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SC Court of Appeals

THE STATE OF SOUTH CAROLINA
IN THE COURT OF APPEALS

APPEAL FROM THE ADMINISTRATIVE LAW COURT
The Honorable H.W. Funderburk, Jr., Administrative Law Judge

APPELLATE CASE NO.: 2019-000358
ADMINISTRATIVE LAW COURT CASE NO.: 16-ALJ-07-0386-CC

Trident Medical Center, LLC, d/b/a Trident Medical
Center,.....Respondent,

v.

South Carolina Department of Health and Environmental Control,
and Roper St. Francis Hospital – Berkeley, Inc., d/b/a Roper St.
Francis Hospital – Berkeley,.....Respondents below,

Of Which South Carolina Department of Health and Environmental
Control is a.....Respondent,

And Roper St. Francis Hospital – Berkeley, Inc., d/b/a
Roper St. Francis Hospital – Berkeley is the.....Appellant.

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VOLUME 1 OF 6
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January 15, 2020
Columbia, South Carolina

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**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

Trident Medical Center, LLC, d/b/a Trident
Medical Center,

Petitioner,

vs.

South Carolina Department of Health and
Environmental Control, and Roper St. Francis
Hospital – Berkeley, Inc., d/b/a Roper St.
Francis Hospital – Berkeley County,

Respondents.

Docket No.: 16-ALJ-07-0386-CC

FINAL ORDER

Appearances:

For Petitioner Trident: William R. Thomas, Esq.

For Respondent Roper: Jennifer J. Hollingsworth, Esq.

For Respondent DHEC: Ashley C. Biggers, Esq.

STATEMENT OF THE CASE

This matter comes before the South Carolina Administrative Law Court (ALC or Court) upon the request of Petitioner Trident Medical Center, LLC, d/b/a Trident Medical Center (Trident) for a contested case hearing to review the decision of the South Carolina Department of Health and Environmental Control (DHEC or Department) granting a Certificate of Need (CON) to Roper St. Francis Hospital - Berkeley, Inc., d/b/a Roper St. Francis Hospital – Berkeley (Roper-Berkeley) for the addition of a new diagnostic cardiac catheterization lab¹ (Project) at its medical facility which is under construction in Berkeley County and is scheduled to open in the fall of 2019.

¹ Diagnostic catheterization is a tool used in the treatment of heart disease whereby a thin flexible tube is inserted into a blood vessel in the arm or leg allowing a doctor to examine the heart and associated blood vessels. See discussion of The Application *infra*.

FILED

DEC 03 2018

SC ADMIN. LAW COURT

Prior to a hearing on the merits, Petitioner filed a Motion for Summary Judgment that was denied by Order dated March 2, 2017. The parties thereafter conducted discovery and prepared the matter for a hearing. The contested case was heard on July 24 and July 25, 2018.²

FINDINGS OF FACT

Pursuant to Rule 25(C) of the Rules of Procedure for the Administrative Law Court (SCALC Rules), the parties submitted written stipulations of fact, which are hereby adopted by the Court and set forth below:

Roper-Berkeley filed a Certificate of Need (CON) Application on May 9, 2016, to construct a catheterization laboratory and provide diagnostic cardiac catheterization services at the Roper-Berkeley Hospital under construction in Berkeley County. The CON Application states that upon approval, the diagnostic catheterization laboratory at Bon Secours St. Francis Xavier Hospital (Bon Secours) will be permanently closed.

The applicable South Carolina Health Plan (State Health Plan) is the Health Plan enacted August 13, 2015.

By decision letter dated July 25, 2016, DHEC approved the CON Application. On August 17, 2016, Bon Secours notified the Department that it permanently closed its diagnostic cardiac catheterization lab effective August 1, 2016.

Trident timely filed a Request for Board Review with the DHEC Board that was denied without review on September 21, 2016.

Trident timely filed a contested case in the Administrative Law Court and is an affected person with standing to challenge DHEC's decision.

Chapter VIII of the State Health Plan is the Chapter addressing cardiovascular care services. Pages VIII-4 and VIII-5 contain the Standards for establishing a new diagnostic catheterization laboratory. Standards 1, 2, 3, and 4 apply to the CON Application. Standards 5 and 6 do not apply the CON Application.

² Prior to the contested case hearing, the parties informed the Court they had agreed to limit the issues before the Court as stated in the parties' stipulation of facts.

Standard 1 sets forth the capacity for cardiac catheterization laboratories in South Carolina based on the complexity of the services provided. Standard 2 sets forth the service area for cardiac catheterization laboratories based on the complexity of the services provided. Standard 3 sets forth the historical utilization threshold for approval of a new diagnostic catheterization laboratory in a service area. Standard 4 sets forth the minimum projected utilization for approval of a new diagnostic catheterization laboratory in a service area.

The facilities in the relevant service area with cardiac catheterization laboratories at the time of the CON Application's submission were Trident Medical Center, Roper Hospital, Medical University of South Carolina, and Bon Secours. All of the catheterization laboratories except Bon Secours were comprehensive catheterization laboratories. In 2014, Bon Secours reported in its Joint Annual Report to DHEC that 4 diagnostic catheterization procedures had been performed in its catheterization lab. In 2015, Bon Secours reported in its Joint Annual Report to DHEC that 2 diagnostic catheterizations had been performed.

The catheterization laboratories at Trident, Roper Hospital, and the Medical University satisfy the historical utilization threshold under Standard 3. The parties dispute whether the CON Application satisfies Standard 3 and, therefore, whether it complies with S.C. Code Ann. Regs. 61-15 § 802.1.

Initially, Trident challenged many aspects of the CON Application, but for efficiency and judicial economy, it has decided to withdraw its challenge to the CON Application in every respect with the exception of challenging whether the CON Application satisfies Standard 3. Trident asserts that because the CON Application does not satisfy Standard 3, the Application does not comply with the State Health Plan and, as such, is not consistent with the State Health Plan per Reg. 61-15 § 801.3 and S.C. Code Ann. § 44-7-210(B). Therefore, Trident contends that DHEC erred in approving the CON Application.

The parties recognize that Trident has withdrawn its challenges to the CON Application save the challenge concerning Standard 3, and while Trident may not agree with the following conclusions, the parties so stipulate to effectuate the contested case hearing for purposes of limiting the issues in dispute:

- (a) The CON Application satisfies Standard 4.

- (b) Reg. 61-15 is applicable to the CON Application.
- (c) The CON Application sufficiently projects Community Need to satisfy Section 802.2 of the Project Review Criteria (PRC).
- (d) The CON Application sufficiently meets the requirements for Distribution (Accessibility) set forth in Section 802.3 of the PRC.
- (e) The CON Application establishes financial feasibility set forth in Section 802.15 and related financial sections of the PRC.
- (f) The CON Application sufficiently meets the requirements of cost containment set forth in Section 802.16 of the PRC.
- (g) The CON Application will not have an adverse effect on other facilities as defined by Sections 802.23 and 802.24 of the PRC.
- (h) Any additional PRC applicable to the CON Application have been satisfied with the exception of Section 802.1, which relates to the parties' dispute as to Standard 3.
- (i) Section 500 of Reg. 61-15 is not applicable to the CON Application.

Dan Sullivan is qualified to testify as an expert witness pursuant to Rule 702 of the South Carolina Rules of Evidence (SCRE), under the designations of healthcare planning and the State Health Plan.

Kathy Platt is qualified to testify as an expert witness pursuant to Rule 702, SCRE, under the designations of healthcare planning and the State Health Plan.

In addition to these stipulations of fact, and having observed the witnesses and exhibits presented at the hearing and closely passed upon their credibility, taking into consideration the burden of proof upon the parties, I make these additional Findings of Fact by a preponderance of the evidence:

Parties

The Roper St. Francis Healthcare system consists of four hospitals: Roper Hospital on the Charleston Peninsula; Bon Secours in West Ashley; Mount Pleasant Hospital in Mount Pleasant; and Roper-Berkeley under construction in Berkeley County. At the time the CON Application was

filed in May 2016, Roper St. Francis Healthcare had four (4) licensed cardiac catheterization laboratories: three comprehensive catheterization laboratories at Roper Hospital and one diagnostic catheterization laboratory at Bon Secours in West Ashley.

Trident is an existing provider of cardiac catheterization services in Roper-Berkeley's proposed service area.

The Application

Roper-Berkeley filed a CON Application on May 9, 2016, proposing to establish diagnostic catheterization services at the Roper-Berkeley Hospital under construction in Goose Creek. DHEC reviewed the Application under the 2015 South Carolina Health Plan, which was enacted August 13, 2015.

Cardiovascular services subject to CON review include diagnostic catheterizations, therapeutic catheterizations, and percutaneous coronary interventions, as well as pediatric catheterizations and open-heart surgery.

A diagnostic catheterization is a procedure that involves threading a catheter through a vessel and using imaging equipment to photograph what is happening in those vessels. A therapeutic catheterization involves the same vessel imaging but also includes treatment procedures such as removing a blockage or inserting a stent.

Cardiac catheterizations are performed in a catheterization laboratory. Laboratories may be designated as providing only diagnostic catheterization services or may be designated as a comprehensive catheterization laboratory if both diagnostic and therapeutic catheterization services are provided in the laboratory. Roper-Berkeley's CON Application seeks to provide diagnostic catheterizations in a diagnostic catheterization laboratory.

The State Health Plan includes an inventory of cardiac catheterization services showing existing cardiac catheterization providers in the various regions of the state. The relevant region in this case is Region 4. In addition to the number of catheterization labs that each provider operates by region, the inventory also shows the historical utilization of those catheterization labs for certain years, in this case 2011, 2012, and 2013.

The purpose of the State Health Plan inventory for cardiac catheterization is to allow interested parties to identify existing providers in the service area and the historical utilization of each lab in

a given area. It also provides a reference point for applicants for health services to determine if existing providers are operating in conformity with the applicable standards, such as Standard 3. In doing so, the State Health Plan's cardiac catheterization lab inventory also allows a potential applicant to determine whether a new cardiac catheterization lab is needed in the service area.

CON applicants also obtain and review the relevant Joint Annual Reports (JAR) filed by the hospitals to analyze more recent utilization data. Moreover, it is standard practice for the Department to rely on the updated utilization data in the JAR when making a decision according to a State Health Plan that may be one or two years old.

Among the applicable standards in the Health Plan that must be satisfied for new diagnostic catheterization services, Trident only challenges Standard 3, which states that "[n]ew diagnostic catheterization services, including mobile services, shall be approved **only if all existing labs** in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year (emphasis added)."³

Standard 3 is a community-need standard that references utilization in the service area. In this case, the service area is a 45-minute drive time around the proposed Goose Creek location for new diagnostic catheterization services. Standard 3 is used to determine whether the existing labs in the service area are well utilized, which is of paramount importance for health planning. To measure the need for another cardiac catheterization lab one must know whether existing labs are being sufficiently utilized.

Standard 3 is an objective measure of utilization and uses the phrase "have performed," which calls for a retrospective view to determine if existing providers have satisfied the 500-procedure threshold. Standard 4, by contrast, is a prospective standard indicating what the Department expects the applicant to perform in the future.

Standard 3 also establishes whether there is a community need using objective measures. In tandem with the CON Act, the volume threshold set forth in Standard 3 seeks to avoid unnecessary duplication of catheterization labs, which can affect quality.

³ "The most recent year" refers to the completed year for which annual utilization data is available, in contrast to the **current** year.

Although Standard 3 does not directly reference quality, the Department does consider quality throughout the cardiovascular service chapter regarding case volume standards. In the context of Standard 3 and “quality,” approving an unneeded lab could result in reducing the case volumes of existing providers. As stated in the 2015 State Health Plan, reduced case volumes diminish quality because “[o]ptimal performance requires a caseload of adequate size to maintain the skills and efficiency of the staff.” (Cardiovascular Care, p. VIII-2).

Prior to its CON Application for Roper-Berkeley, Roper St. Francis did not notify the Department that it had closed or intended to close its catheterization lab at Bon Secours, although there were years when it reported the facility did not perform any catheterization procedures. Rather, the Department and Roper St. Francis **agreed** to the closure of Bon Secours’ catheterization lab contingent upon and following approval of the CON Application for Roper-Berkeley.

