South Carolina Board of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201
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Minutes of the June 11, 2015, meeting of the

South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, June 11, 2015, at 9:00 a.m. via conference call in the Board Room (#3420) 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 (in person)
Member-at-Large

Mark Lutz, Vice-Chairman
1st District

Ann B. Kirol, DDS
5th District

R. Kenyon Wells
2nd District

Charles M. Joye, II, P.E.
3rd District

L. Clarence Batts (in person)
4th District

William Lee Hewitt, III
7th District

Also in attendance were Ms. Catherine Heigel, Director; W. Marshall Taylor, Jr., Legal 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 May 7 meeting (Attachment 1-1)

Mr. Batts moved, seconded by Mr. Wells, to approve the minutes as submitted for the May 7 meeting. The Board voted and Motion carried.

Item 2: Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation (Attachment 2-1)

Ms. Bentley White, Health Regulation Program Manager, stated one (1) Administrative Order and one (1) Consent Order had been issued with total penalties of $3,000.

The Board accepted this item as information.

Item 3: Proposed Amendment of Regulation 61-71, Well Standards, Legislative Review is required (Attachment 3-1)

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

The Department of Health and Environmental Control (Department) is authorized to promulgate and enforce rules and regulations that contain the minimum standards for the construction, maintenance, and operation of the following wells: individual residential, irrigation, monitoring (including non-standard installations), and boreholes to ensure that underground sources of drinking water are not contaminated and public health is protected.

The Department proposed to amend Regulation 61-71, Well Standards, to be consistent with the separation distance between private wells (individual residential and irrigation wells) and onsite wastewater systems (septic tank/tile fields) found in Regulation 61-56, Onsite Wastewater Systems, and clarify that Regulation 61-71 applies to injection wells as specified in Regulation 61-87, Underground Injection Control Regulations. Additionally, stylistic changes are made for clarity and consistency in language style to improve the overall quality of the Regulation.

After discussion, ***Mr. Batts moved, seconded by Dr. Kirol, to grant approval to publish the Notice of Proposed Amendment of Regulation 61-71, Well Standards, in the State Register, to provide opportunity for public comments, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted and Motion carried.***

Item 4: Proposed Amendment of Regulation 61-102, Standards for Licensing Birthing Centers for Deliveries by Midwives, Legislative Review is required (Attachment 4-1)

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

Regulation 61-102, Standards for Licensing Birthing Centers for Deliveries by Midwives has not been substantively amended since its promulgation in 1991. The amendments to the regulation are necessary to update definitions, nomenclature, codification, and overall improvements and updates to the text of the regulation.

The proposed amendments include the Department's effort to incorporate updates and clarification relating to licensing procedures, governing authority and management, admission and intake, professional care, functional safety, infection control and sanitation, dietary services, design and construction, fire protection and prevention, and overall requirements for licensure. In addition, corrections have been made for clarity, readability, grammar, references, codification, and overall improvement to the text of the regulation.

After discussion, ***Mr. Lutz moved, seconded by Dr. Kirol, to remand to staff with specific instructions to revise or define further the definition of "on-call" in 1101.B. The Board voted and Motion carried.***

Item 5: Request for second Board Extension of Certificate of Needs (CONs) SC-10-27 and SC-12-04 variously issued to related entities known as PACE Healthcare and Sunnyside Healthcare (PACE/Sunnyside) to design and build a multi-licensed, post acute care campus in Bluffton, S.C. (Attachment 5-1)

The Department awarded Pace/Sunnyside four (4) CONs between 2010 to 2012 for a variety of post-acute care services including:

- one hundred and twenty (120) bed skilled nursing/sub-acute care facility (SC-10-15),
- twenty-two (22) bed geriatric psychiatric hospital (SC-1O-27),
- thirty-two (32) bed long-term acute care hospital (SC-11-36), and
- ten (10) bed rehabilitation hospital (SC-12-04).

Funding difficulties prevented Pace/Sunnyside from making substantial progress on any of the four (4) projects list above which caused Pace/Sunnyside to request extensions for CONs SC-10-15, SC-11-36, SC-10-27 & SC-12-04 from the Board in October of 2014. The Board granted these requests.

In November of 2014, Pace/Sunnyside and a new business partner, Reliant Hospital Partners, LLC (hereinafter collectively Pace/Sunnyside/Reliant), filed an additional CON application seeking additional rehabilitation beds to increase the size of the rehabilitation hospital authorized by SC-12-04. If approved by the Department, the larger rehabilitation facility would be known as Reliant Bluffton, LLC. Staff is in the process of reviewing Pace/Sunnyside/Reliant's application for the larger facility. Pace/Sunnyside/Reliant proposes to co-locate the 22 bed geriatric psychiatric hospital approved by SC-1 0-27 with the expanded rehabilitation hospital, but does not seek to pursue Pace/Sunnyside's remaining two (2) CONs (SC-10-15 and SC-11-36).

Pace/Sunnyside/Reliant claims the geriatric psychiatric hospital is only economically viable if built in conjunction with a larger rehabilitation facility; hence, Pace/Sunnyside/Reliant had to await approval of its pending CON application for additional rehabilitation beds before it could pursue either the geriatric psychiatric or rehabilitation projects.

Pace/Sunnyside has candidly kept the Department informed regarding the status of funding for its various CONs and its progress in obtaining that funding. The geriatric sychiatric/rehabilitation facility it seeks to build is supported by both the State Health Plan and affected persons in Beaufort County. The County's only acute care hospital, Beaufort County Memorial Hospital,

supports the project and has agreed to transfer its existing rehabilitation beds to the geriatric psychiatric/rehabilitation facility once it is finally approved. The Department finds nothing in the administrative record that suggests the delay in moving forward with the aforementioned CONs have prejudiced existing facilities or proposed projects in the area.

