

BOARD:
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 October 9, 2014, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, October 9, 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

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 September 11 meeting and September 25 conference call (Attachment 1-1)

Mr. Joye moved, seconded by Mr. Hewitt, to approve the minutes as submitted for the September 11 and September 25 meetings. 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 forty-one (41) Consent Orders had been issued with total penalties of \$156,610.

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 three (3) Consent Orders had been issued with total penalties of \$32,200.

The Board accepted this item as information.

Item 4: Public Hearing and Request for Final Approval – Proposed Amendment of Regulation 61-63, Radioactive Materials (Title A), State Register Document No. 4462, Legislative Review is not required (Attachment 4-1)

Ms. Susan Jenkins, Manager, Infectious and Radioactive Waste Management Section, presented this item to the Board.

The Nuclear Regulatory Commission (USNRC) promulgates amendments to 10 CFR 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 51, 70, and 71 throughout each calendar year. Recent amendments include requirements for Decommissioning Planning (RATS-ID 2011-1), Licenses, Certifications, and Approvals for Materials Licensees (RATS-ID 2011-2), Technical Corrections (RATS-ID 2012-3), Requirements for Distribution of Byproduct Material (RATS-ID 2012-4), Physical Protection of Byproduct Material (RATS-ID 2013-1), and Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions (RATS-ID 2013-2) These final rules have been published in the Federal Register at 76 FR 35512 on June 17, 2011, 76 FR 56951 on September 15, 2011, 77 FR 39899 on July 6, 2012, 77 FR 43666 on July 25, 2012, 78 FR 16922 on March 19, 2013, and 78 FR 32310 on May 29, 2013, respectively. The Department is proposing to amend R.61-63 to incorporate the above-described federal regulations to maintain conformity with federal requirements found in 10 CFR Parts 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 51, and 71 to ensure compliance with federal standards as required by Section 274 of the Atomic energy Act of 1954.

The Department amended R.61-63 on March 26, 2010 to adopt federal regulations published as final rules in the Federal Register at 71 FR 65685, 72 FR 55864, and 73 FR 42761. The Department is also proposing to make minor corrections to 61-63 RHA 2.4, General Licensing Requirements, to clarify the order of text in this section and will add a paragraph at RHA 3.58, Appendix G, Nationally Tracked Sources-Serialization and Reports of Transactions, that was inadvertently omitted in the prior promulgation. These amendments will conform R.61-63 with the federal regulations.

A public hearing was conducted; however, no one in attendance spoke. (Attachment 4-2)

After discussion, *Mr. Wells moved, seconded by Mr. Batts, find for the need and reasonableness of the Proposed Amendment of Regulation 61-63, Radioactive Materials (Title A), 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 4-3)

Item 5: Public Hearing and Request for Final Approval – Proposed Amendment of Regulation 61-91, Standards for Licensing Ambulatory Surgical Facilities, State Register Document No. 4471, Legislative Review is require (Attachment 5-1)

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

Statutory authority for Regulation 61-91, Standards for Licensing Ambulatory Surgical Facilities, can be found in Code Section 44-7-260. The Department substantively amended the regulation on June 27, 2003. The purpose of the regulation is to provide a set of standards for facilities defined as a distinct, freestanding, self-contained entity that is organized, administered, equipped, and operated exclusively for the purpose of performing surgical procedures or related care, treatment, procedures and/or services, for which patients are scheduled to arrive and be discharged the same day. The proposed amendments herein include the efforts of the Department's Bureau of Health Facilities Licensing to incorporate current construction requirements and overall improvements to the text of the regulation.