It is clear from the record that as far back as 2010, DHEC Staff was aware of the substantial underperformance occurring in the catheterization lab at Bon Secours. In a May 27, 2010, letter involving a separate CON Application, the Department informed the Chief Operating Officer of East Cooper Medical Center that, “[b]ased on our review of the standards in the 2008-2009 South Carolina Health Plan and the CON law and regulations, we have determined that [the Department] does not currently have a mechanism in place that would allow the Department to discount the existence of the [Bon Secours] cardiac catheterization lab when computing the average utilization for the service area.” The Department went on to “...recognize that continuing to inventory a service that has remained idle for three years can negatively impact the ability of other providers to offer that service.” This letter was generated in the context of East Cooper Medical Center’s desire to apply for a CON for new diagnostic catheterization services in 2010 while recognizing that Bon Secours’ catheterization lab had been operating at very low or zero volumes in the previous years. The Department acknowledged that the appropriate remedy would be to amend the State Health Plan for 2010-2011 to allow adjustments for “unused” beds or equipment; however, no such steps were taken.⁴

DHEC Staff again became aware of the low catheterization utilization at Bon Secours following the Department’s receipt of another East Cooper Medical Center CON Application on February 4,

⁴ See Joint Exhibit 2, p.081.

2016. In this application, East Cooper contended that the Bon Secours' catheterization lab should be considered non-operational for purposes of the Health Plan inventory because Bon Secours' lab was in violation of S.C. Reg. 61-15, Section 102(1)(e), which requires a person or facility to obtain a CON before offering any health service that was not offered in the preceding twelve-month period.⁵

Louis Eubank, the CON Program Director for DHEC, reviewed Roper-Berkeley's CON Application and made the decision on behalf of the Department to approve the Application. When applying CON Standard 3 to Roper-Berkeley's CON Application, he was aware that the diagnostic catheterization lab at Bon Secours was underutilized. Specifically, the JAR data showed that Bon Secours performed zero catheterization procedures in 2007, 2008, and 2009, resuming in 2010 with very low utilization.⁶

In fact, Mr. Eubank emailed counsel for Roper-Berkeley on April 14, 2016, a few weeks prior to Roper-Berkeley's submission of its CON Application, to inform him that the Department was considering enforcement action against Bon Secours for violating S.C. Reg. 61-15, Section 102(1)(e) by failing to obtain a new CON prior to performing diagnostic catheterization procedures beginning in 2010, after performing no catheterization procedures for the previous three years. Eubank wrote that the continued operation of the Bon Secours catheterization lab at such low volume was prohibiting the entry of any additional catheterization labs in the service area as outlined in State Health Plan standards for such services. Further, Eubank noted that the low volume would also likely prohibit the transfer of Bon Secours' catheterization lab from the operator's facility to another Roper St. Francis-owned facility under the service transfer criterion which requires adequate historic utilization figures. In the same email, the Department invited Roper to propose a solution within ten business days of the receipt of the email.⁷

Notably, although clearly aware that the lab had been operating in violation of Standard 3 since at least 2010, at no time did the Department undertake any enforcement action against Bon Secours.

⁵ S.C. Reg. 61-15, Section 102(1)(e) states "A person or health care facility as defined in this Regulation is required to obtain a [CON] from the [Department] before undertaking any of the following: ... the offering of any health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan."

⁶ This information is found in Joint Exhibit 2, at page 077 and in Petitioner's Exhibit 3, 007, 008, and 010, and in Petitioner's Exhibit 5, 011. Subsequent references in other documents, *infra*, allude to 2008 and 2009 only.

⁷ See Petitioner's Exhibit 5, p. 001.

Also, Mr. Eubank later testified that, given the period of not performing the required volume of catheterization procedures, he did not consider Bon Secours to be an existing catheterization lab for purposes of review of Standard 3 in 2016. Nevertheless, Bon Secours was included in the inventory of existing cardiac catheterization providers in the service area in the State Health Plan inventory.

In a letter to DHEC dated April 20, 2016, Bon Secours asked to be an affected person with respect to East Cooper's 2016 CON Application for a new diagnostic catheterization lab. As to East Cooper's claim that Bon Secours' catheterization lab was non-operational, Bon Secours wrote that East Cooper's position regarding the Bon Secours catheterization lab was inconsistent with the applicable CON laws and the State Health Plan. It further contended that until the CON Application for diagnostic catheterization services at Roper-Berkeley was approved, Bon Secours intended to operate its catheterization lab. However, at this time, Roper-Berkeley had not yet filed a CON Application for diagnostic catheterization services. Curiously, the letter makes clear that Roper St. Francis did not intend to close the Bon Secours lab if the Roper-Berkeley Application was not approved – only that the Bon Secours lab would be closed upon approval of the Project.

On April 22, 2016, two days after the Department received an affected person letter from Roper-Berkeley's legal counsel regarding East Cooper's CON Application, but more than two weeks prior to receiving Roper-Berkeley's CON Application, Mr. Eubank sent East Cooper's representative an email with the subject line "Notice from Roper/St. Francis" stating that, "I think everything will work out just fine for everyone."

Nineteen days after its affected person letter to DHEC regarding East Cooper's CON Application, Roper-Berkeley submitted its own CON Application stating that upon approval of the Application to establish diagnostic catheterization services at Roper-Berkeley, the diagnostic catheterization laboratory at Bon Secours would be permanently closed.

The CON Application includes relevant detail and documentation establishing the current and projected population growth for Berkeley, Dorchester, Colleton, and Charleston Counties, as well as data establishing the historical and projected utilization for all four of the Roper St. Francis system's cardiac catheterization laboratories.

The diagnostic catheterization laboratory at Bon Secours, discussed *infra*, was being underutilized even though the remaining cardiac catheterization laboratories in the applicable service area were well utilized.

DHEC approved the CON Application to add diagnostic catheterization services at Roper-Berkeley by decision letter dated July 25, 2016.⁸ On August 17, 2016, Bon Secours notified DHEC that it permanently closed its diagnostic catheterization laboratory on August 1, 2016.

Need for a Diagnostic Cardiac Catheterization Lab in the Service Area

The facilities in the relevant service area with cardiac catheterization laboratories at the time of the CON Application's submission were Trident Medical Center, Roper Hospital, Medical University of South Carolina, and Bon Secours. These catheterization laboratories, except Bon Secours' catheterization laboratory, were comprehensive catheterization laboratories. The eleven other catheterization laboratories at Trident, Roper Hospital, and the Medical University satisfy the historical utilization requirements under Standard 3.

In its CON Application, Roper-Berkeley classified Bon Secours as an existing lab and listed the volume for the Bon Secours diagnostic catheterization lab under Exhibit 14 entitled "Historical Utilization of Existing Labs in the Service Area." It also included utilization from 2012 to 2014, which showed that in no year was Bon Secours' catheterization volume over the 500-procedure threshold set forth in Standard 3. Following the table for Exhibit 14, the CON Application states, "[w]hile Bon Secours St. Francis Xavier Hospital is operating below the 500 diagnostic equivalents per year, the lab will be closed upon the approval of this project"

Nowhere in the CON Application does Roper-Berkeley state that the Bon Secours catheterization lab is non-operational or non-existent, only that it **will close** and, therefore, will not exist **after** the approval of the CON Application. The Application does not imply, or otherwise state, that the Department recognizes that Bon Secours is not offering diagnostic catheterization services.

In 2007, 2008, and 2009, Bon Secours reported in its JAR that no catheterization procedures were performed in its lab. The Department also had JAR data available as late as 2015 indicating that Bon Secours was operating well under the 500-catheterization-procedures standard. The Department, however, exercised its discretion not to take enforcement action under the CON

⁸ DHEC also approved East Cooper's CON Application for a diagnostic catheterization lab on the same day.

statute and regulation. The Department also did not suspend or fine Bon Secours, though such measures were available. Thus, Bon Secours' lab was not closed nor was it ever officially determined to be operating in violation of the law. Moreover, Bon Secours was not removed from the catheterization lab inventory of the State Health Plan even though the Department indicated as far back as 2010 that the appropriate remedy would be to amend the Plan.

Furthermore, Roper-Berkeley's legal counsel contended during the 2010 East Cooper application review process that Bon Secours **offered** catheterization services during two zero years (2008 and 2009). Indeed, Roper-Berkeley's position in its affected-person letter during the 2016 East Cooper application process emphasized that Bon Secours was an existing facility, had not lost its CON authorization, and would continue to operate its catheterization lab until Roper-Berkeley's CON Application was approved.

The most recent report available for DHEC review in considering the CON Application was the 2015 JAR. In it, Bon Secours reported that two diagnostic catheterization procedures had been performed in its lab; it reported four for 2014. Mr. Sullivan, on behalf of Trident, stated in his July 21, 2016, opposition letter to Roper-Berkeley's Catheterization Lab Project that "[a]ll existing labs in the service area have not performed a minimum of 500 diagnostic catheterization procedures per laboratory in 2015." Mr. Sullivan includes in his letter a chart, prepared from the relevant hospital JAR, also showing that four catheterization procedures were performed in Bon Secours' catheterization lab.⁹

Because Bon Secours' catheterization lab was still included in the 2015 State Health Plan inventory, it reported catheterization procedures, as required, to the Department in 2015, the year immediately preceding the Roper-Berkeley CON Application at issue.

At the hearing, Ms. Platt, who served as the health planning consultant for Roper-Berkeley, testified that she considered Bon Secours to be non-existing because it would not exist at the same time as Roper-Berkeley's proposed catheterization lab. However, Bon Secours is prominently included in the Roper-Berkeley CON Application exhibit entitled "Historical Utilization of Existing Labs in the Service Area."

⁹ The JAR actually states two diagnostic catheterizations, while "four" refers to a total of "other" procedures.

As mentioned above, Roper-Berkeley's CON Application provides that upon approval of the Application to establish diagnostic catheterization services at Roper-Berkeley, the diagnostic catheterization laboratory at Bon Secours would be permanently closed.

Typically, an applicant will agree to close a service upon the approval of a CON Application if it involves the transfer of the service. However, as Trident's expert, Mr. Sullivan, testified and stated in Trident's opposition letter to Roper-Berkeley's CON Application, Bon Secours did not have a historical utilization pattern that could merit a transfer. Indeed, the Department agreed with this position in the aforementioned April 14, 2016, email from Mr. Eubank to counsel for Roper-Berkeley stating that the low volume at Bon Secours' catheterization lab "prohibits the entry of any additional catheterization labs in the service area as outlined in SC Health Plan standards for such services" and would likely prohibit the transfer of the lab from Bon Secours to Roper-Berkeley. Nevertheless, despite taking such a position on April 14th and within days of receiving Trident's letter in opposition to the Roper-Berkeley Project, the Department issued the letter of July 25, 2016, approving the Roper-Berkeley CON Application.

In the decision letter approving the Roper-Berkeley Project, DHEC acknowledges that Bon Secours' catheterization lab fell below the 500 procedure-threshold mandated by the State Health Plan in discussing Standard 3. DHEC also noted that the applicant agreed to shut down its diagnostic catheterization lab upon approval of the Application under consideration for Roper-Berkeley. Purportedly, DHEC staff believed this prospective closing allowed the Department to discount the historical utilization levels of the Bon Secours lab. The Department states in its decision letter that with the agreed upon closure of the Bon Secours lab, the Department concludes that the other remaining diagnostic catheterization labs within the service area operate at a capacity that would not preclude the addition of the diagnostic catheterization lab at Roper-Berkeley.

The approval letter does not imply that DHEC ever considered the Bon Secours catheterization lab as not existing. In fact, the decision letter references Bon Secours' catheterization lab utilization during the years 2010-2014, all years in which Bon Secours reported few procedures performed. Even though the Department later claims to have used Bon Secours' zero-volume years (2007—2009) as a basis to find that its catheterization lab did not exist for purposes of Standard 3, its

approval letter does not refer to those years, nor does it state that Bon Secours was not offering diagnostic catheterization services during those years.¹⁰

On August 17, 2016, Bon Secours sent the Department a letter indicating it had “permanently closed its diagnostic cardiac catheterization lab on August 1, 2016,” which is seven days after the Roper-Berkeley Catheterization Lab Project was approved. It is clear that Bon Secours discontinued operations of its catheterization lab only after the Department issued its decision letter approving the Project.