After discussion, ***Mr. Wells moved, seconded by Mr. Hewitt, to find PACE Healthcare and Sunnyside Healthcare have demonstrated substantial progress and approve the extension requests for CON SC-10-27 and SC-12-04, thereby extending the CON for an additional nine (9) months. The Board voted and Motion carried.***

Item 6: Placement of Acetyl Fentanyl into Schedule I for Controlled Substances (Attachment 6-1)

Ms. Lisa Thomson, Director, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of Laws. Section 44-53-160 is titled "Manner in which changes in schedule of controlled substances shall be made." Pursuant to § 44-53-160, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule I substances are listed in § 44-53-190. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate a substance as a controlled substance if the federal government has so designated.
§ 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 Chairman 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 U.S. Department of Justice, Drug Enforcement Administration (DEA), published on May 21, 2015, its notice of intent to temporarily schedule the synthetic opioid, N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl), into schedule I of the Controlled Substances Act (CSA), effective upon publication of the final order. F.R. Volume 80, Number 98, pp. 29227-29230; http://www.gpo.gov/fdsys/pkg/FR-2015-05-21/pdf/2015-12331.pdf.

Substances listed in schedule I are those that have a high potential for abuse, no currently acceptable medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Acetyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide), is an opioid analgesic that has been found in powder and tablet form. The DEA noted that acetyl fentanyl has an abuse potential similar to heroin and prescription opioid analgesics. In 2012 and 2013, acetyl fentanyl was associated with 39 deaths in several states. In August 2013, the Centers for Disease Control and Prevention (CDC) published a report discussing a series of deaths associated with acetyl fentanyl, at http://www.cdc.gov/mmwr/pdf/wk/mm6234.pdf. In February 2014, the North Carolina Department of Health and Human Services issued a health advisory following at least three deaths related to acetyl fentanyl, at http://www.ncdhhs.gov/pressrel/2014/2014-02-19_health_advisory.htm. Available information for acetyl fentanyl indicates this substance has a high potential for abuse, no currently acceptable medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Therefore, the DEA has determined that placing acetyl fentanyl into schedule I is necessary to avoid an imminent hazard to the public safety.

After discussion, ***Mr. Batts moved, seconded by Mr. Lutz, to adopt the federal scheduling of acetyl fentanyl and amend Section 44-53-190 by adding and designating N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl), its optical, positional, and geometric isomers, salts and salts of isomers into Schedule I of the South Carolina Controlled Substances Act. The Board voted and Motion carried.*** (Attachment 6-2)

Item 7: Removal of [123I]ioflupane from Schedule II for Controlled Substances (Attachment 7-1)

Ms. Lisa Thomson, Director, Bureau of Drug Control, presented this item to the Board.

The U.S. Department of Justice, Drug Enforcement Administration (DEA), published on June 3, 2015, its intent to remove [123I]ioflupane from the Schedule II controlled substances list. http://www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13455.pdf

The Assistant Secretary for Health of the Department of Health and Human Services (HHS) has recommended the removal of Federal Drug Administration (FDA) approved products containing [123I]ioflupane from schedule II of the Controlled Substances Act. The DEA found no basis to remove only FDA approved products containing [123I]ioflupane, and therefore proposed to remove the substance [123I]ioflupane from the CSA schedule. Data currently supports the removal of substances containing [123I]ioflupane, primarily because the substance itself has a lethal radioactive barrier and its manufacturing process is highly regulated and technically complex, thereby making abuse highly unlikely. [123I]Ioflupane is currently a schedule II controlled substance because it is derived from cocaine via ecgonine, both of which are schedule II substances. [123I]Ioflupane is the active pharmaceutical ingredient in DaTscan, which was approved by the FDA on January 14, 2011 for use as a diagnostic tool for visualizing dopamine transporters in the brains of patients with suspected Parkinsonian syndromes. According to HHS, there have been no reports of abuse of [123I]ioflupane, and evidence suggests that there is no psychic or physiological dependence potential of FDA approved diagnostic products containing [123I]ioflupane due to the extremely high and lethal quantities needed to achieve a subjective "high".

Based upon the recommendation of HHS and its own review of relevant data, the DEA found that [123I]ioflupane has no comparable potential for abuse relative to substances in schedule V, has a currently acceptable medical use in the United States, and is not abusable and thus is not likely to lead to physical or psychological dependence and therefore [123I]ioflupane does not warrant control under the CSA.

After discussion, ***Mr. Batts moved, seconded by Mr. Joye, to remove [123I]ioflupane from Schedule II of the Controlled Substance list, amending S.C. Code Section 44-53-210 accordingly. The Board voted and Motion carried.*** (Attachment 7-2)

Item 8: Agency Affairs

Chairman Amsler welcomed Ms. Heigel as Director who updated the Board on the Greenwood E. coli outbreak.

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 August 2015.

ATTEST:

Mark Lutz, Vice- Chairman

Attachments

0-1 Agenda
0-2 Attendance Roster
1-1 May 7, 2015 minutes
2-1 Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation
3-1 Proposed Amendment of R.61-72, Well Standards
4-1 Proposed Amendment of R.61-102, Standards for Licensing Birthing Centers for Deliveries by Midwives
5-1 Request for second Board Extension of Certificate of Needs (CONs) SC-10-27 and SC-12-04 variously issued to related entities known as PACE Healthcare and Sunnyside Healthcare (PACE/Sunnyside) to design and build a multi-licensed, post-acute care campus in Bluffton, S.C.
6-1 Placement of Acetyl Fentanyl into Schedule I for Controlled Substances
6-2 Board Designation
7-1 Removal of [123I]ioflupane from Schedule II for Controlled Substances
7-2 Board Designation