SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

May 7, 2020

(X) ACTION/DECISION

( ) INFORMATION

I. **TITLE:** Placement of Norfentanyl into Schedule II for Controlled Substances in South Carolina.

II. **SUBJECT:** Placement of Norfentanyl into Schedule II of the South Carolina Controlled Substances Act.

III. **FACTS:** 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.

IV. ANALYSIS: 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).

1) The DEA finds 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.

2) The DEA finds 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.

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

V. RECOMMENDATION: The Drug Enforcement Administration concludes 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 recommends the 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).

Submitted by:

Lisa Thomson

Director

Bureau of Drug Control

Gwendolyn C. Thompson

Director

Healthcare Quality

Attachment:

April 17, 2020 Issue of the *Federal Register*, Volume 85, Number 75, Pages 21320-21325

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6410, Tail Rotor Blades.

Issued on April 13, 2020.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–08072 Filed 4–16–20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–496]

Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is designating the precursor chemical, *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl) as an immediate precursor for the schedule II controlled substance fentanyl. Furthermore, DEA is finalizing the control of norfentanyl as a schedule II substance under the Controlled Substances Act (CSA).

DATES: This rulemaking becomes effective May 18, 2020.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

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 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. 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.

DEA is extremely concerned with the recent increase in the illicit manufacture and distribution of fentanyl. Therefore, on September 17, 2019, DEA published a Notice of Proposed Rulemaking (NPRM) to designate the precursor chemical, *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl), as an immediate precursor of the schedule II controlled substance fentanyl under the definition set forth in 21 U.S.C. 802(23), and to control it as a schedule II substance under the CSA. 84 FR 48815. This rulemaking finalizes that NPRM.

Legal Authority

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, if the substance meets the requirements of an immediate precursor under 21 U.S.C. 802(23).

Background

The DEA is extremely concerned with the increase in the illicit manufacture and distribution of fentanyl abroad. Fentanyl is a synthetic opioid and was first synthesized in Belgium in the late 1950's. Fentanyl is controlled in schedule II of the CSA due to its high potential for abuse and dependence, and accepted medical use in treatment in the United States. Fentanyl was introduced into medical practice and is approved in the United States for anesthesia and analgesia. However, due to its pharmacological effects, fentanyl can 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 the public safety. Since 2012, fentanyl has shown a dramatic increase in the illicit drug supply as a single substance, in mixtures with other illicit drugs (*i.e.* heroin, cocaine, and methamphetamine), or in forms that mimic pharmaceutical preparations including 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. A recent report [1] from the Centers for Disease Control and Prevention (CDC) highlights this trend. According to this report, of the 41,430 drug overdose deaths occurring in the United States in 2011, 1,662 (4.0 percent) involved fentanyl.[2] Of the 63,632 drug overdose deaths in 2016, 18,335 (28.8 percent) involved fentanyl. This was the first time that fentanyl was reported in more drug related fatalities than heroin.

The increase of drug overdose deaths continued into 2017. According to the CDC,[3] there were 70,237 drug overdose deaths in the United States in 2017, an increase from the 63,632 overdose deaths recorded in 2016. Of the 70,237 overdose deaths in 2017, 47,600 (67.8 percent) involved an opioid. Deaths involving prescription opioids and heroin remained stable from 2016 to 2017; synthetic opioid overdose deaths (other than methadone), which include deaths related to fentanyl, increased 45.2 percent from 19,413 deaths in 2016 to 28,466 deaths in 2017.

The increase in overdose fatalities involving fentanyl coincides with a dramatic increase of law enforcement encounters of fentanyl. According to the National Forensic Laboratory Information System (NFLIS),[4] submissions to forensic laboratories that contained fentanyl increased exponentially beginning in 2012: 694 in 2012, 1,044 in 2013, 5,537 in 2014, 15,455 in 2015, 37,294 in 2016, 61,382 in 2017, and 70,453 in 2018.

Role of Norfentanyl in the Synthesis of Fentanyl

Fentanyl is not a naturally occurring substance. As such, the manufacture of fentanyl requires it to be produced through synthetic organic chemistry. Synthetic organic chemistry is the process for creating a new organic molecule through a series of chemical reactions, which involve precursor chemicals. In the early 2000's, a synthetic process, commonly known as the Siegfried method, was utilized to manufacture fentanyl in several domestic and foreign clandestine laboratories. 72 FR 20039. At that time, DEA had determined that two primary synthesis routes (*i.e.*, the Janssen method and the Siegfried method) were being used to produce fentanyl clandestinely, although it believed the Janssen synthesis route to be difficult to perform and beyond the rudimentary skills of most clandestine laboratory operators. The Siegfried synthetic route involves two important intermediates, *N*-phenethyl-4-piperidone (NPP) and 4-anilino-*N*-phenethylpiperidine (ANPP).

[1] Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2011–2016. National Vital Statistics Reports; vol 67 no 9. Hyattsville, MD: National Center for Health Statistics, 2018.

[2] The fentanyl category includes fentanyl, fentanyl metabolites, precursors, and analogs.

[3] Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and Opioid-Involved Overdose Deaths—United States, 2013–2017. MMWR Morb Mortal Wkly Rep 2019;67:1419–1427.

[4] The National Forensic Laboratory Information System (NFLIS) is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by Federal, State and local forensic laboratories in the United States. NFLIS data was queried on March 26, 2019.