A public hearing was conducted with the following making comments: Scott Hultstrand and Jodi Taylor, SC Ambulatory Surgery Center Association; Lynn Bailey, Lynn Bailey Associates; Joey Fischer, Southeastern Spine Institute; Ann Margaret McGraw, Midlands Ortho Surgery Center; Mary Elkins, Center for Ortho Surgery; Jimmy Walker, SC Hospital Association; and Chris Lupo, Surgery Center of Murrells Inlet. (Attachment 5-2)

After discussion, *Mr. Batts moved, seconded by Mr. Hewitt, find for the need and reasonableness of the Proposed Amendment of R.61-91, Standards for Licensing Ambulatory Surgical Facilities, and approve for submission to the Legislature for review with the following revisions that were raised, considered, or discussed by public comment: eliminate the word "local" from Section 504.E. 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: Request for a second Board extension of Certificate of Need ("CON) SC-10-15 issued to Sunnyside Healthcare Commons of Hilton Head, LLC d/b/a Beacon Harbor Subacute Care ("Sunnyside/Beacon Harbor"), Bluffton, South Carolina, for the

construction of a one hundred twenty (120) bed nursing home that will not participate in the Medicaid (Title XIX) Program (Attachment 6-1)

Mr. Sam Phillips, Director, Certificate of Need Program, presented this item to the Board.

Sunnyside Healthcare Commons of Hilton Head, LLC d/b/a Beacon Harbor Subacute Care requests additional time to implement CON SC-10-15. The Department has reviewed the documentation set forth in the Emergency Regulation filed September 29, 2014. Because Sunnyside has received has received four previous extensions, staff determined that Board review was required for the fifth and sixth extensions.

After discussion, Mr. Lutz moved, seconded by Dr. Kirol, to find Sunnyside Healthcare Commons of Hilton Head, LLC, d/b/a Beacon Harbor Subacute Care has demonstrated substantial progress and approve Sunnyside's extension requests for CON SC-10-15, thereby extending the CON until May 7, 2015. The Board voted and Motion carried.

Item 7: Request for a second Board extension of Certificate of Need ("CON") SC-10-27 issued to Sunnyside Healthcare Commons of Hilton Head, LLC d/b/a Beacon Harbor Geriatric Psychiatric Care, Bluffton, South Carolina, for the construction of a psychiatric hospital to include twenty-two (22) psychiatric beds (Attachment 7-1)

Mr. Phillips presented this item to the Board.

Sunnyside Healthcare Commons of Hilton Head, LLC d/b/a Beacon Harbor Geriatric Psychiatric Care requests additional time to implement CON SC-10-27. The Department has reviewed the documentation set forth in the Emergency Regulation filed September 29, 2014. Because Sunnyside has received has received three previous extensions, staff determined that Board review was required for the fourth and fifth extensions.

After discussion, Mr. Lutz moved, seconded by Mr. Hewitt, to find Sunnyside Healthcare Commons of Hilton Head, LLC, d/b/a Beacon Harbor Harbor Geriatric Psychiatric Care, has demonstrated substantial progress and approve Sunnyside's extension requests for CON SC-10-27, thereby extending the CON until May 13, 2015. The Board voted and the Motion carried.

Item 8: Request for first Board extension of Certificate of Need ("CON") SC-11-36 issued to PACE Healthcare Commons, LLC, Bluffton, South Carolina, for the development of a thirty-two (32) bed long term acute care hospital (LTACH) (Attachment 8-1)

Mr. Phillips presented this item to the Board.

PACE Healthcare Commons, LLC requests additional time to implement CON SC-11-36. The Department has reviewed the documentation set forth in the Emergency Regulation filed September 29, 2014. Because PACE has received two previous extensions, staff determined that Board review was required for the third and fourth extensions.

After discussion, *Mr. Hewitt moved, seconded by Dr. Kirol, to find PACE Healthcare Commons, LLC, has demonstrated substantial progress and approve PACE's extension requests for CON SC-11-36, thereby extending the CON until April 30, 2015. The Board voted and Motion carried.*

Item 9: Request for first Board extension of Certificate of Need ("CON") SC-12-04 issued to PACE Healthcare Commons, LLC, Bluffton, South Carolina for the construction of a ten (10) bed Inpatient Rehabilitation Hospital (Attachment 8-1)

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

PACE Healthcare Commons, LLC requests additional time to implement CON SC-12-04. The Department has reviewed the documentation set forth in the Emergency Regulation filed September 29, 2014. The Department staff has granted second request for a CON extension. Board review was required for the third nine-month extension.