CONCLUSIONS OF LAW

Based on the foregoing Stipulations and Findings of Fact, I conclude the following as a matter of law:

The ALC has jurisdiction over this matter pursuant to S.C. Const. art. I, § 22; S.C. Code Ann. §§ 1-23-320, -600(B), 44-1-60(F), and 44-7-210(E); 3 S.C. Code Ann. Regs. 61-15; and Rule 11 of the SCALC Rules. Trident timely filed its request for a contested case hearing regarding DHEC’s decision. *See* 3 S.C. Code Ann. Regs. 61-15 § 401. Because Trident is an existing provider of cardiac catheterization services in the service area, it is an “affected person” for the purposes of participating in a contested case related to DHEC’s decision. *See* S.C. Code Ann. § 44-7-130(1) (2018); 3 S.C. Code Ann. Regs. 61-15 § 103(1).

A contested case hearing conducted before this Court in a CON matter is a trial *de novo*, in which “the whole case is tried as if no trial whatsoever had been had in the first instance,” and the administrative law judge conducting the hearing is the sole finder of fact, who “must make sufficiently detailed findings supporting the denial or grant of a permit application.” *Marlboro Park Hosp. v. S.C. Dep’t of Health & Envtl. Control*, 358 S.C. 573, 579, 595 S.E.2d 851, 854 (Ct. App. 2004) (quoting *Blizzard v. Miller*, 306 S.C. 373, 412 S.E.2d 406 (1991) and *Converse Power Corp. v. S.C. Dep’t of Health & Envtl. Control*, 350 S.C. 39, 564 S.E.2d 341 (Ct. App. 2002)). The weight and credibility assigned to evidence presented at the hearing of a matter is within the province of the trier of fact. *S.C. Cable Television Ass’n v. S. Bell Tel. & Tel. Co.*, 308 S.C. 216, 222, 417 S.E.2d 586, 589 (1992). The trier of fact may also give an expert’s testimony the weight he or she determines it deserves, *Florence Cty. Dep’t of Soc. Servs. v. Ward*, 310 S.C. 69, 425

¹⁰ It is curious that the Department appears to negotiate the future closure of a facility (Bon Secours) that it considered to be non-existing at the time.

S.E.2d 61 (Ct. App. 1992), and may accept the testimony of one expert over that of another. *S.C. Cable Television Ass'n, supra*.

Finally, the CON Act states that “the Administrative Law Court ... shall consider the South Carolina Health Plan in place at the time the application was filed and may consider the current South Carolina Health Plan when making its decision.” S.C. Code Ann. § 44-7-225 (2018).

Regulatory Framework

This matter arises under the regulatory program by which the State of South Carolina issues CONs for the development of health care facilities and services. The regulatory scheme consists of the State Certification of Need and Health Facility Licensure Act (CON Act), S.C. Code Ann. § 44-7-110 *et seq.* (2018 & Supp. 2017); 3 S.C. Code Ann. Regs. 61-15 (Supp. 2017); and a State Health Plan, which is revised at least biannually. The purposes of the CON Act, and thus the regulatory program itself, are to “promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure high quality services are provided in health facilities in this State.” *See* S.C. Code Ann. § 44-7-120 (2018).

The CON Regulations require that:

On the basis of staff review of the record established by the Department, including but not limited to, the application, comments from affected persons and other persons concerning the application, data, studies, literature and other information available to the Department, the staff of the Department shall make a proposed decision to grant or deny the Certificate of Need.

3 S.C. Code Ann. Regs. 61-15 § 308 (Supp. 2017).

In determining whether to grant or deny an application for a CON, the Department evaluates the proposed project under the review criteria found in the CON Regulations and under the policies and standards set forth in the applicable State Health Plan. S.C. Code Ann. § 44-7-210(B) (2018). Pursuant to the CON Act, the Department may not issue a CON to an applicant “unless the application complies with the South Carolina Health Plan, Project Review Criteria, and other regulations.” *Id.*; *see also MRI at Belfair, LLC v. S.C. Dep’t of Health and Envtl. Control*, 379 S.C. 1, 9, 664 S.E.2d 471, 475 (2008) (holding that compliance with the State Health Plan and the Project Review Criteria (PRC) were independent requirements for approval of a CON). The Department can refuse to issue a CON based on PRC and other regulations it identifies even if an

application complies with the State Health Plan. S.C. Code Ann. § 44-7-210(B). But no project can be approved unless it is consistent with the State Health Plan. 3 S.C. Code Ann. Regs. 61-15 § 307(1). When CON applications are considered competing, “the [D]epartment shall award a [CON], if appropriate, on the basis of which, if any, most fully complies with the requirements, goals, and purposes of [the CON Act] and the State Health Plan, Project Review Criteria, and the regulations adopted by the department.” S.C. Code Ann. § 44-7-210(B).

The PRC set forth in Regulation 61-15 include thirty-three separate criteria that fall into five general categories: (1) criteria related to the need for the proposed project; (2) criteria related to the economic considerations of the project; (3) criteria related to the project’s impact on the resources of the health care system; (4) criteria related to the suitability of the site of the project; and (5) criteria related to certain special circumstances, such as the project’s ability to serve medically underserved groups. *See* 3 S.C. Code Ann. Regs. 61-15 §§ 801(1), 802. Only the first criterion is at issue in this case.

As required by the CON Act, the State Health Plan contains the following statistics, standards, and findings with regard to the various facilities and services regulated by the CON Act:

(1) an inventory of existing health care facilities, beds, specified health services, and equipment; (2) projections of need for additional health care facilities, beds, health services, and equipment; (3) standards for distribution of health care facilities, beds, specified health services, and equipment including scope of services to be provided, utilization, and occupancy rates, travel time, regionalization, other factors relating to proper placement of services, and proper planning of health care facilities; and (4) a general statement as to the project review criteria considered most important in evaluating Certificate of Need applications for each type of facility, service, and equipment, including a finding as to whether the benefits of improved accessibility to each such type of facility, service, and equipment may outweigh the adverse affects [sic] caused by the duplication of any existing facility, service, or equipment.

S.C. Code Ann. § 44-7-180(B). The State Health Plan section applicable to the establishment of Roper-Berkeley’s Catheterization Lab Project is found in Chapter VIII, beginning at page VIII-1. The Standards applicable to the project begin at page VIII-4.

Standard 3 set forth in the Health Plan’s section on new diagnostic catheterization services states that “[n]ew diagnostic catheterization services, including mobile services, shall be approved **only if all existing labs** in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year (emphasis added)[.]”

“Because the legislature has required these stringent requirements for the State Health Plan’s implementation, it is clear the legislature intended for the State Health Plan to be an enforceable document.” *Trident Med. Ctr. v. S.C. Dep’t of Health & Envtl. Control*, 412 S.C. 341, 350, 772 S.E.2d 177, 182 (Ct. App. 2015), *cert. denied* (Dec. 18, 2015). As such, the Court must interpret the Health Plan using the rules of statutory construction. *See id.* at 355, 772 S.E.2d at 184. “The question of statutory interpretation is one of law for the court to decide.” *Alltel Commc’ns, Inc. v. S.C. Dep’t of Revenue*, 399 S.C. 313, 316, 731 S.E.2d 869, 870 (2012). “Under the plain meaning rule, it is not the court’s place to change the meaning of a clear and unambiguous statute.” *Hodges v. Rainey*, 341 S.C. 79, 85, 533 S.E.2d 578, 581 (2000).

If a statute’s language is plain and unambiguous and conveys a clear and definite meaning, there is no occasion for employing rules of statutory interpretation and the court has no right to look for or impose another meaning. *Paschal v. State Election Comm’n*, 317 S.C. 434, 436, 454 S.E.2d 890, 892 (1995).

“The words of a regulation must be given their plain and ordinary meaning without resort to subtle or forced construction to limit or expand the regulation’s operation.” *Byerly v. Connor*, 307 S.C. 441, 444, 415 S.E.2d 795, 799 (1992).

A two-step process is required when interpreting and applying statutes and regulations administered by an agency. *Kiawah Dev. Partners, II v. S.C. Dep’t of Health & Envtl. Control*, 411 S.C. 16, 32, 766 S.E.2d 707, 717 (2014). “First, a court must determine whether the language of a statute or regulation directly speaks to the issue. If so, the court must utilize the clear meaning of the statute or regulation.” *Id.* (citing *Brown v. Bi-Lo, Inc.*, 354 S.C. 436, 440, 581 S.E.2d 836, 838 (2003)). Statutes and regulations that are silent or ambiguous are entitled to some level of deference. However, when an agency’s interpretation is arbitrary, capricious, or manifestly contrary to the statute or regulation at issue, the agency’s interpretation is not entitled to deference. *Id.* at 34, 766 S.E.2d at 718.

Approval of the Project

The Court must determine whether Roper-Berkeley’s Project should be approved under the CON Act, its regulations, and the State Health Plan. 3 S.C. Code Ann. Regs. 61-15 § 307(1).

While a project does not have to satisfy every Project Review Criterion to be approved, no project may be approved unless it is consistent with the State Health Plan. Here, the approval of the Project violates Standard 3 and is, thereby, inconsistent with the State Health Plan.

Standard 3 states that “[n]ew diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area **have performed** a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year (emphasis added) [.]” Roper-Berkeley would be a new diagnostic catheterization service. Therefore, each of the labs **existing** in the service area in which Roper-Berkeley would operate must have performed at least 500 diagnostic catheterization procedures per laboratory during the twelve months prior to the submission of Roper-Berkeley’s CON Application, when the review process begins. This determination of historical utilization is clearly retrospective, not prospective. There is no dispute that Bon Secours was not performing the minimum of 500 diagnostic catheterization procedures during the year prior to the filing of Roper-Berkeley’s CON Application.

The only remaining issue is whether Bon Secours was “existing.” DHEC and Ms. Platt take the position that “existing labs” means labs that will exist at or following the approval of the project. However, this interpretation is at odds with the plain language of Standard 3, which directs the Department to apply the utilization analysis retrospectively to measure the number of services performed by labs in the service area during the most recent year. Interestingly, this interpretation is also at odds with positions taken by the Department in both 2010 and earlier in 2016 when East Cooper submitted its CON Applications.

A court may look to a dictionary to determine the plain and ordinary meaning of statutory terms. *Liberty Mut. Ins. Co. v. S.C. Second Injury Fund*, 363 S.C. 612, 623-24, 611 S.E.2d 297, 302-03 (“Dictionaries can be helpful tools during the initial stages of legal research for the purpose of defining statutory terms... The words of a statute must be given their plain and ordinary meaning without resorting to subtle or forced construction[.]”) (Ct. App. 2005) (citations omitted). “Existing” may be defined as “in existence or operation at a current time.”¹¹ The Court interprets “existing” as used in Standard 3 to mean that a lab is open and is offering and has the capacity to provide catheterization services to patients, as Bon Secours did, at the time a CON Application is

¹¹ See <https://en.oxforddictionaries.com/definition/existing> (last visited on October 24, 2018).

filed. Given that Bon Secours offered cardiac catheterization services and reported a volume greater than zero during the most recent year prior to Roper-Berkeley's CON Application, it would be illogical to conclude that Bon Secours did not have an "existing lab" for the purposes of Standard 3.

The facts in this case also reflect that DHEC did not properly apply the term "existing" to the Bon Secours lab prior to approving Roper-Berkeley's CON Application.

