

BOARD:
Allen Amsler
Chairman

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, PE.
L. Clarence Batts, Jr.
John O. Hurto, Sr., MD
William Lee Hewitt, III

Minutes of the January 27, 2015, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Tuesday, January 27, 2015, at 10:00 a.m. 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
Member-at-Large

Mark Lutz, Vice-Chairman (by phone)
1st District

Ann B. Kirol, DDS, Secretary
5th District

R. Kenyon Wells
2nd District

Charles M. Joye, II, P.E. (by phone)
3rd District

L. Clarence Batts
4th District

William Lee Hewitt, III (by phone)
7th District

Also in attendance were Elizabeth F. Potter, 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: Request for a first Board extension of Certificate of Need SC-12-29 issued to Springs Memorial Hospital, Lancaster, South Carolina for the addition of twelve (12) acute psychiatric beds for a total of one hundred ninety-nine (199) general acute beds, eighteen (18) substance abuse beds, and twelve (12) psychiatric beds, and the relocation of fourteen (14) bed transitional care unit (Attachment 1-1)

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

Certificate of Need SC-12-29 authorizes Springs Memorial Hospital to relocate its twelve bed geriatric-psychiatric unit to Springs Transitional Care Unit. However, further review showed that relocating the Gero-psych Unit to Lancaster Recover Center improves patient safety and provides additional space for establishing a comprehensive geriatric-psychiatric care unit. The change was approved by the Department and it was determined not to be a substantial amendment to the Certificate of Need.

Certificate of Need SC-12-29 was issued on September 20, 2012. Staff has granted two nine-month extensions.

Springs Memorial Hospital is requesting a first Board issued nine-month extension of Certificate of Need SC-12-29. Staff has reviewed the information submitted and recommends the Board find that substantial progress has been made and the extension request should be approved.

After discussion, Mr. Wells moved, seconded by Dr. Kirol, to find Springs Memorial Hospital has demonstrated substantial progress and approve the nine month extension request for CON SC-12-29. The Board voted and Motion carried.

Item 2: Request for a first Board extension of Certificate of Need SC-12-21, issued to Rice Estate Rehabilitation and Healthcare, Columbia, South Carolina, for the addition of forty-four (44) nursing care beds that will not participate in the Medicaid (Title XIX) program and expansion of rehabilitative therapy and other support services, resulting in a total of eighty (80) nursing care beds (Attachment 2-1)

Mr. Phillips presented this item to the Board.

Certificate of Need SC-12-21, issued on August 6, 2012, authorized Rice Estate Rehabilitation and Healthcare to construct an addition of forty-four nursing care beds that will not participate in the Medicaid (Title XIX) program and expansion of rehabilitative therapy and other support services, resulting in a total of eighty nursing care beds.

Department staff has granted two nine-month extensions and Rice Estate Rehabilitation and Healthcare is requesting the first Board issued nine-month extension of Certificate of Need SC-12-21. Staff has reviewed the information submitted and finds that substantial progress has been made to grant this extension request.

After discussion, Dr. Kirol moved, seconded by Mr. Batts, to find Rice Estate Rehabilitation and Healthcare has demonstrated substantial progress and approve the nine month extension request for CON SC-12-21. The Board voted and Motion carried.

Item 3: Public Hearing and Request for Final Approval - Proposed Revision of Regulation 61-15, Certification of Need for Health Facilities and Services, State Register Document No. 4551, Legislative Review is required (Attachment 3-1)

Mr. Phillips presented this item to the Board.

Pursuant to S.C. Code Section 44-7-150(3), the Department proposes amending S.C. Regulation 61-15, Certification of Need for Health Facilities and Services, as follows:

- The Department proposed amending R.61-15 to update table of contents and delete Section 102(3) regarding the Department's rendering of formal determination letters.
- The Department proposed amending R.61-15 to revise Section 104 (Exemption Determinations) to set forth the procedures and substance of exemption determinations that conform to the functionality of the web-based Certificate of Need application.
- The Department proposed amending R.61-15 to delete Section 105 (Determinations of Non-Applicability) which is unnecessarily duplicative of statutory language or otherwise addressed in Section 104.
- The Department proposed amending R.61-15 to revise Section 201 (Public Notification) regarding the procedure for an applicant to affirm that notice of a new CON application was published in a newspaper in accordance with statutory requirements.
- The Department proposed amending R.61-15 to revise Section 202 (Application) to replace the requirements of a paper-based Certificate of Need application with a web-based CON application.
- The Department proposed amending R.61-15 to revise Section 301 (Submission of Application) to set forth new procedures regarding the payment of a non-refundable filing fee to the Department in conjunction with the filing of a web-based CON application.
- The Department proposed amending R.61-15 to delete the Appendix (Application) to remove the exemplar of a paper-based CON application that was supplanted by the adoption of a web-based application.