In their extension request, PACE mentions that it has a long term objective to consolidate fourteen rehabilitation beds currently licensed to and operated by Beaufort Memorial Hospital with the ten rehabilitation beds approved in CON SC-12-04. The September 12, 2014, extension request also requests that the Board allow PACE "to consolidate the 14 licensed rehab beds that Beaufort Memorial Hospital will transfer to PACE and the 10 approved rehab beds and authorize twenty-four rehabilitation to be located at the new facility on the grounds approved in CON SC-12-04. No CON has been issued authorizing a transfer of Beaufort's fourteen licensed rehabilitation beds to PACE.

After discussion, *Mr. Batts moved, seconded by Mr. Lutz, find PACE Healthcare Commons, LLC, has demonstrated substantial progress and approve PACE's extension requests for CON SC-12-04, thereby extending the CON until April 30, 2015 and that the extension does not constitute approval of any changes in the scope of the CON to include a transfer of rehabilitation beds from Beaufort to PACE. The Board voted and the Motion carried.*

Item 10: Proposed Amendment of Regulation 61-96, Athletic Trainers, Legislative Review is required (Attachment 10-1)

Mr. Robert Wronski, Director, Division of EMS and Trauma, presented this item.

The Department has completed its five year review of R.61-96, Athletic Trainers. Since 2010 there have been no changes in the state Athletic Trainers' Act, S.C. Code Ann. Section 44-75-10 et seq. (Supp. 2006).

As a result of the five-year review, the Department proposed to amend R.61-96 to incorporate changes in the renewal notification process. The Department is also amending the regulation, which includes corrections for clarity and readability, grammar, punctuation, definitions, references, codification and overall improvement of the text of the regulation.

Mr. Wronski provided the Board with an addendum correcting dates to be published in State Register and the date of the public hearing before the Board. (Attachment 10-2)

After discussion, *Dr. Kirol moved, seconded by Mr. Joye, to grant approval to publish the Notice of Proposed Regulation for 61-96, Athletic Trainers, 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 Amendment of Regulation 61-34.1, Pasteurized Milk and Milk Products, Legislative Review is required (Attachment 11-1)

Mr. Rick Caldwell, Assistant Bureau Chief, Bureau of Environmental Health Services, presented this item to the Board.

Statutory authority for Regulation R.61-34.1, Pasteurized Milk and Milk Products, resides in S.C. Code Section 44-1-140. The regulation governs the manufacturing of pasteurized milk and milk products in South Carolina. The current R.61-34.1 was derived from the U.S. Food and Drug Administration (FDA) Grade "A" Pasteurized Milk Ordinance, 2003 Revision.

In the most recent FDA Grade "A" Interstate Milk Shippers (IMS) Program Triennial State Evaluation (FY 2011-2013) report on the South Carolina Dairy Program, the current version of R.61-34.1 was determined to be out of date and to not meet the current Grade "A" IMS Program minimum requirements. FDA Memorandum of Information (M-I-03-2012 - Supplement 1) requires a state to adopt the Grade "A" Pasteurized Milk Ordinance (PMO) or have an equivalent regulation that is not more than six (6) years behind the current National Conference on Interstate Milk Shipments (NCIMS) and the PMO.

The proposed amendments will bring R.61-34.1 into compliance with the most updated procedures of the NCIMS, specifically Sections VI and VII of the Procedures Governing the Cooperative State - Public Health Service, Food and Drug Administration Program of NCIMS and the FDA PMO, 2013 Revision.

In order for South Carolina milk producers and processors to continue the shipment of milk and milk products into interstate commerce and market their milk products as Grade "A," it is essential to keep R.61-34.1 updated with respect to the current edition of the FDA Grade "A" PMO and its inclusive guidance documents.