In 2007, 2008, and 2009, Bon Secours reported that there were no catheterization procedures performed in its lab. The Department reviews these reports to determine utilization of **existing** providers. For 2015, Bon Secours reported that only two diagnostic catheterization procedures were performed. Bon Secours was not removed from the catheterization lab inventory and was included through 2015, the most recent year prior to Roper-Berkeley's CON Application. Roper itself, in its affected person's letter dated April 20, 2016, responding to East Cooper's CON Application, considered Bon Secours to be an existing facility that would continue to operate. Notwithstanding being out of compliance with the Standard 3 threshold, Bon Secours remained open and available to perform procedures up to and days after the approval of the Roper-Berkeley Application. For unknown reasons, the Department took no enforcement action to fine or suspend Bon Secours under the CON statute and regulations.

Further, the April 14, 2016, email from Mr. Eubank to counsel for Roper-Berkeley indicated that the low volume at Bon Secours' catheterization lab "prohibits the entry of any additional cath labs in the service area as outlined in SC Health Plan standards for such services" and would likely prohibit the transfer of the lab from Bon Secours to Roper-Berkeley. This statement confirms that DHEC considered Bon Secours to be an existing lab. Even in its approval letter, the Department does not refer to the years in which Bon Secours performed no catheterization procedures, nor does it indicate that Bon Secours did not offer diagnostic catheterization services during the years in which no procedures were reported. In the email, DHEC's invitation to Roper-Berkeley to propose a solution suggests that something needed to be done about Bon Secours as an existing facility in order for Roper-Berkeley to obtain a CON. However, although DHEC and Roper agreed to shut down Bon Secours before beginning operation, this future condition did not change the status of Bon Secours as an existing facility at the inception of the application process. Nor, did

the prospective agreement allow for other providers to submit competing CON Applications with the knowledge that one lab was about to be removed from the State Health Plan inventory.

There are simply no provisions or exceptions in the State Health Plan or in Reg. 61-15 that allow the Department to ignore the fact that a diagnostic catheterization lab is operating below the Standard 3 required threshold or, in the alternative, to agree on its future closing as a condition of approving a new application.

For the Department to allow an applicant to circumvent the requirements specified in the Health Plan by conditional actions, such as closing a lab upon the approval of an application, would allow an underperforming lab to serve as a "place-holder" to frustrate potential applicants who seek to provide a health service. A potential competitor reviews the inventory, finds a below-threshold provider, and concludes that no CON application could comply with Standard 3. On the contrary, a service provider should be able to rely on publicly available information, such as the State Health Plan and the most recent JAR, to find accurate and reliable data upon which to make business decisions in government-regulated areas such as those administered by DHEC.

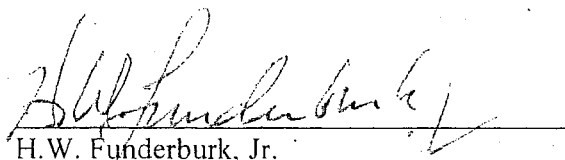
I find that Bon Secours was an existing lab offering and providing cardiac catheterization procedures in the service area in which Roper-Berkeley seeks to establish a new diagnostic catheterization lab, and that Bon Secours was not performing a minimum of 500 diagnostic catheterization procedures as Standard 3 requires for the twelve months prior to the filing of Roper-Berkeley's CON Application. Accordingly, Roper-Berkeley's CON Application to provide new diagnostic catheterization services in the service area is inconsistent with the State Health Plan.

ORDER

IT IS THEREFORE ORDERED that the Certificate of Need for Roper-Berkeley's proposed project for a diagnostic cardiac catheterization lab in Goose Creek, Berkeley County, South Carolina is **DENIED**.

AND IT IS SO ORDERED.

December 3, 2018
Columbia, South Carolina


H.W. Funderburk, Jr.
Administrative Law Judge

FILED

DEC 03 2018

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

Trident Medical Center, LLC, d/b/a Trident
Medical Center,

Petitioner,

vs.

South Carolina Department of Health and
Environmental Control, and Roper St. Francis
Hospital – Berkeley, Inc., d/b/a Roper St.
Francis Hospital – Berkeley County,

Respondents.

Docket No.: 16-ALJ-07-0386-CC

**AMENDED
FINAL ORDER**

Appearances:

For Petitioner Trident: William R. Thomas, Esq.

For Respondent Roper: Jennifer J. Hollingsworth, Esq.

For Respondent DHEC: Ashley C. Biggers, Esq.

STATEMENT OF THE CASE

This matter came before the South Carolina Administrative Law Court (ALC or Court) at the request of Petitioner Trident Medical Center, LLC, d/b/a Trident Medical Center (Trident) for a contested case hearing to review the decision of the South Carolina Department of Health and Environmental Control (DHEC or Department) granting a Certificate of Need (CON) to Roper St. Francis Hospital - Berkeley, Inc., d/b/a Roper St. Francis Hospital – Berkeley (Roper-Berkeley) for the addition of a new diagnostic cardiac catheterization lab¹ (Project) at its medical facility under construction in Berkeley County and scheduled to open in the fall of 2019.

FILED

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SC ADMIN. LAW COURT

¹ Diagnostic catheterization is a tool used in the treatment of heart disease whereby a thin flexible tube is inserted into a blood vessel in the arm or leg allowing a doctor to examine the heart and associated blood vessels. See discussion of cardiac catheterizations *infra*.

Prior to a hearing on the merits, Petitioner filed a Motion for Summary Judgment that was denied by Order dated March 2, 2017. The parties thereafter conducted discovery and prepared the matter for a hearing. The contested case was heard on July 24 and July 25, 2018.²

The Court entered a Final Order in this matter on December 3, 2018. Respondent Roper-Berkeley filed a Motion to Alter or Amend that was followed by a response and replies received through January 18, 2019. The Court substitutes this Amended Final Order for its previous Order.

FINDINGS OF FACT

A. Stipulations of Fact

Pursuant to Rule 25(C) of the Rules of Procedure for the Administrative Law Court (SCALC Rules), the parties submitted written stipulations of fact, which are hereby adopted by the Court and set forth as follows:

Roper-Berkeley filed a Certificate of Need (CON) Application on May 9, 2016, to construct a catheterization laboratory and provide diagnostic cardiac catheterization services at the Roper-Berkeley Hospital under construction in Berkeley County. The CON Application states that upon approval, the diagnostic catheterization laboratory at Bon Secours St. Francis Xavier Hospital (Bon Secours) will be permanently closed.

The applicable South Carolina Health Plan (State Health Plan) is the Health Plan enacted August 13, 2015.

By decision letter dated July 25, 2016, DHEC approved the CON Application. On August 17, 2016, Bon Secours notified the Department that it permanently closed its diagnostic cardiac catheterization lab effective August 1, 2016.

Trident timely filed a Request for Board Review with the DHEC Board that was denied without review on September 21, 2016.

Trident timely filed a contested case in the Administrative Law Court and is an Affected Person with standing to challenge DHEC's decision.

² Prior to the contested case hearing, the parties informed the Court they had agreed to limit the issues before the Court as stated in the Stipulation of Facts.

Chapter VIII of the State Health Plan is the Chapter addressing cardiovascular care services. Pages VIII-4 and VIII-5 contain the Standards for establishing a new diagnostic catheterization laboratory. Standards 1, 2, 3, and 4 apply to the CON Application. Standards 5 and 6 do not apply the CON Application.

Standard 1 sets forth the capacity for cardiac catheterization laboratories in South Carolina based on the complexity of the services provided. Standard 2 sets forth the service area for cardiac catheterization laboratories based on the complexity of the services provided. Standard 3 sets forth the historical utilization threshold for approval of a new diagnostic catheterization laboratory in a service area. Standard 4 sets forth the minimum projected utilization for approval of a new diagnostic catheterization laboratory in a service area.

The facilities in the relevant service area with cardiac catheterization laboratories at the time of the CON Application's submission were Trident Medical Center, Roper Hospital, Medical University of South Carolina, and Bon Secours. All of the catheterization laboratories except Bon Secours were comprehensive catheterization laboratories. In 2014, Bon Secours reported in its Joint Annual Report to DHEC that 4 diagnostic catheterization procedures had been performed in its catheterization lab. In 2015, Bon Secours reported in its Joint Annual Report to DHEC that 2 diagnostic catheterizations had been performed.

The catheterization laboratories at Trident, Roper Hospital, and the Medical University satisfy the historical utilization threshold under Standard 3. The parties dispute whether the CON Application satisfies Standard 3 and, therefore, whether it complies with S.C. Code Ann. Regs. 61-15 § 802.1.

Initially, Trident challenged many aspects of the CON Application, but for efficiency and judicial economy, it has decided to withdraw its challenge to the CON Application in every respect with the exception of challenging whether the CON Application satisfies Standard 3. Trident asserts that because the CON Application does not satisfy Standard 3, the Application does not comply with the State Health Plan and, as such, is not consistent with the State Health Plan per Reg. 61-15 § 801.3 and S.C. Code Ann. § 44-7-210(B). Therefore, Trident contends that DHEC erred in approving the CON Application.

The parties recognize that Trident has withdrawn its challenges to the CON Application save the challenge concerning Standard 3, and while Trident may not agree with the following conclusions, the parties so stipulate to effectuate the contested case hearing for purposes of limiting the issues in dispute:

- (a) The CON Application satisfies Standard 4.
- (b) Reg. 61-15 is applicable to the CON Application.
- (c) The CON Application sufficiently projects Community Need to satisfy Section 802.2 of the Project Review Criteria (PRC).
- (d) The CON Application sufficiently meets the requirements for Distribution (Accessibility) set forth in Section 802.3 of the PRC.
- (e) The CON Application establishes financial feasibility set forth in Section 802.15 and related financial sections of the PRC.
- (f) The CON Application sufficiently meets the requirements of cost containment set forth in Section 802.16 of the PRC.
- (g) The CON Application will not have an adverse effect on other facilities as defined by Sections 802.23 and 802.24 of the PRC.
- (h) Any additional PRC applicable to the CON Application have been satisfied with the exception of Section 802.1, which relates to the parties' dispute as to Standard 3.
- (i) Section 500 of Reg. 61-15 is not applicable to the CON Application.

Dan Sullivan is qualified to testify as an expert witness pursuant to Rule 702 of the South Carolina Rules of Evidence (SCRE), under the designations of healthcare planning and the State Health Plan.

Kathy Platt is qualified to testify as an expert witness pursuant to Rule 702, SCRE, under the designations of healthcare planning and the State Health Plan.

The Court also heard testimony from Louis Eubank, Chief of the Bureau of Healthcare Planning and Construction for the Department. In his capacity at DHEC in 2016 as the CON Program Director, Mr. Eubank reviewed and approved the CON Application for the Roper-Berkley Project.

B. Additional Findings of Fact

In addition to these stipulations of fact, and having observed the witnesses and exhibits presented at the hearing and closely passed upon their credibility, taking into consideration the parties' burdens of proof, I make these additional Findings of Fact by a preponderance of the evidence:

Regulatory Framework

This matter arises under the regulatory program by which the State of South Carolina issues CONs for the development of health care facilities and services. The regulatory scheme consists of the State Certification of Need and Health Facility Licensure Act (CON Act), S.C. Code Ann. § 44-7-110 *et seq.* (2018 & Supp. 2017); 3 S.C. Code Ann. Regs. 61-15 (Supp. 2017); and a State Health Plan, which is revised at least biannually. The purposes of the CON Act, and thus the regulatory program itself, are to "promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State." See S.C. Code Ann. § 44-7-120 (2018).

The CON Regulations require that:

On the basis of staff review of the record established by the Department, including but not limited to, the application, comments from affected persons and other persons concerning the application, data, studies, literature and other information available to the Department, the staff of the Department shall make a proposed decision to grant or deny the Certificate of Need.

3 S.C. Code Ann. Regs. 61-15 § 308 (Supp. 2017).

The Department is guided by the purposes of the CON Act and has a statutory obligation to administer and control the CON Program through its regulations. To effectuate this obligation, the Department is charged with creating the State Health Plan on a biennial basis. S.C. Code Ann. § 44-7-210(B) (2018). In determining whether to grant or deny a CON, the Department evaluates the proposed project under the review criteria found in the CON Regulations and under the policies and standards set forth in the applicable State Health Plan.