The DEA controlled NPP on April 23, 2007 as a list I chemical by interim rule (72 FR 20039), which was finalized on July 25, 2008. 73 FR 43355. By final rule published on June 29, 2010, ANPP was controlled as a schedule II immediate precursor to fentanyl, with an effective date of August 30, 2010. 75 FR 37295.

In 2017, the United Nations Commission on Narcotic Drugs placed NPP and ANPP in Table I of the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (1988 Convention) in response to the international increase of fentanyl on the illicit drug market. As such, member states of the United Nations were required to regulate these precursor chemicals at the national level. In addition, the People's Republic of China regulated NPP and ANPP on February 1, 2018.

Recent law enforcement information indicates that illicit manufacturers of fentanyl also use other synthetic routes in response to regulations placed on NPP and ANPP. One of these other routes is the original published synthetic pathway to fentanyl, known as the Janssen method, previously thought to be beyond the skills of most clandestine laboratory operators. This synthetic route does not involve NPP or ANPP as precursors. This synthetic pathway involves the important precursors *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl). Benzylfentanyl is converted into norfentanyl in one chemical reaction. Norfentanyl is then subjected to one simple chemical reaction to complete the synthesis of fentanyl. The DEA is not aware of any legitimate uses of benzylfentanyl or norfentanyl other than in the synthesis of fentanyl.

According to DEA forensic laboratory data, the Janssen method was confirmed as the synthetic route used in 94 percent of 85 fentanyl drug exhibits that were evaluated to determine the synthetic route. These exhibits were seized in 2018. In addition, the number of law enforcement encounters of benzylfentanyl increased in 2017 and 2018. As stated above, benzylfentanyl is a precursor chemical used to synthesize norfentanyl in the Janssen method. According to NFLIS,[5] there was one identification of benzylfentanyl in 2016; however, benzylfentanyl was identified in 195 reports in 2017 and 237 reports in 2018. This is believed to indicate a change in the synthetic route used by some clandestine chemists to manufacture fentanyl in efforts to evade chemical regulations on NPP and ANPP. The increase in law enforcement encounters coincides with the international control that placed NPP and ANPP in Table I of the 1988 Convention in 2017.

The DEA determined that norfentanyl is commercially available from both domestic and foreign chemical suppliers. The DEA has identified 30 domestic suppliers and 22 foreign suppliers of norfentanyl from Canada (3), China (7), Germany (2), Hong Kong (1), India (1), Japan (2), Switzerland (1), and the United Kingdom (5). Of the 30 domestic suppliers of norfentanyl, only one is a DEA registrant. As it appears that these other 29 suppliers are not registered to manufacture schedule II controlled substances, it is not likely these suppliers are manufacturing fentanyl. Norfentanyl is attractive to illicit manufacturers because of the lack of chemical regulations on this substance, it is readily available from chemical suppliers, and it can easily be converted to the schedule II controlled substance fentanyl, in a one-step chemical reaction.

Designation as an Immediate Precursor

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) meaning a substance being the principal compound used, or which is produced primarily for use in the manufacture of a controlled substance; which is an immediate chemical intermediary used or likely to be used in the manufacture of the controlled substance; and the control of which is necessary to prevent or limit the manufacture of such 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). First, DEA finds that norfentanyl is produced primarily for use in the manufacture of the schedule II controlled substance 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, 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. DEA has not identified any other legitimate uses of norfentanyl and DEA did not receive comment to the contrary during the notice and comment period of the NPRM published on September 17, 2019. 84 FR 48815.

Second, DEA finds that norfentanyl is an immediate chemical intermediary used in the manufacture of the controlled substance 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.

Third, DEA finds that controlling norfentanyl is necessary to prevent, curtail, and limit the unlawful manufacture of the controlled substance, fentanyl. The DEA believes this action is necessary to assist in preventing the possible theft of norfentanyl from legitimate firms. The DEA believes that clandestine manufacturers will attempt to procure unregulated chemicals in their efforts to synthesize fentanyl. As a schedule II substance, norfentanyl will be safeguarded to the same degree that pharmaceutical firms now safeguard the fentanyl that they produce. Since norfentanyl is an immediate chemical intermediary in the manufacture of fentanyl, the increased level of security is necessary to prevent diversion of norfentanyl from legitimate firms. DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing norfentanyl and selling it (as an unregulated material) through the internet and other channels to individuals who may wish to acquire an unregulated precursor for the purpose of manufacturing fentanyl, a schedule II controlled substance.

The DEA believes that the control of norfentanyl is necessary to prevent its production and use in the illicit manufacture of fentanyl. Therefore, DEA is designating norfentanyl as an immediate precursor of fentanyl, a schedule II controlled substance, pursuant to 21 U.S.C. 802(23) and 21 U.S.C. 811(e).

Placement in Schedule II—Findings Required Under CSA Immediate Precursor Provisions

Pursuant to 21 U.S.C. 811(e), once norfentanyl is designated as an immediate precursor under 21 U.S.C. 802(23), it may be placed directly into schedule II (or a schedule with a higher numerical designation). The immediate precursor provision in 21 U.S.C. 811(e)

[5] NFLIS data was queried on March 26, 2019.

permits DEA to schedule an immediate precursor "without regard to the findings required by" section 811(a) or section 812(b) and "without regard to the procedures" prescribed by section 811(a) and (b). Accordingly, DEA need not address the "factors determinative of control" in section 811 or the findings required for placement in schedule II in section 812(b)(2). Based on the finding that norfentanyl is an "immediate precursor" for fentanyl, DEA is hereby placing norfentanyl directly into schedule II.

