (Attachment 4-1)

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

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 related to the vaccine rollout. Mr. Kinney seconded the motion and the motion carried unanimously.

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

Item 5: Agency Affairs

Dr. Linda Bell, State Epidemiologist, provided an overview on the COVID 19 vaccine.

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

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

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

Acting Director W. Marshall Taylor acknowledged the work with our community partners on the COVID 19 vaccine. The Chief Executive Officers from the Medical University of South Carolina, Prisma Health, Tidelands Health, and Lexington Medical Center provided updates on the vaccine response.

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

W. Marshall Taylor acknowledged the work of the board, the agency executive leadership team, the Legislature, and staff during the COVID 19 pandemic.

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

Item 6: Administrative Orders and Consent Orders issued by Healthcare Quality (Attachment 6-1)

Ms. Bentley White, Director of Policy and Communications, Healthcare Quality, stated that for this reporting period, three (3) Consent Orders with assessed civil penalties totaling \$3,400.00, One hundred and twenty (120) Notices of Violation and Civil Penalty totally \$34,000.00 in assessed civil penalties, and no Administrative Orders were issued.

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

Item 7: Administrative Orders and Consent Orders issued by Environmental Affairs (Attachment 7-1)

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, twenty-eight (28) Consent Orders with assessed civil penalties totaling \$30,630.00 and seven (7) Administrative Order with assessed civil penalties totaling \$382,236.00 have been issued.

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

Item 8: Notice of Proposed Regulation Amending Regulation 61-34, Raw Milk for Human Consumption, and Regulation 61-34.1, Pasteurized Milk and Milk Products (Attachment 8-1)

Ms. Sandra Craig, Director, Division of Food and Lead Risk Assessments, presented this item to the Board.

The Bureau of Environmental Health Services ("Bureau") proposed the Notice of Proposed Regulation amending Regulation 61-34, *Raw Milk for Human Consumption*, and Regulation 61-34.1, *Pasteurized Milk and Milk Products*, for publication in the January 22, 2021, *South Carolina State Register* ("State Register"). Legal authority resides in S.C. Code Sections 44-1-140 and 44-1-150, which allow the Department of Health and Environmental Control ("Department") to promulgate regulations for the production, storing, labeling, transportation, and selling of milk and milk

products, filled milk and filled milk products, imitation milk and imitation milk products, synthetic milk and synthetic milk products, milk derivatives, and any other products made in semblance of milk or milk products. Furthermore, S.C. Code Section 44-1-150 allows for the enforcement of these regulations. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

Pursuant to Regulation 61-34, *Raw Milk for Human Consumption*, the Department provides sanitation oversight for the production and sale of raw milk that has not been pasteurized for food safety in South Carolina. The Bureau proposed amending Regulation 61-34 to address the further processing and sale of raw milk products, specifically, cream and buttermilk, and any additional consumer advisory changes that would be needed for products that receive further processing or become necessary as a byproduct of further processing (if allowed). The proposed revisions would also update raw milk standards as needed to align certain requirements with the 2019 version of the U.S. Food and Drug Administration Pasteurized Milk Ordinance ("PMO").

Pursuant to Regulation 61-34.1, *Pasteurized Milk and Milk Products*, the Department provides sanitation oversight of the production and sale of pasteurized milk and milk products for both intrastate and interstate commerce. The Bureau proposes adopting requirements of the 2019 PMO through amendment of Regulation 61-34.1. The regulation is currently based on the 2013 PMO and will not meet the federal standards after this year. The amendment of Regulation 61-34.1 to incorporate the updated requirements of the 2019 PMO would enable South Carolina milk producers to continue to meet federal standards and ship milk and milk products for interstate commerce. The Bureau further proposes clarification of requirements for potable water sources.

The Bureau also proposed changes for clarity and readability, grammar, punctuation, and codification, and other regulatory text improvements. Proposed amendments to both regulations also include updates to administrative and enforcement provisions.

The Department had a Notice of Drafting published in the March 27, 2020, *State Register*. A copy of the Notice of Drafting was provided. The Department received public comments from forty-eight parties by the April 27, 2020, close of the public comment period. A summary of these public comments received and Department responses.

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

The Bureau conducted two separate stakeholder meetings on December 7, 2020. The first meeting for Regulation 61-34.1 had five stakeholders in attendance, and the second meeting for Regulation 61-34 had twenty-one stakeholders in attendance. Comments made in these meetings included support for the amendments, suggestions for terminology, and discussion of the scope of raw milk products

addressed in Regulation 61-34. The Bureau considered these comments and, where appropriate, incorporated them into these proposed regulations.

The Bureau will hold additional stakeholder meetings during the public comment period for the Notice of Proposed Regulation to ensure that all concerns have been addressed. Stakeholders have expressed appreciation for the Department's industry engagement.