Pursuant to the CON Act, the Department may not issue a CON to an applicant "unless the application complies with the South Carolina Health Plan, Project Review Criteria, and other regulations." *Id.*; see also *MRI at Belfair, LLC v. S.C. Dep't of Health and Envtl. Control*, 379 S.C. 1, 9, 664 S.E.2d 471, 475 (2008) (holding that compliance with the State Health Plan and the

Project Review Criteria (PRC) were independent requirements for approval of a CON). The Department can refuse to issue a CON based on PRC and other regulations it identifies even if an application complies with the State Health Plan. S.C. Code Ann. § 44-7-210(B). But no project can be approved unless it is consistent with the State Health Plan. 3 S.C. Code Ann. Regs. 61-15 § 307(1):

The PRC, set forth in Regulation 61-15, include thirty-three separate criteria that fall into five general categories: (1) criteria related to the need for the proposed project; (2) criteria related to the economic considerations of the project; (3) criteria related to the project's impact on the resources of the health care system; (4) criteria related to the suitability of the site of the project; and (5) criteria related to certain special circumstances, such as the project's ability to serve medically underserved groups. *See* 3 S.C. Code Ann. Regs. 61-15 §§ 801(1), 802. Only the first criterion is at issue in this case.

As required by the CON Act, the State Health Plan contains the following statistics, standards, and findings with regard to the various facilities and services regulated by the CON Act:

- (1) an inventory of existing health care facilities, beds, specified health services, and equipment; (2) projections of need for additional health care facilities, beds, health services, and equipment; (3) standards for distribution of health care facilities, beds, specified health services, and equipment including scope of services to be provided, utilization, and occupancy rates, travel time, regionalization, other factors relating to proper placement of services, and proper planning of health care facilities; and (4) a general statement as to the project review criteria considered most important in evaluating Certificate of Need applications for each type of facility, service, and equipment, including a finding as to whether the benefits of improved accessibility to each such type of facility, service, and equipment may outweigh the adverse affects [sic] caused by the duplication of any existing facility, service, or equipment.

S.C. Code Ann. § 44-7-180(B).

The State Health Plan and Standard 3

Generally, the State Health Plan serves as a roadmap for the review and consideration of CON applications by DHEC in "guid[ing] the development of certain healthcare facilities and services across the state." (Eubank Trial Tr. 265:11-20.) The Plan "allows the state to essentially adapt its healthcare planning practices to meet current needs." *Id.* at 266:3-6.

Specifically, among the applicable standards in the Health Plan that must be satisfied for new diagnostic catheterization services, Trident only challenges compliance with Standard 3, which states that “[n]ew diagnostic catheterization services, including mobile services, **shall be approved only if all existing labs** in the service area **have performed** a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year (emphasis added).”³

The State Health Plan also includes an inventory of cardiac catheterization services showing existing cardiac catheterization providers in the various regions of the state. The relevant region in this case is Region 4. In addition to the number of catheterization labs that each provider operates by region, the inventory also shows the historical utilization of those catheterization labs for certain years, in this case 2011, 2012, and 2013.

While the inventory of cardiac catheterization services is vital to DHEC for purposes of CON review, it also allows interested parties to identify existing providers in a service area and the historical utilization of each lab in that given area. This provides a reference point for applicants for health services to determine if existing providers are operating at, above, or below utilization markers established by the Department. In doing so, the State Health Plan’s cardiac catheterization lab inventory and the accompanying utilization data also allow a potential applicant to determine whether a new cardiac catheterization lab might be needed in the service area under the guidance identified in Standard 3. Stated another way, Standard 3 should discourage potential providers from applying for a new catheterization lab when all of the existing labs in the service area are not operating at or above the Plan’s utilization threshold. (See Eubank Trial Tr. 309:15-20.)

The determination of whether the existing labs in the service area are well utilized is of paramount importance for health planning. In referencing utilization within a service area,⁴ Standard 3 addresses community-need. To measure the need for another cardiac catheterization lab, one must know whether existing labs are being sufficiently utilized. Standard 3 imposes an objective measure of utilization and contains the phrase “have performed,” which directs a historical accounting to determine if all existing providers have crossed the 500-procedure threshold for the

³ “The most recent year” refers to the completed year for which annual utilization data is available, in contrast to the current year.

⁴ In this case, the service area is a 45-minute drive time around the proposed Goose Creek location for new diagnostic catheterization services.

most recently reported year. On the other hand, Standard 4 (not contested here) requires a prospective analysis by projecting the number of services the Department should expect the applicant to perform annually within three years of initiating the service. (See Eubank Trial Tr. 357:11-24.)

The objective measures found in Standard 3 not only establish whether there is a community need based on historic utilization, but also assure quality by assessing the number of procedures that have been performed. Although Standard 3 does not directly reference quality, the Department does consider quality throughout the cardiovascular service chapter regarding case volume standards. As stated in the 2015 State Health Plan, reduced case volumes diminish quality because “[o]ptimal performance requires a caseload of adequate size to maintain the skills and efficiency of the staff.” (Cardiovascular Care, p. VIII-2.) In tandem with the CON Act, the volume threshold set forth in Standard 3 seeks to avoid unnecessary duplication of catheterization labs, which can reduce quality.

The Department and others involved in the CON process also review the relevant Joint Annual Reports (JARs) filed by service providers to analyze more recent utilization data. Moreover, it is standard practice for the Department to rely on the updated utilization data contained in the relevant JARs when making a decision according to a State Health Plan that may be one or two years old.

Cardiac Catheterization

Cardiovascular services subject to CON review include diagnostic catheterizations, therapeutic catheterizations, and percutaneous coronary interventions, as well as pediatric catheterizations and open-heart surgery. A diagnostic catheterization is a procedure that involves threading a catheter through a vessel and using imaging equipment to photograph what is happening in those vessels. A therapeutic catheterization involves the same vessel imaging but also includes treatment procedures such as removing a blockage or inserting a stent.

Cardiac catheterizations are performed in a catheterization laboratory. Laboratories may be designated as providing only diagnostic catheterization services or may be designated as a comprehensive catheterization laboratory if both diagnostic and therapeutic catheterization services are provided. Roper-Berkeley’s CON Application seeks to provide only diagnostic catheterizations in a diagnostic catheterization laboratory.

A total of 12 cardiac catheterization laboratories were operating in the service area at the time of the Roper-Berkeley CON Application's submission. Of these, Bon Secours was the only diagnostic catheterization lab; all others were classified as comprehensive. With the exception of Bon Secours, all of the other catheterization laboratories operated at levels sufficient to satisfy the historical utilization threshold set out in Standard 3.⁵

C. The Application and Approval

Parties

The Roper St. Francis Healthcare System (Roper St. Francis) consists of four hospitals: Roper Hospital on the Charleston Peninsula; Bon Secours in West Ashley; Mount Pleasant Hospital in Mount Pleasant; and Roper-Berkeley under construction in Berkeley County. At the time the CON Application was filed in May 2016, Roper St. Francis had four (4) licensed cardiac catheterization laboratories: three comprehensive catheterization laboratories at Roper Hospital and the one diagnostic catheterization laboratory at Bon Secours in West Ashley.

Trident is an existing provider of cardiac catheterization services in Roper-Berkeley's proposed service area, which is primarily Berkeley County.

While not a party in this case, East Cooper Medical Center (East Cooper) also filed a CON Application to establish a catheterization laboratory in the Mount Pleasant section of the service area in February 2016. Roper-Berkeley submitted an Affected Person letter with respect to East Cooper's 2016 application. Trident did not. Both the East Cooper and the Roper-Berkeley applications were approved by Louis Eubank on behalf of the Department in August 2016.

Pre-Application History

There is no dispute that the catheterization lab at Bon Secours had been operating at low levels in the years preceding the applications. In its JARs, Bon Secours reported to DHEC that it performed no catheterization procedures in 2008 and 2009, resuming in 2010 with very low utilization.⁶ The facility reported only 7, 9, and 3 procedures in 2011, 2012, and 2013, respectively. In 2014, Bon Secours reported that 4 diagnostic catheterization procedures were performed in its lab; it reported

⁵ Joint Exhibit 1, p. 206-7.

⁶ This information is found in Joint Exhibit 2, p. 077 and in Petitioner's Exhibit 3, 007, 008, and 010, and in Petitioner's Exhibit 5, p. 011.

2 for 2015. All data available to the Department as late as 2015 indicated that Bon Secours was a severely under-utilized lab.

It is clear from the record that as far back as 2010, DHEC staff was aware of the substantial underperformance of the catheterization lab at Bon Secours. In correspondence involving a separate potential CON application in which East Cooper first sought to establish a catheterization lab in Mount Pleasant, two officials at the Department addressed the very issue of the Bon Secours lab.

In a May 8, 2010, email to Les Shelton of the DHEC Division of Planning and CON, the Chief Operating Officer of East Cooper directly asked if East Cooper would be able to move forward with a CON application to establish a catheterization lab in Mount Pleasant since the Bon Secours lab had not been operational in 2008 or 2009. In that scenario, much like the one presented in this matter, all other labs in the area were performing adequately; Bon Secours was the only potential barrier to East Cooper's approval with respect to need calculations. The next day, Shelton replied, "...it is certainly a fair question to ask whether it should be considered in the need calculations. We don't want to create a scenario where stockpiling an unused service unduly impacts the service area."⁷ Shelton advised that this was a matter to be discussed internally and that DHEC would respond to the concern that East Cooper raised.

Subsequently, the COO of East Cooper requested a determination as to whether the Bon Secours lab should be included in the utilization calculations for the Charleston area under the CON program. In a letter from DHEC dated May 27, 2010, Beverly Brandt, the Chief of the Bureau of Health Facilities and Services Development, replied: "[b]ased on our review of the standards in the 2008-2009 South Carolina Health Plan and the CON law and regulations, we have determined that [DHEC] does not currently have a mechanism in place that would allow the Department to discount the existence of the [Bon Secours] cardiac catheterization lab when computing the average utilization for the service area." The Department went on to "...recognize that continuing to inventory a service that has remained idle for three years can negatively impact the ability of other providers to offer that service."⁸ This letter was generated in the context of East Cooper's request to discount Bon Secours for the purposes of submitting a successful CON application that

⁷ Joint Exhibit 2, p. 074-75.

⁸ Joint Exhibit 2, p.081.

would comply with the State Health Plan in effect in 2010. At that time, the prior version of Standard 3 was much the same except the prior standard addressed the average lab utilization, as opposed to the per lab utilization threshold in the 2015 State Health Plan.

In recognizing then that it could not discount the existence of the Bon Secours lab even after years of zero or very low utilization, the Department acknowledged that the appropriate remedy would be to amend the State Health Plan for 2010-2011 to allow adjustment for "unused" beds or equipment; however, no such steps were taken. Thus, the Bon Secours lab was not closed nor was it ever officially determined to be operating in violation of the law.⁹

The Department also exercised its discretion not to take enforcement action to address the Bon Secours dilemma, though such measures were available under the CON statute and regulations. S.C. Reg. 61-15, Section 102(1)(e) (hereinafter "Reg. 61-15"). Moreover, Bon Secours was not removed from the catheterization lab inventory of the State Health Plan even though the Department indicated as far back as 2010 that the appropriate remedy would be to amend the Plan.

Six years later, DHEC staff again became aware of the low utilization levels at Bon Secours following the Department's receipt of the East Cooper CON Application on February 4, 2016. At this time, Louis Eubank was the CON Program Director who reviewed and eventually approved both CON applications. In this Application, East Cooper reaffirmed its prior position -- that the Bon Secours lab should not be considered operational for purposes of the need analysis in Standard 3 with respect to its Application. Directly citing Reg. 61-15, East Cooper asserted that Bon Secours required a CON application if it were to be included in the current inventory of catheterization labs since it failed to obtain a new CON in 2010 before offering a health service that had not been offered in the preceding twelve-month period.¹⁰

Once Mr. Eubank began reviewing the 2016 East Cooper Application, he testified that he began inquiring about the Bon Secours lab. Specifically, he reached out to Shannon Cantwell, the Regulatory Affairs Specialist at Roper St. Francis. On February 22, 2016, in response to a requested follow-up, Cantwell sent Eubank a copy of the aforementioned correspondence between

⁹ S.C. Reg. 61-15, Section 102(1)(e) states: "A person or health care facility as defined in this Regulation is required to obtain a [CON] from the [Department] before undertaking any of the following: ... the offering of any health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan."