NPRM Comments

As part of the proposed rulemaking published on September 17, 2019 (84 FR 48815), DEA specifically solicited input from all potentially affected parties regarding: (1) The types of legitimate industries using norfentanyl; (2) the legitimate uses of norfentanyl; (3) the size of the domestic market for norfentanyl; (4) the number of manufacturers of norfentanyl; (5) the number of distributors of norfentanyl; (6) the level of import and export of norfentanyl; (7) the potential burden these proposed regulatory controls of norfentanyl may have on legitimate commercial activities; (8) the potential number of individuals/firms that may be adversely affected by these proposed regulatory controls (particularly with respect to the impact on small businesses); and (9) any other information on the manner of manufacturing, distribution, consumption, storage, disposal, and uses of norfentanyl by industry and others.

As part of the proposed rulemaking published on September 17, 2019 (84 FR 48815), DEA solicited information on any possible legitimate uses of norfentanyl unrelated to fentanyl production (including industrial uses) in order to assess the potential commercial impact of scheduling norfentanyl. The DEA searched information in the public domain for legitimate uses of norfentanyl and could not document legitimate commercial uses for norfentanyl other than as an intermediary chemical in the manufacture of fentanyl. DEA sought, however, to document any unpublicized use(s) and other proprietary use(s) of norfentanyl not in the public domain. Therefore, DEA solicited comment on the uses of norfentanyl in the legitimate marketplace. The DEA also solicited comment on the regulatory burden to legitimate commercial activities that would result from the placement of norfentanyl in schedule II of the CSA. The DEA did not receive comment on these topics.

The DEA invited all interested parties to provide any information on any legitimate uses of norfentanyl in industry, commerce, academia, research and development, or other applications. The DEA sought both quantitative and qualitative data; however, DEA did not receive comments on these topics.

The DEA received 15 comments in response to the NPRM. Thirteen of the 15 commenters were in support of controlling norfentanyl as a schedule II immediate precursor. The other two commenters did not specifically object to this rule. One of those two commenters stated that substance abuse is a public health issue and not a law enforcement issue. The other stated that this rule is not sufficient to disrupt the fentanyl market in the United States because illicit fentanyl is not produced in the United States. The commenter proposed access restriction and harm reduction strategies, including increased public awareness of drugs mixed with fentanyl and increased law enforcement at entry locations, as additional recommendations to reduce fentanyl misuse and abuse in the United States.

Of the 13 commenters in support of controlling norfentanyl as a schedule II immediate precursor, four commenters also included statements that the control of norfentanyl is not the only solution to address the opioid epidemic. These commenters stated that control of norfentanyl will not solve the issue of fentanyl being shipped into our country from foreign producers; that control of norfentanyl is not the only policy that should be addressed and implemented, and that alternate pathways to fentanyl should be monitored; and that control of norfentanyl will not end the opioid epidemic.

DEA response: The DEA appreciates the comments in support of controlling norfentanyl as a schedule II immediate precursor. The DEA is concerned with the abuse of illicitly manufactured fentanyl in the United States and abroad. While DEA remains aware that a comprehensive approach, to include community outreach and education, is required to combat the opioid epidemic, DEA believes that supply reduction strategies, which this rule attempts to address, are important aspects to reduce drug abuse in the United States. The control of norfentanyl as a schedule II immediate precursor is one aspect of the overall effort to combat the opioid epidemic. The DEA believes this rule will have a significant effect on reducing the supply of illicitly manufactured fentanyl.

With respect to the comments about illicit fentanyl being manufactured outside of the United States and shipped into the country from foreign producers, the designation of norfentanyl as a schedule II immediate precursor will subject this substance to the regulatory requirements of schedule II substances, including the import and export regulations. 21 CFR part 1312. The DEA believes that regulating the import and export of norfentanyl will reduce the quantity of norfentanyl destined to illicit fentanyl manufacturers, both domestically and internationally, by removing the United States as a transshipment point and as a source of diverted norfentanyl to foreign illicit fentanyl manufacturers.

The DEA is the leading agency on enforcement of drug control laws and remains committed to protecting the public by interrupting and reducing drug supply and availability in the United States. The DEA believes that the control of norfentanyl as an immediate precursor of the schedule II controlled substance fentanyl will have a significant impact on reducing the supply of illicitly manufactured fentanyl; however, DEA remains aware that supply reduction is not the only aspect of combatting the opioid epidemic. The DEA realizes that a comprehensive approach, to include community outreach and education, is required to combat the opioid epidemic. In response to the comment regarding access restriction and harm reduction strategies and the comment stating that substance abuse is a public health issue and not a law enforcement issue, DEA intends this scheduling action to reduce the supply of illicitly manufactured fentanyl, which is part of a multi-faceted strategy to combat the opioid epidemic. DEA continues to work with other federal agencies on holistic and comprehensive approaches to reduce drug abuse; however, such approaches are beyond the scope of this rule.

Requirements for Handling Norfentanyl

This rulemaking finalizes two actions. It (1) designates norfentanyl as an immediate precursor for the schedule II controlled substance, fentanyl, under the definition set forth in 21 U.S.C. 802(23); and (2) controls norfentanyl as a schedule II substance pursuant to the authority in 21 U.S.C. 811(e).