The Department intends to incorporate into R.61-34.1 statutory changes so as to match the administrative appeals process pursuant to S.C. Code Ann. Section 44-1-60 (Supp. 2013).

After discussion, *Mr. Joye moved, seconded by Mr. Batts, to grant approval to publish the Notice of Proposed Regulation for 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 the Motion carried.*

Item 12: Proposed Amendment of Regulation 61-75, Standards for Licensing Day Care Facilities for Adults, Legislative Review is required (Attachment 12-1)

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

Statutory authority for Regulation 61-75, Standards for Licensing Hospices can be found in Code Sections 44-7-260. The Department promulgated Regulation 61-75 on June 28, 1991 and amended the regulation December 5, 2003. The purpose of the regulation is to provide a set of minimum standards for day care facilities for adults. Facilities for adults 18 years of age or older, which offer in a group setting a program of individual and group activities and therapies are affected by this regulation. The proposed new amendments herein include the Department's Bureau of Health Facilities Licensing effort to improve licensing procedures, care of participants, infection control and sanitation, functional safety, emergency procedures, design and construction, fire and life safety, and overall licensing requirements for day care facilities for adults. The Department also intends to add language to incorporate current provider wide exceptions and memoranda that are applicable to day care facilities for adults.

Code Section 1-23-120(J) requires state agencies to perform a review of its regulations every five years and update them if necessary. The proposed amendments herein include recommendations from the Department's five-year review.

The Department is amending R.61-75 in an effort to make the regulation current and to incorporate improvements to current care standards. The Department worked with South Carolina Adult Day Coalition and LeadingAge South Carolina in the development of the regulation amendments.

After discussion, Mr. Lutz moved, seconded by Dr. Kirol, to grant approval to publish the Notice of Proposed Regulation for 61-75, Standards for Licensing Day Care Facilities for Adults, 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

Director Templeton reported on the following: Ebola and the SC Obesity Grant recently awarded to the Department.

Item 14: Legal Report

Mr. Taylor reported on the new expedited Procedure for the Expedited Provision of Certain Public Records.

Chairman Amsler asked for an executive session to discuss a personnel matter.


Mr. Lutz moved, seconded by Mr. Batts, to go into Executive Session for the purpose of discussing a personnel matter. The Board voted and the Motion carried.

Chairman announced that while in Executive Session no actions were taken.

Chairman Amsler adjourned the meeting.

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

Respectfully submitted,


Ann B. Kirol, DDS, Secretary

Minutes approved this 13th day of November 2014.

ATTEST:


Mark Lutz, Vice Chairman

Attachments

- 0-1 Agenda
- 0-2 Attendance Roster
- 1-1 Minutes September 11 and September 25 conference call meetings
- 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 Public Hearing – Proposed Amendment of R.61-63, Radioactive Materials (Title A)
- 4-2 Public Hearing Sign-in Sheet
- 4-3 Verbatim Transcript of Public Hearing
- 5-1 Public Hearing – Proposed Amendment of R.61-91, Standards for Licensing Ambulatory Surgical Facilities
- 5-2 Sign-in Sheet for Public Hearing
- 5-3 Verbatim Transcript of Public Hearing
- 6-1 Request for Extension of CON SC-10-15 Sunnyside Healthcare Commons of Hilton Head
- 7-1 Request for Extension of CON SC 10-27 Sunnyside Healthcare Commons of Hilton Head
- 8-1 Request for Extension of CON SC 11-36 Pace Healthcare Commons, LLC
- 9-1 Request for Extension of CON SC 12-04 Pace Healthcare Commons, LLC
- 10-1 Proposed Amendment of Regulation 61-96, Athletic Trainers
- 10-2 Addendum to Board Package
- 11-1 Proposed Amendment of Regulation 61-34.1, Pasteurized Milk and Milk Products
- 12-1 Proposed Amendment of Regulation 61-75, Standards for Licensing Day Care Facilities for Adults