¹⁰ In this case, it was actually a 24-month period during 2008 and 2009.

DHEC officials and East Cooper "...relative to the issues of whether or not the lab should be excluded from the market analysis for new providers...when it brought up this issue to the CON Division back in 2010." Cantwell quotes Les Shelton, "[w]e do not have the ability to 'close' the lab and remove it from the inventory."¹¹

In addressing this very problem, Mr. Eubank emailed counsel for Roper St. Francis on April 14, 2016, a few weeks prior to Roper-Berkeley's submission of its CON Application, to inform him that the Department was considering enforcement action against Bon Secours for violating Reg. 61-15 by failing to obtain a new CON prior to performing diagnostic catheterization procedures beginning in 2010 after performing no catheterization procedures for the previous two years. Eubank wrote, "the continued operation of the [Bon Secours] cath lab at such low volume prohibits the entry of any additional cath labs in the service area as outlined in the SC Health Plan standards for such services." Further, Eubank noted that the low volume would also likely prohibit the transfer of the Bon Secours catheterization lab from the operator's facility to another Roper St. Francis-owned facility under the service transfer criterion which also requires adequate historic utilization. In the same email, the Department invited Roper St. Francis to propose a solution within ten business days of the receipt of the email.¹²

In a letter to DHEC dated April 20, 2016, Roper St. Francis asked to be an affected person with respect to East Cooper's 2016 CON Application for a new catheterization lab. As to the Department's and East Cooper's position that the Bon Secours lab was operating in violation of Reg. 61-15 and should be excluded from the service area analysis, Roper St. Francis contended that such a position was inconsistent with the applicable CON laws and the State Health Plan and was the same position rejected by the Department in 2010. Again, Roper St. Francis provided Eubank with copies of the 2010 correspondence from Beverly Brandt and Les Shelton of DHEC to support this position.

The letter also stated that Roper St. Francis intended to file its own CON application to establish a new catheterization lab at Roper-Berkeley. "If [the] application is approved, Roper St. Francis intends to close its cath lab at Bon Secours....This should allow DHEC to also approve the East Cooper Application consistent with the South Carolina Health Plan and the applicable CON laws.

¹¹ Petitioner's Exhibit 3, p.001.

¹² Petitioner's Exhibit 5, p. 001.

Until [the Roper-Berkeley] CON application is approved, Roper St. Francis intends to continue to operate the cath lab at [Bon Secours].”¹³

On April 22, 2016, two days after Roper St. Francis sent the Department this affected person letter, but more than two weeks prior to receiving Roper-Berkeley’s actual CON Application, Louis Eubank sent East Cooper’s representative an email with the affected person letter attached stating, “I think everything will work out just fine for everyone.”¹⁴

Nineteen days after the affected person letter to DHEC regarding East Cooper’s CON Application, Roper-Berkeley submitted its own CON Application stating that, upon approval of the Application to establish diagnostic catheterization services at Roper-Berkeley, the diagnostic catheterization laboratory at Bon Secours would be permanently closed.

The Application

Roper-Berkeley filed its CON Application on May 9, 2016, proposing to establish diagnostic catheterization services at the Roper-Berkeley Hospital under construction in Goose Creek. The Application included relevant detail and documentation establishing the current and projected population growth for Berkeley, Dorchester, Colleton, and Charleston Counties, as well as data establishing the historical and projected utilization for all four of the Roper St. Francis system’s cardiac catheterization laboratories.

In the Application, Roper-Berkeley classified Bon Secours as an existing lab and listed the volume for the Bon Secours diagnostic catheterization lab under Exhibit 14 entitled “Historical Utilization of Existing Labs in the Service Area.” It also included utilization from 2012 to 2014, which showed that in no year was Bon Secours’ catheterization volume even close to the 500-procedure threshold set forth in Standard 3. Following the table for Exhibit 14, the CON Application states, “[w]hile Bon Secours St. Francis Xavier Hospital is operating below the 500 diagnostic equivalents per year, the lab will be closed upon the approval of this project[.]”

Typically, an applicant will agree to close a service upon the approval of a CON Application that involves the transfer of the service. However, as Trident’s expert, Mr. Sullivan, testified and stated in Trident’s opposition letter to Roper-Berkeley’s CON Application, Bon Secours did not have a historical utilization pattern that could merit a transfer. Indeed, the Department agreed with this

¹³ Petitioner’s Exhibit 5, p.004.

¹⁴ Petitioner’s Exhibit 6, p.001.

position in the aforementioned April 14, 2016, email from Mr. Eubank to counsel for Roper St. Francis stating that the low volume at Bon Secours lab “prohibits the entry of any additional catheterization labs in the service area as outlined in SC Health Plan standards for such services” and would likely prohibit the transfer of the lab from Bon Secours to Roper-Berkeley for the same reason – low historical utilization.

Nowhere in the CON Application does Roper-Berkeley state that the Bon Secours catheterization lab is non-operational or non-existent, only that it **will close** and, therefore, **will not exist after the approval** of the CON Application. Curiously, the letter also makes clear that Roper St. Francis did not intend to close the Bon Secours lab if the Roper-Berkeley Application was not approved – only that the Bon Secours lab would be closed upon the Project’s approval.

The Decision and Approval

The most recent report available for DHEC review in considering the CON Application was the 2015 JAR. In it, Bon Secours reported that 2 diagnostic catheterization procedures had been performed in its lab; it reported 4 for 2014. Mr. Sullivan, on behalf of Trident, stated in his July 21, 2016, opposition letter to Roper-Berkeley’s Catheterization Lab Project that “[a]ll existing labs in the service area have not performed a minimum of 500 diagnostic catheterization procedures per laboratory in 2015.” Mr. Sullivan includes in his letter a chart, prepared from the relevant hospital JAR, also showing that 4 catheterization procedures were performed in Bon Secours’ catheterization lab.¹⁵

Louis Eubank reviewed the Application under the 2015 South Carolina Health Plan, which was enacted August 13, 2015. At the time, Mr. Eubank had been the CON Director for several months and, when he started in the position, he had no prior experience with the CON Program or the State Health Plan. Eubank testified that when applying Standard 3 to Roper-Berkeley’s CON Application, he was aware that the diagnostic catheterization lab at Bon Secours was underutilized. He also testified that he was aware of the prior positions taken by the Department in 2010 with respect to the existence of the Bon Secours lab and the problems it imposed.

Mr. Eubank concluded that, given the period between 2008-2009 when Bon Secours performed zero catheterizations and its subsequent failure to obtain a new CON before performing

¹⁵ The JAR actually states two diagnostic catheterizations, while “four” refers to a total of “other” procedures.

catheterizations again in 2010, he did not consider Bon Secours to be an existing catheterization lab even though Bon Secours was included in the State Health Plan inventory of existing providers in the service area. “[W]e didn’t really consider that lab to be existing though it was clearly operational.” (Trial Tr. 324:21-23.) When asked how he ultimately chose to treat the Bon Secours lab in relation to Standard 3, Eubanks answered, “[w]ell, my ultimate decision was that given my firm belief that the [Bon Secours] lab had not offered the service for two years and would have required a CON to again be an existing lab that it was, in fact, not an existing lab for the purpose of review under Standard 3.” (Trial Tr. 286:6-12.)

In terms of his intent expressed in the April 14, 2016, email to counsel for Roper St. Francis, Eubank testified that he believed enforcement action on behalf of the Department potentially to shut down the Bon Secours lab was warranted and was obtainable through either a cease and desist action, an administrative order from DHEC, or by consent. (See Trial Tr. 279:18-25; 281:16-20; 367:12-20.) He went on to opine that a costly and lengthy process would likely have ensued through litigation if Roper St. Francis were to challenge the Department’s enforcement action. (See Trial Tr. 281:5-9; 326:1-2.) Recognizing that a court could ultimately side with Roper St. Francis in determining that the Bon Secours lab was indeed an existing lab, Eubank concluded that it would be appropriate to see what Roper St. Francis “...might propose as a remedy to this situation that would save both the Department and Roper St. Francis significant time and effort in litigation if we would [have] set a formal enforcement action that was later contested.” (Trial Tr. 281:4-9.)

Rather, than pursuing that course of action, a plan was devised in which the Department and Roper St. Francis **agreed** to the closure of the Bon Secours catheterization lab contingent upon and following approval of the CON Application for Roper-Berkeley. Eubank testified that he later chose not to pursue enforcement action after he received notice of the closure of the Bon Secours lab as that was “the intended result.” (Trial Tr. 368:12.)

However, despite Eubank’s testimony that he ultimately concluded that the Bon Secours lab was non-existent under Reg. 61-15 for failing to obtain a new CON in 2010, the decision letter approving the Roper-Berkeley Project does not reference this position at all. In fact, the decision letter even references the utilization data of the Bon Secours catheterization lab during the years 2010-2014, all years after which the lab “ceased to exist” according to the logic that served as the

basis for Eubank's approval. The approval letter does not state or imply that DHEC ever considered the Bon Secours catheterization lab as not existing.

Instead, in discussing Standard 3, DHEC identifies the Bon Secours catheterization lab as the "one notable exception" in that it fell below the 500 procedure-threshold mandated by the State Health Plan by performing "no more than 9 procedures per year in any year from 2010-2014, according to available JAR data."¹⁶ In noting that the Department explained this inconsistency to Roper St. Francis, the letter goes on to say that the Applicant agreed to shut down the Bon Secours lab upon approval of the Application under consideration for Roper-Berkeley, "thus allowing the Department to discount the utilization figures of the lab at [Bon Secours]. As such, the Department concludes that other diagnostic catheterization labs within the service area operate at such an equivalent capacity as to not preclude the addition of the diagnostic catheterization lab [at Roper-Berkeley]." *Id.* Thus, in order to satisfy Standard 3, DHEC justified its ability to discount the inadequate historical utilization levels at Bon Secours based upon the proffered closing of the lab, not based upon the non-existence of the lab per Reg. 61-15, as Eubank claimed.¹⁷

Four days after receipt of Trident's letter in opposition to the Application, the Department approved the CON Application to add diagnostic catheterization services at Roper-Berkeley in the decision letter authored by Mr. Eubank dated July 25, 2016. The same day, DHEC also approved the East Cooper CON Application seeking to establish its catheterization lab in Mount Pleasant. In a letter dated July 26, 2016, the Department sent Roper St. Francis a request for evidence of the closure of the Bon Secours lab no later than August 26, 2016. On August 17, 2016, Bon Secours sent the Department a letter indicating it had permanently closed its diagnostic cardiac catheterization lab on August 1, 2016, seven days after the Roper-Berkeley Project was approved. It is clear that Bon Secours shuttered its catheterization lab only after the Department issued its decision letter granting the Roper-Berkeley CON.

It is not clear when, or if, the Bon Secours lab ceased to "exist" for purposes of the Standard 3 analysis of the CON Application.

¹⁶ Joint Exhibit 1, p. 206-7.

¹⁷ See Trial Tr. 286:6-12.

ISSUE

Did the Department err in determining that Roper-Berkeley's CON Application satisfied Standard 3 so as to comply with or be consistent with the State Health Plan per Regulation 61-15 §801.3 and S.C. Code Ann. § 44-7-210(B)?

CONCLUSIONS OF LAW

Based on the foregoing Stipulations and Findings of Fact, I conclude the following as a matter of law:

A. Standard of Review

The ALC has jurisdiction over this matter pursuant to S.C. Const. art. I, § 22; S.C. Code Ann. §§ 1-23-320, -600(B), 44-1-60(F), and 44-7-210(E); 3 S.C. Code Ann. Regs. 61-15; and Rule 11 of the SCALC Rules. Trident timely filed its request for a contested case hearing regarding DHEC's decision. *See* 3 S.C. Code Ann. Regs. 61-15 § 401. Because Trident is an existing provider of cardiac catheterization services in the service area, it is an "affected person" for the purposes of participating in a contested case related to DHEC's decision. *See* S.C. Code Ann. § 44-7-130(1) (2018); 3 S.C. Code Ann. Regs. 61-15 § 103(1).