The scheduling of norfentanyl as an immediate precursor of the schedule II controlled substance, fentanyl, subjects norfentanyl to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a schedule II controlled substance. The regulatory requirements will include the following:

1. *Registration.* Any person who manufactures, distributes, dispenses, imports, or exports norfentanyl, engages in research with respect to norfentanyl, or proposes to engage in such activities will be required to submit an application and be accepted for schedule II registration in accordance with 21 CFR part 1301.

2. *Security.* Norfentanyl will be subject to schedule II security requirements. In order to prevent diversion, norfentanyl will be manufactured, distributed, and stored in accordance with the standards for physical security and the operating procedures set forth in 21 CFR 1301.71, 1301.72(a), (c), and (d), 1301.73, 1301.74, 1301.75(b),(c), and (d) 1301.76, and 1301.77.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of norfentanyl that are distributed will be required to comply with the requirements of 21 CFR 1302.03–1302.07.

4. *Quotas.* Quotas for norfentanyl will be established pursuant to 21 CFR part 1303.

5. *Inventory.* Every registrant who possesses any quantity of norfentanyl will be required to keep an inventory of all stocks of the substance on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11.

6. *Records and Reports.* Every DEA registrant will be required to maintain records and submit reports with respect to norfentanyl pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes norfentanyl will be required to comply with the order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of norfentanyl will be required to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, or otherwise dispose of a controlled substance or where records relating to those activities are maintained, are controlled premises as defined in 21 U.S.C. 880(a) and 21 CFR 1316.02(c). The CSA allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A. 21 U.S.C. 880.

10. *Liability.* Any activity with norfentanyl in violation of or not authorized under the Controlled Substances Act or the Controlled Substances Import and Export Act will be unlawful and potentially subject to criminal penalties. 21 U.S.C. 841–863 and 959–964.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This rulemaking was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. DEA has determined that this rule is not a "significant regulatory action" under Executive Order 12866, section 3(f). Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation.[6] In furtherance of this requirement, Executive Order 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.[7] According to guidance provided by OMB, the requirements of Executive Order 13771 only apply to each new "significant regulatory action that . . . imposes costs."[8] This rule is not expected to be an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

The scheduling of norfentanyl as an immediate precursor of the schedule II controlled substance, fentanyl, subjects norfentanyl to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a schedule II controlled substance. Norfentanyl is the immediate chemical intermediary in a synthesis process currently used by clandestine laboratory operators for the manufacture of the schedule II controlled substance 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 DEA has not identified any industrial use for norfentanyl, other than its role as an intermediary chemical in the manufacture of fentanyl. Based on the review of import and quota information for ANPP and fentanyl, DEA believes the vast majority, if not all, of legitimate pharmaceutical fentanyl is produced from ANPP (schedule II immediate precursor for fentanyl), not norfentanyl. The quantities of ANPP permitted in the U.S., imported or manufactured pursuant to a quota, generally correspond with the quantities of legitimate pharmaceutical fentanyl produced in the United States. Additionally, DEA is not aware of norfentanyl being used for the manufacturing of legitimate pharmaceutical fentanyl; however, DEA cannot rule out the possibility that minimal quantities of norfentanyl are used for this purpose. If there are any quantities of norfentanyl used for the manufacturing of legitimate pharmaceutical fentanyl, the quantities are believed to be small and economically insignificant.

The DEA evaluated the costs and benefits of this action.

[6] Sec. 2(a).

[7] Sec. 2(c).

[8] OMB Guidance Implementing Executive Order 13771 titled "Reducing Regulation and Controlling Regulatory Costs" (April 5, 2017).

Costs

The DEA believes the market for norfentanyl for the legitimate manufacturing of pharmaceutical fentanyl is minimal. As stated above, the only use for norfentanyl of which DEA is aware is for the manufacturing of fentanyl. Any manufacturer, distributor, importer, or exporter of norfentanyl for the production of legitimate pharmaceutical fentanyl, if they exist at all, would incur costs. The primary costs associated with this rule include costs associated with complying with registration, physical security, labeling and packaging, quota, inventory, recordkeeping and reporting, and importation and exportation requirements. Other than the annual registration fees ($3,047 for manufacturers and $1,523 for distributors, importers, and exporters), due to the many unknowns and variability between entities, it is highly difficult to quantify the potential total cost burden of this regulation. However, any manufacturer that uses norfentanyl for legitimate pharmaceutical fentanyl production would already be registered with DEA and have all security and other handling processes in place, resulting in minimal cost. Any lost sales or profit attributed to those manufacturers or suppliers that are not for legitimate pharmaceutical fentanyl are excluded from the analysis as they are, whether passively or actively, facilitating the manufacture of illicit fentanyl.

The DEA has identified 30 domestic suppliers of norfentanyl, 29 of which are not registered with DEA to handle schedule II controlled substances. It is difficult to estimate how much norfentanyl is distributed by these suppliers. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Based on the review of import and quota information for fentanyl and ANPP, where the quantities of ANPP imported and manufactured generally correspond with the quantities of fentanyl produced, DEA believes any quantity of sales from these distributors for the legitimate pharmaceutical fentanyl manufacturing is minimal. Suppliers for the legitimate use of norfentanyl are expected to choose the least-cost option, and stop selling the minimal quantities, if any, of norfentanyl, rather than incur the costs of complying with the regulatory requirements. Because DEA believes the quantities of norfentanyl supplied for the legitimate manufacturing of pharmaceutical fentanyl is minimal, DEA estimates that the cost of foregone sales is minimal; and thus, the cost of this rule is minimal.