Mr. Phillips provided the Board with “Attachment F Summary of Public Comments and Department Responses.” (Attachment 3-2)

A public hearing was conducted; however, no one in attendance spoke. (Attachment 3-3)

After discussion, *Mr. Batts moved, seconded by Mr. Wells, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-15, Certificate of Need for Health Facilities and Services, and approve it for submission to the Legislature for review. The Board voted and Motion carried.*

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 3-4)

Item 4: Removal of Naloxegol from Schedule II for Controlled Substances (Attachment 4-1)

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 this section, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule IV substances are listed in Section 44-53-250. Section 44-53-160(C) provides a process by

which DHEC can expeditiously remove a substance as a controlled substance if the federal government has so designated.

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 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 January 23, 2015, its final rule to remove Naloxegol (5[alpha],6[alpha]-17-allyl-6-((20-hydroxy-3,6,9,12,15,18-hexaoxaicos-1-yl)oxy)-4,5-epoxymorphinon-3,14-diol or alpha-6mPEG7-O-naloxol from the Schedule II controlled substances list.

The DEA received a petition from the drug sponsor dated March 22, 2012, requesting that the DEA amend 21 CFR 1308.12(b)(1) to exclude naloxegol as a schedule II controlled substance. The DEA accepted the petition for filing on October 1, 2012.

After review of all available data by HHS, FDA and DEA, including the scientific and medical evaluation and the recommendation to decontrol naloxegol from HHS, the Deputy Administrator of the DEA published in the Federal Register a notice of proposed rulemaking (NPRM) entitled "Schedules of Controlled Substances: Removal of Naloxegol from Control" which proposed removal of naloxegol and its salts from the schedules of the CSA. 79 FR 64349, October 29, 2014. The proposed rule provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations by November 28, 2014. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before November 28, 2014.

Based on the consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA's consideration of its own eight-factor analysis, the DEA Administrator found that these facts and all relevant data demonstrated that naloxegol does not meet the requirements for inclusion in any schedule, and it

was removed from control under the CSA. The final rule was published in the Federal Register January 23, 2015.

After discussion, *Mr. Batts moved, seconded by Mr. Wells, to adopt the final rule removing Naloxegol from Schedule II of the Controlled Substances List as defined in the Board package and Federal Register Volume 80, No. 15/Friday, January 23, 2015, pp. 3468-3470; to further amend Section 44-53-210 to delete Naloxegol from the SC Controlled Substances Act Schedule II. The deletion shall be identical in substance to the order in the federal register, by adding Naloxegol to the list of drugs excluded from Schedule II, as follows:*

Section 44-53-210. Schedule II.

*(b) * * **

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their respective salts,

** * * * **

The Board voted and Motion carried. (Attachment 4-2)

Chairman Amsler asked for an Executive Session for the purpose of discussing a Personnel matter relative to the agency.

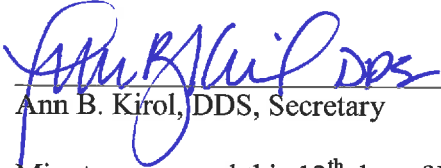
Mr. Wells moved, seconded by Dr. Kirol, to go into Executive Session for the purpose of discussing a Personnel matter. The Board voted and the Motion carried.

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

The meeting adjourned.

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

Respectfully submitted,



Ann B. Kirol, DDS, Secretary

Minutes approved this 12th day of March 2015.

ATTEST:



Allen Amsler, Chairman

Attachments

- 0-1 Agenda
- 0-2 Attendance Roster
- 1-1 Springs Memorial Hospital Request for CON Extension
- 2-1 Rice Estate Rehabilitation and Healthcare Request for CON Extension
- 3-1 Public Hearing – Proposed Amendment of R.61-15, Certificate of Need for Health Facilities and Services
- 3-2 Attachment F – Public Comments and Staff Responses
- 3-3 Sign-in Sheet for Public Hearing
- 3-4 Verbatim Transcript of Public Hearing
- 4-1 Removal of Naloxegol from Schedule II for Controlled Substances
- 4-2 Board Designation