



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 May 7, 2020, meeting of the South Carolina Board of Health and Environmental Control**

The South Carolina Board of Health and Environmental Control met on Thursday, May 7, 2020, 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 via telephone:

Mark Elam, Chairman  
Jim P. Creel, Jr., Vice-Chairman  
J.B. (Sonny) Kinney, 1<sup>st</sup> District  
Seema Shrivastava-Patel, 2<sup>nd</sup> District  
Charles M. Joye, II, P.E., 3<sup>rd</sup> District  
Richard V. Lee, Jr., 5<sup>th</sup> District  
Alex A. Singleton, 6<sup>th</sup> District

The 4<sup>th</sup> Congressional District seat is currently vacant.

Also, in attendance were Richard K. Toomey, Director, W. Marshall Taylor, Legal Counsel; M. Denise Crawford, Clerk; Department staff, and members of the public.

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 April 9, 2020 meeting** (Attachment 1-1)

**Mr. Lee moved, seconded by Ms. Shrivastava-Patel, to approve the minutes as presented. The Board voted and Motion carried.**

### **Item 2: Request for Placement of Norfentanyl into Schedule II of the South Carolina Controlled Substances Act** (Attachment 2-1)

Ms. Christie Frick, Director, Prescription Monitoring Program, Bureau of Drug Control, Health Quality presented this matter to the Board.

Controlled substances are governed by the Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the S.C. Code of Laws. Schedule II substances are listed in Section 44-53-210. Section 44-53-160 is titled "Manner in which changes in schedule of controlled substances shall be made." Pursuant to Section 44-53-160, controlled substances are generally designated by the General Assembly upon recommendation by the Department of Health and Environmental Control ("Department"). Section 44-53-160(C) provides a process by which the Department can expeditiously designate a substance as a controlled substance if the federal government has so designated.

South Carolina Code 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.

Norfentanyl is the immediate chemical intermediary in a synthesis process currently used by clandestine laboratory operators for the illicit manufacture of the schedule II controlled substance known as fentanyl. The distribution of illicitly manufactured fentanyl has caused an unprecedented outbreak of thousands of fentanyl-related overdoses in the United States in recent years. The Drug Enforcement Administration ("DEA") believes that the control of norfentanyl as a schedule II controlled substance is necessary to prevent its diversion as an immediate chemical intermediary for the illicit manufacture of fentanyl.

On September 17, 2019, the DEA published a Notice of Proposed Rule-Making (NPRM) to designate the precursor chemical, N-phenyl-N-(piperidin-4-yl) propionamide (norfentanyl), as an immediate precursor of the schedule II controlled substance known as fentanyl under the definition set forth in 21 U.S.C. 802(23), and to control it as a schedule II substance under the Controlled Substances Act. This rule-making finalizes that NPRM and will become effective on May 18, 2020, as stated in the April 17, 2020 issue of the *Federal Register*, Volume 85, Number 75, pages 21320-21325; <https://www.govinfo.gov/content/pkg/FR-2020-04-17/pdf/2020-07381.pdf>.

The DEA is extremely concerned with the increase in the illicit manufacture and distribution of fentanyl within the nation and abroad. Fentanyl is a synthetic opioid and was first synthesized in Belgium in the late 1950s. Fentanyl is controlled in schedule II of the CSA due to accepted medical use in the United States, though having high potential for abuse and dependence. Fentanyl was introduced into medical practice and is still approved in the United States for anesthesia and analgesia today. However, due to its pharmacological effects, fentanyl can also serve as a substitute for heroin, oxycodone, and other opioids in opioid-dependent individuals. The trafficking of fentanyl in the United States continues to pose an imminent hazard to public safety. Since 2012, fentanyl supply has had a dramatic increase in the illicit drug supply as a single substance, in mixtures with other illicit drugs (e.g., heroin, cocaine, and methamphetamines), and in forms that mimic pharmaceutical preparations that include prescription opiates and benzodiazepines. The DEA has noted a significant increase in overdoses and overdose fatalities from fentanyl in the United States in recent years.

Under 21 U.S.C. 811(e), the Attorney General may place an immediate precursor into the same schedule as the controlled substance that the immediate precursor is used to make. The substance must meet the requirements of an immediate precursor under 21 U.S.C. 802(23). The term "immediate precursor" is defined in 21 U.S.C. 802(23) as 1) a substance being the principal compound used, or which is produced primarily for use, in the manufacture of a controlled substance; 2) an immediate chemical intermediary used or likely to be used in the manufacture of the controlled substance; and 3) a control necessary to prevent or limit the manufacture of such a controlled substance. The DEA finds that norfentanyl meets the three criteria for the definition of an immediate precursor under 21 U.S.C. 802(23).

The DEA found that norfentanyl is produced primarily for use in the manufacture of the schedule II controlled substance known as fentanyl. As stated in the preceding section, under the Janssen method, norfentanyl is typically produced from the starting material benzylfentanyl and is then subjected to a simple one-step chemical reaction to obtain the schedule II controlled substance, known as fentanyl. The DEA is not aware of any legitimate use of benzylfentanyl other than in the synthesis of norfentanyl and, subsequently, fentanyl. The DEA has also not identified an industrial or other use for norfentanyl beyond the manufacture of fentanyl. The DEA has not identified any other legitimate uses of norfentanyl.