This analysis excludes consideration of economic impact to those businesses that facilitate the manufacturing and distribution of norfentanyl for the manufacture of illicit fentanyl. The only use for norfentanyl of which DEA is currently aware is the manufacture of fentanyl. Although these suppliers are selling a currently unregulated substance, they wittingly or unwittingly facilitate the manufacturing of illicit fentanyl. As a law enforcement organization and as a matter of principle, DEA believes considering the economic utility of facilitating the manufacture of illicit fentanyl would be improper.

Benefits

Controlling norfentanyl is expected to prevent, curtail, and limit the unlawful manufacture and distribution of the controlled substance, fentanyl. This action is also expected to assist preventing the possible theft or diversion of norfentanyl from any legitimate firms. As a schedule II substance, norfentanyl will be safeguarded to the same degree that pharmaceutical firms now safeguard the fentanyl that they produce. The DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing norfentanyl and selling it (as an unregulated material) through the internet and other channels, to individuals who may wish to acquire an unregulated precursor for the purpose of manufacturing illicit fentanyl.

In summary, DEA conducted a qualitative analysis of costs and benefits. DEA believes this action will minimize the diversion of norfentanyl. The DEA believes the market for norfentanyl for the legitimate manufacturing of pharmaceutical fentanyl is minimal. Therefore, any potential cost as a result of this regulation is minimal. Therefore, the estimated economic impact of this rule is less than $100 million in any given year.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. This rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. As discussed above, the scheduling of norfentanyl as an immediate precursor of the schedule II controlled substance, fentanyl, subjects norfentanyl to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a schedule II controlled substance. 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 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 DEA has not identified any use for norfentanyl, other than its role as an intermediary chemical in the manufacture of fentanyl. Based on the review of import and quota information for ANPP and fentanyl, DEA believes the vast majority, if not all, of legitimate pharmaceutical fentanyl is produced from ANPP (schedule II immediate precursor for fentanyl), not norfentanyl. The quantities of ANPP permitted in the U.S., imported or manufactured pursuant to a quota, generally correspond with the quantities of

legitimate pharmaceutical fentanyl produced in the United States. Additionally, DEA is not aware of norfentanyl being used for the manufacturing of legitimate pharmaceutical fentanyl; however, DEA cannot rule out the possibility that minimal quantities of norfentanyl are used for this purpose. If there are any quantities of norfentanyl used for the manufacturing of legitimate pharmaceutical fentanyl, the quantities are believed to be small and economically insignificant.

The DEA has identified 30 domestic suppliers of norfentanyl. Based on the Small Business Administration size standard for chemical distributors and Statistics of United States Business data, 94.5 percent or 28.4 (rounded to 28) are estimated to be small entities. It is difficult to know how much norfentanyl is distributed by these suppliers. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Based on the review of import and quota information for fentanyl and ANPP, where the quantities of ANPP imported and manufactured generally correspond with the quantities of fentanyl produced, DEA believes any quantity of sales from these distributors for the legitimate pharmaceutical fentanyl manufacturing is minimal. Therefore, DEA estimates the cost of this rule on any affected small entity is minimal.

Because of these facts, this rule will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, DEA determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, that this action will not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act

This action does not impose a new collection of information under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action does not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, drug traffic control, reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.12 by adding paragraph (g)(3)(ii) to read as follows.

§ 1308.12 Schedule II.

* * * * *

(g) * * *

(3) * * *

(ii) *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl)	8366

* * * * *

Dated: March 5, 2020.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–07381 Filed 4–16–20; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2019–0083; FRL–10007–78–Region 7]

Air Plan Approval; Nebraska; Infrastructure SIP Requirements for the 2015 Ozone National Ambient Air Quality Standards (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve elements of a State Implementation Plan (SIP) submission from the State of Nebraska addressing the applicable requirements of the Clean Air Act (CAA) section 110 for the 2015 Ozone (O_3) National Ambient Air Quality Standards (NAAQS). Whenever the EPA promulgates a new or revised NAAQS, CAA section 110 requires that each State adopt and submit a SIP submission to establish that the State's SIP meets infrastructure requirements for the implementation, maintenance, and enforcement of each such new or revised NAAQS. These SIP submissions are commonly referred to as "infrastructure" SIPs. The infrastructure requirements are designed to ensure that the structural components of each State's air quality management program are adequate to meet the State's responsibilities under the CAA.

DATES: This final rule is effective on May 18, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2019–0083. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional information.

FOR FURTHER INFORMATION CONTACT: Lachala Kemp, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number (913) 551–7214; email address *kemp.lachala@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document "we," "us," and "our" refer to EPA.

Table of Contents

I. Background

On May 9, 2019, the EPA proposed to approve Nebraska's infrastructure SIP submission for the 2015 O_3 NAAQS in the **Federal Register**. 84 FR 20318 (May 9, 2019). The EPA solicited comments on the proposed approval of the infrastructure SIP submission and

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

May 7, 2020

(X) ACTION/DECISION

( ) INFORMATION

I. TITLE: 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.

II. SUBJECT: BMC requests Board approval for extension of CON SC-16-19.

III. FACTS: CON SC-16-19 was issued to BMC on May 26, 2016 for the referenced 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.

IV. ANALYSIS: Department staff have 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.

V. RECOMMENDATION: Department staff recommend that the Board finds BMC has demonstrated substantial progress in connection with CON SC-16-19, and that the Board grant BMC's request.