A contested case hearing conducted before this Court in a CON matter is a trial *de novo*, in which "the whole case is tried as if no trial whatsoever had been had in the first instance," and the administrative law judge conducting the hearing is the sole finder of fact, who "must make sufficiently detailed findings supporting the denial or grant of a permit application." *Marlboro Park Hosp. v. S.C. Dep't of Health & Envtl. Control*, 358 S.C. 573, 579, 595 S.E.2d 851, 854 (Ct. App. 2004) (quoting *Blizzard v. Miller*, 306 S.C. 373, 412 S.E.2d 406 (1991) and *Converse Power Corp. v. S.C. Dep't of Health & Envtl. Control*, 350 S.C. 39, 564 S.E.2d 341 (Ct. App. 2002)). The weight and credibility assigned to evidence presented at the hearing of a matter is within the province of the trier of fact. *S.C. Cable Television Ass'n v. S. Bell Tel. & Tel. Co.*, 308 S.C. 216, 222, 417 S.E.2d 586, 589 (1992). The trier of fact may also give an expert's testimony the weight he or she determines it deserves, *Florence Cty. Dep't of Soc. Servs. v. Ward*, 310 S.C. 69, 425 S.E.2d 61 (Ct. App. 1992), and may accept the testimony of one expert over that of another. *S.C. Cable Television Ass'n, supra*.

The CON Act states that "the Administrative Law Court ... shall consider the South Carolina Health Plan in place at the time the application was filed and may consider the current South

Carolina Health Plan when making its decision.” S.C. Code Ann. § 44-7-225 (2018). “Because the legislature has required these stringent requirements for the State Health Plan’s implementation, it is clear the legislature intended for the State Health Plan to be an enforceable document.” *Trident Med. Ctr. v. S.C. Dep’t of Health & Envtl. Control*, 412 S.C. 341, 350, 772 S.E.2d 177, 182 (Ct. App. 2015), *cert. denied* (Dec. 18, 2015). As such, the Court must interpret the Health Plan using the rules of statutory construction. *See id.* at 355, 772 S.E.2d at 184. “The question of statutory interpretation is one of law for the court to decide.” *Alltel Commc’ns, Inc. v. S.C. Dep’t of Revenue*, 399 S.C. 313, 316, 731 S.E.2d 869, 870 (2012).

The Court must determine whether Roper-Berkeley’s Project should be approved under the CON Act, its regulations, and the State Health Plan. 3 S.C. Code Ann. Regs. 61-15 § 307(1). While a project does not have to satisfy every Project Review Criterion to be approved, no project may be approved unless it is consistent with the State Health Plan.

Here, the Roper-Berkeley CON Application did not satisfy Standard 3. As such, the Department erred in its decision to grant a CON that is inconsistent with the State Health Plan.

B. Statutory Interpretation

If a statute’s language is plain and unambiguous and conveys a clear and definite meaning, there is no occasion for employing rules of statutory interpretation and the court has no right to look for or impose another meaning. *Paschal v. State Election Comm’n*, 317 S.C. 434, 436, 454 S.E.2d 890, 892 (1995). “Under the plain meaning rule, it is not the court’s place to change the meaning of a clear and unambiguous statute.” *Hodges v. Rainey*, 341 S.C. 79, 85, 533 S.E.2d 578, 581 (2000). “The words of a regulation must be given their plain and ordinary meaning without resort to subtle or forced construction to limit or expand the regulation’s operation.” *Byerly v. Connor*, 307 S.C. 441, 444, 415 S.E.2d 795, 799 (1992).

Standard 3 states that “[n]ew diagnostic catheterization services, including mobile services, **shall be approved only if all existing labs** in the service area **have performed** a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year (emphasis added) [.]” Roper-Berkeley applied to establish new diagnostic catheterization services. Therefore, each of the labs existing in the service area in which Roper-Berkeley would operate must have performed at least 500 diagnostic catheterization procedures per laboratory during the twelve

months prior to the submission of Roper-Berkeley's CON Application, when the review process begins.

By its plain meaning, "have performed" clearly calls for a historical (i.e. retrospective) determination of the utilization of the existing labs. When asked about the language of Standard 3 specifically, Mr. Eubank testified that the past tense in the phrase "have performed" indicates that the Department, applicants, and other affected persons should view historic utilization retroactively when applying Standard 3 analysis. (See Trial Tr. 357:11-17.) There is no contention that Bon Secours was performing the minimum of 500 diagnostic catheterization procedures during the year prior to the filing of Roper-Berkeley's CON Application.

A court may look to a dictionary to determine the plain and ordinary meaning of statutory terms. *Liberty Mut. Ins. Co. v. S.C. Second Injury Fund*, 363 S.C. 612, 623-24, 611 S.E.2d 297, 302-03 ("Dictionaries can be helpful tools during the initial stages of legal research for the purpose of defining statutory terms... The words of a statute must be given their plain and ordinary meaning without resorting to subtle or forced construction[.]") (Ct. App. 2005) (citations omitted). "Existing" may be defined as "in existence or operation at a current time."¹⁸

Therefore, "existing" as used in Standard 3 means that a lab is open and is offering and has the capacity to provide catheterization services to patients, as Bon Secours did, at the time a CON Application is filed and under review. Given that Bon Secours offered cardiac catheterization services and reported a volume greater than zero during the most recent year prior to Roper-Berkeley's CON Application, it is illogical to conclude that Bon Secours was not an "existing lab" for the purposes of Standard 3. As such, the Department's determination that Bon Secours did not exist for purposes of the Standard 3 analysis in approving the Roper-Berkeley CON Application was contrary to the meaning of the clear language contained in Standard 3.

C. Agency Deference

Roper-Berkeley asserts that because the word "existing" is not defined in the State Health Plan, the Department is entitled to agency deference to interpret and apply a statute or regulation it administers. Where the agency's interpretation of an undefined term is reasonable and consistent with the plain language of the Health Plan, there is no reason to deviate from that interpretation

¹⁸ See <https://en.oxforddictionaries.com/definition/existing> (last visited on October 24, 2018).

and application. *Murphy v. S.C. Dept. of Health and Env'tl. Control*, 396 S.C. 633, 640-641, 723 S.E.2d 191, 195 (2012).

A two-step process is required when interpreting and applying statutes and regulations administered by an agency. *Kiawah Dev. Partners, II v. S.C. Dep't of Health & Env'tl. Control*, 411 S.C. 16, 32, 766 S.E.2d 707, 717 (2014). "First, a court must determine whether the language of a statute or regulation directly speaks to the issue. If so, the court must utilize the clear meaning of the statute or regulation." *Id.* (citing *Brown v. Bi-Lo, Inc.*, 354 S.C. 436, 440, 581 S.E.2d 836, 838 (2003)). Statutes and regulations that are silent or ambiguous are entitled to some level of deference. However, when an agency's interpretation is arbitrary, capricious, or manifestly contrary to the statute or regulation at issue, the agency's interpretation is not entitled to deference. *Id.* at 34, 766 S.E.2d at 718. "The words of a regulation must be given their plain and ordinary meaning without resort to subtle or forced construction to limit or expand the regulation's operation." *Byerly v. Connor*, 307 S.C. 441, 444, 415 S.E.2d 795, 799 (1992).

Because the language in Standard 3 does speak directly to the issue, approval of the Roper-Berkeley CON Application while Bon Secours was operating below the required utilization threshold, the Court must utilize the plain, ordinary meaning of the language, as prescribed in *Kiawah*, and should not resort to forced or subtle construction to expand the regulation's operation. *Id.* The Court finds that under the plain, ordinary meaning of the language in Standard 3, Bon Secours was an existing lab offering and providing cardiac catheterization procedures in the service area in which Roper-Berkeley seeks to establish a new diagnostic catheterization lab. Bon Secours was not performing a minimum of 500 diagnostic catheterization procedures as Standard 3 requires for the twelve months prior to the filing of the Application.

In contending that the Department should be afforded agency deference to interpret and apply the meaning of a statute or regulation administered by the agency, Roper St. Francis asserts that the Department correctly interpreted "existing" to mean all labs that "will exist" at or following the approval of the Project. As Ms. Platt testified when describing how Roper St. Francis interpreted existing, "[t]he lab will be closed upon the approval of the [P]roject. As a result, all labs which will exist following the approval of this project are currently operating well above the [500-procedure threshold] and meet the utilization requirements of the [S]tandard." (Trial Tr. 408:11-18.)

However, this interpretation is at odds with the plain language of Standard 3, which directs the Department to apply the utilization analysis retrospectively to measure the number of services that **have been performed by all existing** labs in the service area during the most recent year. Interestingly, this interpretation is also at odds with positions taken by the Department in both 2010 and in February 2016 when East Cooper first submitted its CON Application.

The Department's forced construction by converting the terms "existing" and "have performed" to "will exist" and "will perform" under the principle of agency deference completely negates the meaning and intent of Standard 3 and circumvents the importance of historical utilization as a necessary tool for proper health planning.

In this case, the testimony and evidence presented show that the Department actually used two different interpretations of the term "existing," both contrary to each other and inconsistent with the plain, ordinary meaning of the statutory term.

First, Mr. Eubank testified that he did not consider the Bon Secours lab to be existing because it was operating in violation of Reg. 61-15 because it did not obtain a new CON in 2010 after not performing any cardiac catheterizations in 2008 and 2009. "[M]y ultimate decision was that given my firm belief that the [Bon Secours] lab had not offered the service for two years and would have required a CON to again be an existing lab that it was, in fact, not an existing lab for the purpose of review under Standard 3." (Trial Tr. 286:6-12; *See also* Trial Tr. 322:2-9.) "[W]e didn't really consider that lab to be existing though it was clearly operational." (Trial Tr. 324:21-23.)

While the Court appreciates that Mr. Eubank attempted to clean up a long-standing problem he inherited with respect to the Bon Secours lab, this application of the term "existing" is inconsistent with the prior positions taken by the Department in 2010. Enforcement action was available to remedy a lab operating in violation of Reg. 61-15. For reasons unknown, no enforcement action was ever taken, and the Department concluded that it could not discount the existence of the lab for purposes of Standard 3 even though it had failed to obtain a new CON. Compounding the problem, the Department opined that the appropriate remedy would be to amend the State Health Plan, but that amendment was never made. For the next six years, the lab remained open, offering and performing cardiac catheterization services. It appeared in the State Health Plan inventory as an existing lab through and after the filing of the Application and approval of the Project. Further,

Roper St. Francis also repeatedly asserted that it maintained an existing lab at Bon Secours up until August 1, 2016, after the Department approved its CON Application.

To assign the Bon Secours lab a classification such as “operational but not existing” in terms of Standard 3 nearly six years after the initial Reg. 61-15 violation is to assign it a classification that is contrary to the prior interpretations of the Department and is, therefore, arbitrary and capricious. Furthermore, while Eubank testified that this was his ultimate decision and that it served as the basis for his ability to discount the insufficient historical utilization of the lab to satisfy Standard 3, this was not the basis he gave for his decision to grant the CON in his approval letter.

The second interpretation of “existing” came in the form of Eubank’s letter of CON approval for the Roper-Berkeley Project on July 25, 2016. This letter does not state or otherwise imply that DHEC ever considered the Bon Secours catheterization lab to be non-existent under Reg. 61-15 for purposes of its Standard 3 analysis. Instead, the letter states that Roper St. Francis agreed to shutter the Bon Secours lab upon approval of the Roper-Berkeley CON, “[t]hus allowing the Department to discount the utilization figures of the lab at [Bon Secours].” In fact, Eubank also testified to this interpretation stating that the prospective agreement to close the lab allowed the Department “[t]o render the utilization of that lab mute [sic] for purposes of the decision.” (Trial Tr. 317:17-18.)