The Bureau requested the Board grant approval of the Notice of Proposed Regulation for publication in the January 22, 2021, *State Register*.

After discussion, **Dr. Morgan moved, seconded by Mr. Kinney, to grant approval to publish a Notice of Proposed Regulation amending Regulation 61-34, Raw Milk for Human Consumption, and Regulation 61-34.1, Pasteurized Milk and Milk Products, 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 9: Continuation of Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-24, Licensed Midwives, Document No. 4974 (Attachment 9-1)

A Public Hearing was continued from the November 12, 2020 meeting concerning the Regulation. Mr. Russ Morrison, Office of Policy and Communications, Healthcare Quality, presented this item to the Board.

The Division of Healthcare Quality ("Healthcare Quality") proposed amending Regulation 61-24, *Licensed Midwives*, pursuant to South Carolina Code Sections 44-1-140 *et seq.*, which enables 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 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 Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

A Public Hearing for Notice of Final Regulation Amending R.61-24, *Licensed Midwives*, Document No. 4974, was conducted before the Board on November 12, 2020. After hearing comments from the public, the Board decided to continue the Public Hearing to the December 10, 2020, Board meeting. Specifically, the Board directed

Department staff to provide additional information and revisions to the proposed regulations as it relates to the use of Lidocaine, the use of antihemorrhagics, mandatory 911 transport, physician sign-off on low risk birth, and any other items mentioned or reviewed in the comments. Staff's review of these issues and pertinent sections of the current regulation were provided, the proposed language as presented, justification for the proposed amendments, and potential alternative language for the Board's consideration.

A Continuation of the Public Hearing for Notice of Final Regulation Amending Regulation 61-24, *Licensed Midwives*, Document No. 4974, was conducted before the Board on December 10, 2020. After the presentation from Department staff, the Board decided to continue the Public Hearing to the January 7, 2021, Board meeting. Specifically, the Board directed Department staff to meet with two (2) representatives from the Midwifery Advisory Council ("MAC") review the proposed alternative text was provided, and an update was provided at the January 7, 2021, Board meeting.

On December 22, 2020, Department staff met with the two (2) representatives from the MAC to conduct a review of the proposed alternative text as provided.

Healthcare Quality requested the Board find need and reasonableness of its proposed amendments of Regulation 61-24, *Licensed Midwives*, for submission to the General Assembly.

After discussion, **Dr. Morgan moved, seconded by Mr. Joye, that based on the public hearing and all associated documents, to find the need and reasonableness and grant approval for submission to the General Assembly the proposed amendment of Regulation 61-24, Licensed Midwives, Document No. 4974, presented to staff November 12, 2020, but with all the revisions presented to the board at the meeting. 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: Request for a nine-month Board extension of Certificate of Need (CON) SC-18-37, issued to Trident Medical Center, LLC d/b/a Trident Medical Center (TMC) for development of a freestanding psychiatric hospital and behavioral health unit with the addition of 43 psychiatric beds and the relocation of 17 psychiatric beds from Trident's main campus for a total of 60 beds. (Attachment 10-1)

Mr. Louis Eubank, Chief, Bureau of Planning and Construction, Healthcare Quality, presented this item to the Board.

CON SC-18-37 was issued to TMC on August 6, 2018 for development of a freestanding psychiatric hospital and behavioral health unit with the addition of 43

psychiatric beds and the relocation of 17 psychiatric beds from the TMC main campus for a total of 60 beds. The original CON SC-18-37 had an expiration date of August 6, 2019.

TMC requested a first staff extension of the CON on July 1, 2019, which was more than 30 days prior to expiration. TMC received an extension, CON SC-18-37-EXT-1, on August 9, 2019, and it was valid until May 6, 2020, a period of nine months from original expiration of the CON.

TMC requested a second staff extension of the CON on April 2, 2020, which was 30 days prior to expiration. The Department engaged with TMC to more fully understand the circumstances behind the request, and held multiple conversations with Trident leadership, including their new planning executive. These conversations were of an extended nature due to the time necessary for Department staff to make inquiries of TMC and for TMC to respond. CON SC-18-37-EXT-1 was tolled for the duration of this engagement. Ultimately, TMC received CON SC-18-37-EXT-2 on September 16, 2020, which will expire on February 6, 2021. Pursuant to Regulation 61-15, *Certification of Need for Health Facilities and Services*, Section 601, TMC submitted a third extension request to the Department on November 6, 2020 which is 90 days prior to expiration.

Department staff reviewed all relevant information concerning this third extension request and find that circumstances beyond the control of TMC have contributed to the need for further extension of CON SC-18-37. Specifically, TMC references delays resulting from COVID-19 response as the primary driver of the request for extension. TMC has provided with its extension request an updated timeline for the project, which Department staff believe is achievable given the significant expertise and resources available to TMC. Department staff expect that subsequent extensions by the Board may be unnecessary given TMC's timeline showing execution of a construction contract for the Project on or about August 1, 2021. This contract will satisfy the requirement for implementation of the Project pursuant to Regulation 61-15, *Certification of Need for Health Facilities and Services* and will render moot the need for further extension of CON SC-18-37.