Approved by:

_____

Gwen C. Thompson
Director, Healthcare Quality

Attachments:
A) CON SC-16-19
B) Letter granting first extension of CON
C) Letter granting second extension of CON
D) Letter granting third extension of CON
E) Letter granting fourth extension of CON
F) Letter requesting fifth extension of CON

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until May 26, 2017 which is a period of twelve (12) months from the date of issuance unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 26th day of May, 2016.

Louis W. Eubank
Director, Certificate of Need Program

D H E C
PROMOTE PROTECT PROSPER

Article #: 9214896900999790140838699 1

May 17, 2017

VIA EMAIL AND CERTIFIED MAIL
William R. Thomas
Parker Poe
1221 Main Street, Suite 1100
Columbia, SC 29201

Re: Request for an Extension of Certificate of Need No. SC-16-19
Project: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.
Berkeley Medical Center

Dear Mr. Thomas:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a nine (9) month initial extension** for Certificate No. SC-16-19. The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Sincerely,

Louis Eubank
Director, Certificate of Need Program

Enclosures: Guide to Board Review.
CON SC-16-19-EXT-1

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
   - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:

   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201

   Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.
NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
    - include the place, date and time of the Conference;
    - state the presentation times allowed in the Conference;
    - state evidence may be presented at the Conference;
    - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
    - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
    - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
        - Type of decision (permit, enforcement, etc.) and description of the program.
        - Parties
        - Description of facility/site
        - Applicable statutes and regulations
        - Decision and materials relied upon in the administrative record to support the staff decision.
    - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
    - Rebuttal by Department staff [15 minutes]
    - Rebuttal by Requestor(s) [10 minutes]
      Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19-EXT-1

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until February 26, 2018 which is a period of nine (9) months from the date of prior Certificate of Need expiration unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 17th day of May.

Louis W. Eubank
Director, Certificate of Need Program

dhec
Healthy People. Healthy Communities.

Article #: 9214896900999790141109103 5

March 5, 2018

VIA EMAIL AND CERTIFIED MAIL
William R. Thomas, Esquire
Parker Poe
1221 Main Street, Suite 1100
Columbia, SC 29201

Re: Request for an Extension of Certificate of Need No. SC-16-19
Project: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.
Berkeley County, South Carolina

Dear Mr. Thomas:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a second nine (9) month extension** for Certificate No. SC-16-19. The original The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

Based on the assurances you have provided the Department, it is understood that the wetlands permitting process currently before the U.S. Army Corps of Engineers will be complete, or nearly complete, by the time of expiration of this second CON extension. Further extensions of SC-16-19 may be granted by the Department Board, with recommendations made by staff, based on current information **to include the status of this permitting process**.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Sincerely,

Louis Eubank, Chief
Bureau of Healthcare Planning and Construction

cc: M. Elizabeth Crum, Esquire (email)

Enclosures: Guide to Board Review.
CON SC-16-19-EXT-2

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
   - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:

   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201

   Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.
NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
    - include the place, date and time of the Conference;
    - state the presentation times allowed in the Conference;
    - state evidence may be presented at the Conference;
    - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
    - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
    - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
        - Type of decision (permit, enforcement, etc.) and description of the program.
        - Parties
        - Description of facility/site
        - Applicable statutes and regulations
        - Decision and materials relied upon in the administrative record to support the staff decision.
    - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
    - Rebuttal by Department staff [15 minutes]
    - Rebuttal by Requestor(s) [10 minutes]

    Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19-EXT-2

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until November 26, 2018 which is a period of nine (9) months from the date of prior Certificate of Need expiration unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 5th day of March, 2018.

Louis W. Eubank, Chief
Bureau of Healthcare Planning and Construction

dhec
Healthy People. Healthy Communities.

Healthy People. Healthy Communities.

Article #: 9214896900999790141344465 5

November 28, 2018

VIA EMAIL AND CERTIFIED MAIL
William R. Thomas, Esquire
Parker Poe
1221 Main Street, Suite 1100
Columbia, SC 29201

Re: Request for an Extension of Certificate of Need No. SC-16-19
Project: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.
Berkeley County, South Carolina

Dear Mr. Thomas:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a second nine (9) month extension** for Certificate No. SC-16-19. The original The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

Please note that all subsequent requests for extension of SC-15-26 are subject to approval by the Department Board. Requests for such extension must be received 90-days prior to expiration of the current extension.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Sincerely,

Louis Eubank, Chief
Bureau of Healthcare Planning and Construction

cc: William R. Thomas, Esquire (email)
M. Elizabeth Crum, Esquire (email)

Enclosures: CON SC-16-19-EXT-3

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19-EXT-3

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until August 26, 2019 which is a period of nine (9) months from the date of prior Certificate of Need expiration unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 28th day of November, 2018.

Louis W. Eubank, Chief
Bureau of Healthcare Planning and Construction

dhec
Healthy People. Healthy Communities.

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
   - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:

   South Carolina Board of Health and Environmental Control
   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201

   Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.

NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
   - include the place, date and time of the Conference;
   - state the presentation times allowed in the Conference;
   - state evidence may be presented at the Conference;
   - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
   - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
   - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
     - Type of decision (permit, enforcement, etc.) and description of the program.
     - Parties
     - Description of facility/site
     - Applicable statutes and regulations
     - Decision and materials relied upon in the administrative record to support the staff decision.
   - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
   - Rebuttal by Department staff [15 minutes]
   - Rebuttal by Requestor(s) [10 minutes]

   Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council.. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

Healthy People. Healthy Communities

Article #: 9214896900999790141570677 5

August 26, 2019

VIA EMAIL AND CERTIFIED MAIL

Jim Rardin
Trident Medical Center
9330 Medical Plaza Drive
North Charleston, SC 29406

Re: Request for an Extension of Certificate of Need No. SC-16-19
Project: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.
Berkeley County, South Carolina

Dear Mr. Thomas:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a fourth nine (9) month extension** for Certificate No. SC-16-19. The original The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

Please note that all subsequent requests for extension of SC-15-26 are subject to approval

by the Department Board. Requests for such extension must be received 90-days prior to expiration of the current extension.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Sincerely,

Louis Eubank, Chief
Bureau of Healthcare Planning and Construction

cc: William R. Thomas, Esquire (email)

Enclosures: CON SC-16-19-EXT-4

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of $100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars ($100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
   - The grounds for amending, modifying, or rescinding the staff decision;
   - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
   - the relief requested;
   - a copy of the decision for which review is requested; and
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   Attention: Clerk of the Board
   2600 Bull Street
   Columbia, South Carolina 29201

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7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.

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   - state evidence may be presented at the Conference;
   - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
   - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
   - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
     - Type of decision (permit, enforcement, etc.) and description of the program.
     - Parties
     - Description of facility/site
     - Applicable statutes and regulations
     - Decision and materials relied upon in the administrative record to support the staff decision.
   - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
   - Rebuttal by Department staff [15 minutes]
   - Rebuttal by Requestor(s) [10 minutes]

   Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
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3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
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9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-16-19-EXT-4

IS HEREBY ISSUED TO FACILITY: Berkeley Medical Center

FACILITY LOCATION: Moncks Corner, South Carolina
Berkeley County

LICENSEE: Trident Medical Center, LLC

AGENT: Jim Rardin

FOR: Construction of a new 50 bed acute care hospital to include an MRI and CT scanner.

TOTAL PROJECT COST: $115,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until May 26, 2020 which is a period of nine (9) months from the date of prior Certificate of Need expiration unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 26th day of August, 2019.

Louis W. Eubank, Chief
Bureau of Healthcare Planning and Construction

dhec
Healthy People. Healthy Communities.

Parker Poe

William R. Thomas
Partner
t: 803.253.8658
f: 803.255.8017
willthomas@parkerpoe.com

Atlanta, GA
Charleston, SC
Charlotte, NC
Columbia, SC
Greenville, SC
Raleigh, NC
Spartanburg, SC
Washington, DC

February 25, 2020

Via Hand Delivery

The Honorable M. Denise Crawford
Clerk of the Board
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

Re: **Trident Medical Center, LLC, d/b/a Berkeley Medical Center**
Certificate of Need for the Construction of a New 50-Bed Hospital to Include an MRI and CT Scanner
CON Number: SC-16-19
Fifth Extension Request

Dear Ms. Crawford:

On behalf of our client, Trident Medical Center, LLC, d/b/a Berkeley Medical Center ("Trident"), and pursuant to S.C. Code Ann. § 44-7-230(D) and S.C. Reg. 61-15, §§ 601 – 603, Trident respectfully requests an extension of the above-referenced Certificate of Need (SC-16-19). The CON is due to expire on May 26, 2020. Thus, Trident is requesting that the Board extend SC-16-19 expiration date to February 26, 2021. As required, Trident is submitting this request more than three months before the expiration date of the Certificate of Need, and is providing the information required under Sections 601(4), 602 and 603.

a. A detailed description of any changes in the configuration, costs, services, or scope of the project.

RESPONSE: There are no changes to the scope of the project, its configuration, costs, or services. As the Board is aware, Trident experienced delays in implementing the project due to an unforeseen wetlands issue and opposition filed by the Medical University Hospital Authority's ("MUHA") in connection with the Department's staff approval of Trident's second CON extension request, and the Department's Board decision to grant a third extension request. MUHA's opposition was defeated after the Administrative Law Court granted Trident summary judgment motion in the action filed by MUHA.

To date, Trident has incurred in costs approximately $3,772,322, which includes the cost of the wetlands mitigation credits, the purchase of the property, consultant costs related to the wetlands issues, and wetlands construction costs.

b. A detailed description and documentation of any progress on the project including preparation of construction drawings, the securing of necessary funds and building permits, and commencement of any construction.

RESPONSE: The site has been procured, conceptual site plans for the hospital have been completed, and the wetlands mitigation credits were released in August 2019. The USACOE issued the required permit to relocate the man-made ditch/stream that was classified as wetlands, and after working with the engineers and site contractors to plan for site grading and erosion control, Trident released the contractors to begin construction to relocate the ditch/stream. The relocation of the ditch/stream was completed in January 2020 as shown below:

Trident is currently negotiating with the architect in connection with the construction documents.

c. An estimated timetable for commencement and completion of all remaining components of the project.

Trident proposes the following timeline for completion of the project now the wetlands mitigation issue is resolved.

Finalize Site	February 2020
Architectural Contract	March 2020
Architectural Design	August 2020
Construction Contract	October 2020
Start of Construction	November 2020
Completion of Construction	July 2022
Occupy new hospital	September 2022

d. Documentation of compliance with the approved timetable or documented evidence that extenuating circumstance[s] beyond the control of the applicant [exist] if the timetable was not met.