The DEA found that norfentanyl is an immediate chemical intermediary used in the manufacture of the controlled substance known as fentanyl. As stated earlier, norfentanyl is produced as an intermediary in the fentanyl synthetic pathway. After it is synthesized, norfentanyl is subjected to a simple chemical reaction that converts it directly to fentanyl.

The DEA found that controlling norfentanyl is necessary to prevent, curtail, and limit the unlawful manufacture of the controlled substance known as fentanyl.

The Drug Enforcement Administration concluded that the control of norfentanyl in schedule II of the federal CSA is necessary to prevent its production and use in the illicit manufacture of fentanyl.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommended placement of norfentanyl into Schedule II of the South Carolina Controlled Substances Act and the amendment of Section 44-53-210 of the South Carolina Code of Laws to include:

( ) N-phenyl-N- (piperidin-4-yl)propionamide (norfentanyl).

After discussion, **Mr. Kinney moved, seconded by Mr. Creel, to designate, for consistency with the Federal scheduling published in the Federal Register on April 17, 2020, placement of norfentanyl into Schedule II of the South Carolina Controlled Substances Act and, therefore, amend Section 44-53-210 of the South Carolina Code of Laws to include ( )N-phenyl-N- (piperidin-4-yl)propionamide (norfentanyl). The Board voted and Motion carried.** Designation Order signed by Chairman Elam (Attachment 2-2)

**Item 3: Request for Request for a third nine-month Board extension of Certificate of Need (CON) SC-16-19, issued to Trident Medical Center, LLC d/b/a Berkeley Medical Center (BMC) for construction of a new 50 bed acute care hospital to include an MRI and a CT scanner** (Attachment 3-1)

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

CON SC-16-19 was issued to BMC on May 26, 2016 for the project. The original CON had an expiration date of May 26, 2017. BMC requested a first staff extension of the CON on April 24, 2017, which was more than 30 days prior to expiration. BMC received CON SC-16-19-EXT-1 on May 17, 2017, and it was valid until February 26, 2018, a period of nine months from the original expiration of the CON. BMC requested a second staff extension of the CON on January 26, 2018, which was 30 days prior to expiration. BMC received CON SC-16-19-EXT-2 on March 5, 2018, and it was valid until November 26, 2018, a period of nine months from the revised expiration of the CON. BMC requested a third extension from the Board (first Board extension) on August 24, 2018, which was 90 days prior to expiration, and the Board approved this request on November 11, 2019. BMC requested and subsequently received CON SC-16-19-EXT-3 on November 28, 2018 and expired it on August 26, 2019. BMC submitted a fourth extension request (second Board extension request) to the Department on May 22, 2019 and received its extension on August 26, 2019. BMC submitted its fifth extension request (third Board extension) to the Department on February 25, 2020, which is more than 90-days prior to expiration of the current Certificate. The current Certificate expires on May 26, 2020.

Department staff reviewed all relevant information concerning this fifth extension request and find that BMC has demonstrated substantial progress sufficient to warrant further extension of CON SC-16-19. BMC's stated grounds for its previous requests were delays in implementing the project due to: 1) an unforeseen wetlands issue, and 2) opposition by Medical University Hospital Authority (MUHA), the parent of MUSC, in connection with BMC's second and third extension requests. Department staff were unmoved by the claims of delay due to litigation; however, BMC has now demonstrated additional progress towards development of final architectural drawings upon the completion of the wetlands mitigation work detailed in its extension request. On the day of its previous presentation to the Board for an extension of the Certificate, BMC received notice it had secured the mitigation credits necessary to move forward with site work and explained to the Board and staff that it would make a good faith effort to complete the work as described. Based on information presented by BMC in its most recent request for extension of CON SC-16-19, the mitigation work has concluded, and BMC now stands ready to continue with architectural and construction contracting. Department staff expect that, prior to the request for any further extension, BMC will continue to work with its architect(s) of choice to complete design schematics, and will begin meeting with representatives of DHEC's Division of Health Facilities Construction to have those schematics reviewed and approved in an effort to proceed towards execution of a bona fide construction contract for the facility.

Department staff recommended that the Board find that BMC has demonstrated substantial progress in connection with CON SC-16-19, and that the Board grant BMC's request.

After discussion, **Mr. Singleton moved, seconded by Mr. Creel, to find that Trident Medical Center, LLC d/b/a Berkeley Medical Center has demonstrated substantial progress on this project and approve the extension request for CON SC-16-19 issued to Trident Medical Center, LLC d/b/a Berkeley Medical Center. The Board voted and Motion carried.**

**Item 4: Agency Affairs**

Dr. Joan Duwve, Director of Public Health, provided an update on the COVID 19 (Coronavirus).

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


Richard K. Toomey, Director, updated the Board on:

- the HCR 911 Network;
- the continued operations of the agency during COVID 19;
- Accelerate SC;
- Legislative affairs.

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

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

Respectfully submitted,

  
Charles M. Joyce, II, PE  
Minutes approved this 11<sup>th</sup> day of June 2020.

ATTEST:

  
Mark R. Elam, Chairman

Attachments

- 0-1 Agenda
- 0-2 Sign in Sheet
- 1-1 April 9, 2020 minutes

- 2-1 Request for Placement of Norfentanyl into Schedule II of the South Carolina Controlled Substances Act
- 3-1 Request for Request for a third nine-month Board extension of Certificate of Need (CON) SC-16-19, issued to Trident Medical Center, LLC d/b/a Berkeley Medical Center (BMC) for construction of a new 50 bed acute care hospital to include an MRI and a CT scanner