Department staff recommended the Board find that TMC has demonstrated extenuating circumstances beyond its control that have prevented the Project from advancing, that the Project is likely to be implemented during the period of extension, and that a nine-month extension of CON SC-18-37 be granted.

After discussion, Mr. Singleton moved, seconded by Dr. Morgan, to find that Trident Medical Center, LLC d/b/a Trident Medical Center has demonstrative substantial progress on this project and approves the extension request for CON SC-18-37 issued to Trident Medical Center, LLC d/b/a Trident Medical Center on August 6, 2018. The Board voted and Motion carried.

Item 11: Final Review Conference - Final Review Conference - Docket No. 20-RFR-54, Ambulatory Partners, LLC - Issuance of denial of application for a Certificate of Need for the construction of a 16,640 sf Multi-Specialty Ambulatory Surgery Facility with 2 operating rooms and diagnostic imaging in Orangeburg county at a total project cost of \$12,537,535, Matter No. 2781

A Final Review Conference was held concerning a staff decision to deny the issuance of an application for a Certificate of Need. Chairman Elam announced the agenda item and asked board counsel to introduce the matter.

Ms. Maggie Murdock and Mr. Vito Wicevic, Esquire represented on behalf of the Department. Ms. Murdock presented a PowerPoint on the matter. (Attachment 11-2)

Dr. Dion Franga and, Mr. Wes Jackson, Esquire represented Ambulatory Partners, LLC. They presented a PowerPoint to the board.

Maggie Murdock, Dr. Dion Franga, Dr. Amit Sanghi, and Dr. Robert Puchalski were sworn in as witnesses in this matter.

Dr. Morgan recused himself from this matter as one of the affected parties was his employer.

After discussion, **Mr. Kinney moved, seconded by Chairman Elam, to go into Executive Session for the purpose of deliberations and legal advice in this matter. The Board voted and Motion carried.**

Chairman Elam announced the Board was back in public session and while in Executive Session, no actions were taken.

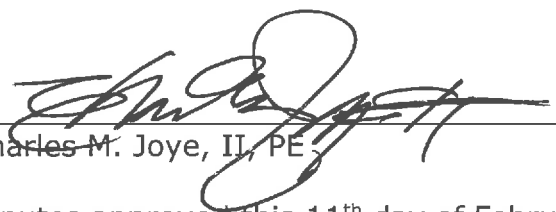
After further discussion, **Mr. Lee moved, seconded by Ms. Shrivastava-Patel to uphold the staff decision. The Board voted and by a vote of three to three, with one recusal, the Motion did not carry.**

After additional discussion, **Mr. Joye moved, seconded by Mr. Kinney to overturn the staff decision. The Board voted and by a vote of four to one, with one recusal, and one abstaining, the Motion carried.**

Being no further business, Chairman Elam adjourned the meeting.

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

Respectfully submitted,



Charles M. Joye, II, PE

Minutes approved this 11th day of February 2021.

ATTEST:



Mark R. Elam, Chairman

Attachments

- 0-1 Agenda
- 0-2 Sign in Sheet
- 1-1 Minutes of December 1, 2020 meeting
- 2-1 Minutes of December 10, 2020 meeting
- 3-1 Minutes of December 17, 2020 meeting
- 4-1 Minutes of December 22, 2020 meeting
- 6-1 Administrative Orders and Consent Orders issued by Healthcare Quality
- 7-1 Administrative Orders and Consent Orders issued by Environmental Affairs
- 8-1 Notice of Proposed Regulation Amending Regulation 61-34, *Raw Milk for Human Consumption*, and Regulation 61-34.1, *Pasteurized Milk and Milk Products*
- 9-1 Continuation of Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-24, *Licensed Midwives*, Document No. 4974 43,
- 10-1 Request for a nine-month Board extension of Certificate of Need (CON) SC-18-37, issued to Trident Medical Center, LLC d/b/a Trident Medical Center (TMC) for development of a freestanding psychiatric hospital and behavioral health unit with the addition of 43 psychiatric beds and the relocation of 17 psychiatric beds from Trident's main campus for a total of 60 beds.
- 11-1 Final Review Conference - Final Review Conference - Docket No. 20-RFR-54, Ambulatory Partners, LLC - Issuance of denial of application for a Certificate of Need for the construction of a 16,640 sf Multi-Specialty Ambulatory Surgery Facility with 2 operating rooms and diagnostic imaging in Orangeburg county at a total project cost of \$12,537,535, Matter No. 2781