RESPONSE: As described above, the Berkeley Medical Center project has been delayed due to unforeseen wetlands issues and a lawsuit brought by another hospital challenging Trident's CON extension. These two issues constitute extenuating circumstances beyond Trident's control. While wetlands issues are not uncommon in the low country, the extent of this particular wetlands issue was unforeseen, and Trident has worked diligently to resolve it, as evidenced by the copious documentation it has submitted to the Department staff and Board over the past two years, the money expended, and the testimony presented to the DHEC Board by Trident's outside engineering and environmental consulting firms. Trident presents a timeline below detailing the events associated with this project:

May 2, 2016	Request for an Approved Jurisdictional Determination is made to the Army Corp of Engineers
May 26, 2016	CON issued by the Department
August 2016	S&ME, a geotechnical engineering firm, is engaged to provide assistance with wetlands issue
August 23, 2016	Request for quote to move ditches on the property is submitted
September 20, 2016	Survey awarded to Atlantic Surveying, Inc.
September 21, 2016	Department of the Army's response to May 2, 2016 request
October 3, 2016	Decision to engage work in May 2017 for Nationwide Permit #46 to avoid reapplication
December 6, 2016	Trident closed on property
April 24, 2017	Trident's first CON extension request filed
May 17, 2017	First extension request granted
August 7, 2017	Received Corps determination letter
August 7, 2017	S&ME submits Nationwide Permit Application
September 22, 2017	Department of the Army's response to 8/7/17 Nationwide Permit Application, determining it does not meet terms of a Nationwide Permit and must be evaluated as an Individual Permit, also requesting additional information
October 2, 2017	Nationwide Permit denied due to linear feet of stream bed. Individual permit must be submitted

October 6, 2017	S&ME's Request for Nationwide Permit Waiver
November 6, 2017	S&ME's Individual Permit Application – Coastal Zone Consistency Request re: relocation of drainage canal and freshwater wetland
December 4, 2017	Joint Public Notice
January 12, 2018	USACE working on Comment Letter
January 15, 2018	DHEC's State Certification
January 26, 2018	Trident's second CON extension request filed
February 7, 2018	Medical University Hospital Authority ("MUHA") files with DHEC CON notice of affected person status and opposition to Trident's second extension request
February 16, 2018	Trident's files response to MUHA's 2/7/18 affected person/opposition notice
February 16, 2018	MUHA files additional submission opposing Trident's second extension request
February 22, 2018	Trident's files response to MUHA's 2/16/18 submission
March 5, 2018	Second extension request granted
March 19, 2018	MUHA files with the DHEC Board a Request for Final Review of the Department's 3/5/18 decision to grant Trident's second extension request
March 20, 2018	MUHA's files with the DHEC Board its response to Trident's 2/16/18 submission
April 2, 2018	Trident's files its response to MUHA's Request for Final Review
April 25, 2018	DHEC Board denies to hear MUHA's Request for Final Review
May 9, 2018	MUHA files with the Administrative Law Court ("ALC") its Petition for Review and Request for Contested Case Hearing in connection with Trident's second extension request
July/August 2018	USACE requiring either the purchase of mitigation credits in full at a cost of $660,000 or requiring Trident to enter into a plan whereby credits are purchased and creation credits are realized at a cost of $440,000 with a five year monitoring period. Trident is pursuing funding for these credits and does not anticipate problems with obtaining such funding
August 24, 2018	Trident files third extension request with the DHEC Board
October 25, 2018	MUHA files with the DHEC Board its opposition to Trident's third extension request
October 29, 2018	Trident files with the DHEC Board its response to MUHA's third extension request
November 28, 2018	Trident's third extension request granted
November 28, 2018	Mitigation Credit Reservation Agreement executed between ICA Engineering, Inc. and Trident to purchase 3,462 stream restoration and preservation credits
December 10, 2018	MUHA files with the ALC its Petition for Review and Request for Contested Case Hearing in connection with Trident's third extension request
December 18, 2018	USACE Permit #SAC-2016-00782 executed on behalf of Trident and submitted to the USACE with appropriate fees to be counter-signed by the District Engineer
December 21, 2018	Receipt confirming payment by Trident reserving 3,462 mitigation credits

January 4, 2019	ALC grants Trident summary judgment, MUHA's case is dismissed in connection with its opposition to Trident's 2nd extension request
January 29, 2019	Consent Order of Dismissal filed dismissing MUHA's case in connection with its opposition to Trident's 3rd extension request
April 11, 2019	Amendment to 11/28/18 Mitigation Credit Reservation Agreement delaying credit release to July 26, 2019 due to weather conditions, unavoidable construction delays
May 22, 2019	Trident files fourth extension request with the DHEC Board
July 2019	Caton Creek completed necessary construction
August 8, 2019	DHEC Board hearing on Trident's third extension request; Trident's third extension request granted
August 8, 2019	Mitigation credits released and USACOE has issued required permit to relocate the ditch/stream
January 2020	Relocation of the ditch/stream completed

For these reasons, Trident respectfully requests that the Board find (i) that Trident has made substantial progress on its Berkeley Medical Center project to the extent possible; (ii) that Trident has been delayed in implementing the project due to extenuating circumstances beyond its control; and (iii) that a fifth extension of Berkeley Medical Center project is justified and approved.

With best regards, I am

Sincerely,

William R. Thomas

cc: Margaret P. Murdock, Esquire (via hand delivery)
Todd Gallati (via email)