At the outset, the Court recognizes that these two positions taken by Mr. Eubank in rendering his decision to approve the CON are conflicting and, as such, arbitrary. Either he considered the Bon Secours lab to be non-existent under the terms of Reg. 61-15, or, he considered the lab to be existing but the promise of its future closure would render it discountable under the historical utilization analysis of Standard 3. From the evidence presented, the Court is unable to clearly identify which position actually served as the basis for Eubank’s and, by extension, the Department’s decision to approve the CON. In that respect, the agency’s interpretation of “existing” is arbitrary and capricious. Furthermore, both interpretations of “existing” are inconsistent with the plain, ordinary meaning of the word, contrary to the meaning of Standard 3, and should not be entitled to deference.

D. Conclusion

Although DHEC and Roper St. Francis agreed to shut down the Bon Secours lab before beginning operation at the Roper-Berkeley location, this future condition did not change the status of Bon

Secours as an existing facility at the inception of and during the application and review process. Nor, did the prospective agreement allow for other providers to submit competing CON applications with the knowledge that one problematic outlier lab was about to be removed from the State Health Plan inventory. After all, Roper St. Francis did not agree to shutter the Bon Secours lab if the Application were not approved. Roper St. Francis only agreed to shutter it *in exchange* for approval and, by extension, in exchange for clearing up a longstanding and meddlesome situation plaguing DHEC.

There are simply no provisions or exceptions in the State Health Plan or in Reg. 61-15 that allow the Department to ignore the fact that a diagnostic catheterization lab is operating below the Standard 3 required threshold of Standard 3 or, in the alternative, to agree on its future closing as a condition of approving a new application.

Thus, to satisfy Standard 3 in this case, the Department had to find a “mechanism”¹⁹ to discount the historical underutilization of the Bon Secours lab in order to determine that Roper-Berkeley’s application satisfied Standard 3 and complied with the State Health Plan. To do so, the Department concluded that the Bon Secours lab did not exist for purposes of Standard 3. By utilizing agency deference in its interpretation of the word “existing,” DHEC ignored the plain meaning of “existing” in Standard 3. Because the Department’s interpretation of an undefined term is not reasonable and is inconsistent with the plain language of the State Health Plan, there is no reason to afford the interpretation deference so as to strain the plain and ordinary meaning of the standard.

For the Department to allow an applicant to circumvent the requirements specified in the Health Plan by conditional actions, such as closing a lab upon the approval of an application, would allow an underperforming lab to serve as a “place-holder” to frustrate potential applicants who seek to provide a health service. A potential competitor reviews the inventory, finds a below-threshold provider, and concludes that no CON application could comply with Standard 3, which is basically what occurred when East Cooper contemplated their application in 2010. On the contrary, a service provider should be able to rely on publicly available information, such as the State Health Plan

¹⁹ *Infra.* at p.10. (“...[DHEC] does not currently have a mechanism in place that would allow the Department to discount the existence of the [Bon Secours] cardiac catheterization lab...”) Joint Exhibit 2, p.081. (excerpt from 2010 letter by DHEC official)

and the most recent JARs, to find accurate and reliable data upon which to make business decisions in government-regulated areas such as those administered by DHEC.

While this approval may have worked to solve the problem of the Bon Secours lab, it cannot be based on the premise of agency deference to arbitrarily interpret a word that has plain and ordinary meaning. As Mr. Eubank testified, there is no historic guideline or prior interpretation upon which to base such an interpretation but “[o]nly that precedent which we’ve set through these decisions [in this case].” (Trial Tr. 278:25-279:1.) While the Court agrees that the Department should have flexibility in interpreting the State Health Plan in order to properly administer the CON Program, that flexibility should not extend so far so as to allow for an arbitrary and capricious interpretation that is manifestly contrary to the plain, ordinary meaning of Standard 3 and the purposes of the CON Act.

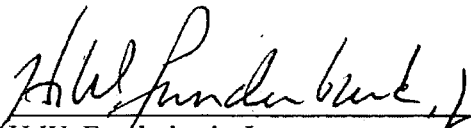
Bon Secours was an existing lab offering and providing cardiac catheterization procedures in the service area in which Roper-Berkeley seeks to establish a new diagnostic catheterization lab. Bon Secours was not performing a minimum of 500 diagnostic catheterization procedures as Standard 3 requires for the twelve months prior to the filing of the Application. Because Roper-Berkeley’s CON Application to provide new diagnostic catheterization services in the service area does not satisfy Standard 3, the Application does not comply with the State Health Plan per Regulation 61-15 §801.3 and S.C. Code Ann. § 44-7-210(B). As such, the Department erred in approving the CON Application and the Roper-Berkeley Certificate of Need should not have been granted because it is inconsistent with the 2015 State Health Plan.

ORDER

IT IS THEREFORE ORDERED that the Certificate of Need for Roper-Berkeley’s proposed project for a diagnostic cardiac catheterization lab in Goose Creek, Berkeley County, South Carolina is **DENIED**.

AND IT IS SO ORDERED.

February 21, 2019
Columbia, South Carolina


H.W. Funderburk, Jr.
Administrative Law Judge

FILED

FEB 21 2019

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

Trident Medical Center, LLC, d/b/a
Trident Medical Center,

) Docket No.: _____

Petitioner,

PETITION FOR ADMINISTRATIVE REVIEW AND REQUEST FOR CONTESTED CASE HEARING

VS.

South Carolina Department of Health and
Environmental Control and Roper St.
Francis Hospital – Berkeley, Inc., d/b/a
Roper St. Francis Hospital – Berkeley,

⁶ Respondents.

Pursuant to S.C. Const. art. I, § 22; S.C. Code Ann. § 1-23-320, § 1-23-600(B), § 44-1-60(G), and §§ 44-7-110 *et seq.*; S.C. Code Ann. Regs. 61-15; and Rule 11 of the RPALC, Petitioner Trident Medical Center, LLC, d/b/a Trident Medical Center (“Trident”), by and through its undersigned counsel, petitions the Court for administrative review and requests a contested case hearing on (1) the South Carolina Department of Health and Environmental Control’s (“Department”) July 25, 2016 staff decision to grant a Certificate of Need (“CON”) to Respondent Roper St. Francis Hospital – Berkeley, Inc., d/b/a Roper St. Francis Hospital – Berkeley (“Roper–Berkeley”) for the addition of cardiac catheterization services to Roper–Berkeley at a total project cost of \$2,873,366 (“Staff Decision”) (Exhibit A); and (2) the Department Board’s September 21, 2016 decision to not to hold a final review conference on this matter, rendering the Department’s Staff Decision the final agency decision (Exhibit B). In support of this Petition, Trident respectfully submits the following:

PROCEDURAL BACKGROUND

1. On May 9, 2016, Roper-Berkeley submitted a CON application for the addition of diagnostic cardiac catheterization services at a total project cost of \$2,873,366 ("Proposed Project").
2. By letter, dated May 26, 2016, the Department deemed the CON application complete. (**Exhibit C**)
3. On June 24, 2016, Trident notified the Department of its status as an affected person and its opposition to the Proposed Project. Trident also requested that the Department hold a Project Review Meeting. (**Exhibit D**)
4. Subsequently, on July 21, 2016, Trident submitted a letter from its consultant, Sullivan Consulting Group, Inc., detailing its reasons for opposing the Proposed Project. (**Exhibit E**)
5. On July 25, 2016, the Department issued its decision letter, approving Roper-Berkeley's CON application, without conducting a Project Review Meeting. (**Exhibit A**)
6. By letter, dated August 9, 2016, Trident requested that the Department Board conduct a final review conference on the matter. (**Exhibit F**) The Department staff responded to Trident's request for a final review conference on September 16, 2016. (**Exhibit G**)
7. On September 21, 2016, The Department Board issued its letter notifying Trident that it would not hold a final review conference on the matter, rendering the Department's Staff Decision the final agency decision. (**Exhibit B**)
8. Trident now seeks administrative review and a contested case hearing before this Court.

FACTUAL BACKGROUND

9. The South Carolina Health Plan, enacted August 13, 2015 (“State Health Plan”) prohibits the approval of new diagnostic cardiac cath labs unless “all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year.” State Health Plan, p. VIII-5, ¶ 3. Bon Secours St. Francis Xavier Hospital (“Bon Secours”), Roper-Berkeley’s sister facility, has not met this threshold in several years, and, in fact, has averaged less than 10 cardiac catheterization cases per year for the last four years. *Id.* at p. XIII-33.

10. Roper-Berkeley stated in its CON application that, upon approval, Bon Secours would close its diagnostic cath lab, and by letter dated August 17, 2016, Bon Secours confirmed the closure. *See Exhibit G.* However, the subsequent closure of Bon Secours’ cath lab does not change the fact that at the time the Department approved Roper-Berkeley’s CON application, the application did not comply with the provisions of the State Health Plan. More importantly, it does not cure the issues that the addition of a new cardiac cath service in the area presents.

11. Roper-Berkeley could have submitted its CON application as a proposed transfer of services from Bon Secours, but it knew it could not meet the State Health Plan requirements for a transfer. *See generally* State Health Plan, p. II-2. For example, Roper-Berkeley could not demonstrate need for additional capacity based on historical and projected utilization patterns. *Id.* Instead, Roper-Berkeley and the Department chose to treat the CON application as a request for a new diagnostic cath service, disregarding the fact that the CON application failed to meet those State Health Plan requirements as well. The Department’s decision to grant Roper-Berkeley’s CON application as a “new service” allows Roper-Berkeley to skirt compliance with

the State Health Plan by creating its own procedural process. It is fundamentally unjust to create a separate set of standards merely because a provider cannot meet the applicable standards of the State Health Plan.

12. The State Health Plan provides that “[t]he service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes one way automobile travel time. . . .” *Id.* at p. VIII-4, ¶ 2. Roper-Berkeley’s CON application fails to comply with this State Health Plan requirement as well. Roper-Berkeley’s service area is much broader than the 45 minute one way automobile travel time standard and is defined as encompassing four counties: Berkeley, Dorchester, Charleston, and Colleton. Many portions of Charleston and Colleton Counties lie well outside of the 45 minute drive time service area established by the State Health Plan.

13. In its response to Trident’s request for a final review conference before the Department Board, the Department staff stated that “[n]either the Plan nor applicable law require an applicant to limit its projected utilization to only those individuals residing in the Plan-defined service area.” See Exhibit G, p. 3, ¶ 2. The 45 minute drive time service area is a CON standard for diagnostic cardiac cath services. CON standards were formulated by the Department “to guide medical providers throughout the State. Inclusion of these standards in the application process is designed to give applicants *notice of its requirements and to elicit from them a commitment to incorporate these standards into both their applications and finished projects.*” *Id.* at p. I-2 (emphasis added).

14. The State Health Plan prescribes service areas based on “an assessment of existing resources and need in the relevant service area, along with other factors set forth in [the] Plan, applicable statutes, and regulations.” State Health Plan, p. II-2. Thus, the services area is

defined through a reasonable analysis of the needs of an area. There is nothing reasonable about Roper-Berkley's service area. To allow an applicant to create a service area as broad as necessary to allow the applicant to ramp up sufficient utilization to justify a proposed project would defeat the need for the inclusion of a service area within the State Health Plan CON standards and render the Department's review with respect to projected utilization meaningless. Yet, this is exactly what the Department did when it accepted Roper's unrealistic service area.

15. Roper-Berkeley's service area is unrealistic, *inter alia*, because it illogically assumes that patients would travel greater distances past other providers with existing cardiac cath programs, including providers operating comprehensive programs, to have the procedure performed at Roper-Berkeley, which will be a small 50 bed community hospital.

16. Roper-Berkley's sister facility, Roper Hospital, is located in downtown Charleston. Roper Hospital aligned physicians historically referred all patients to the comprehensive cardiac catheterization program at Roper Hospital, not the diagnostic-only catheterization program at Bon Secours. Consequently, Bon Secours' diagnostic program was essentially non-existent. Physicians who believe there is a likelihood that a patient will require percutaneous coronary intervention ("PCI") will naturally refer that patient to a comprehensive cardiac cath program where both procedures can be performed during the same visit. It is highly unlikely that the physician instead would send that patient to a facility with only a diagnostic program available and risk having to transfer the patient to another facility or require the patient to be scheduled for another procedure at a different time, thereby unnecessarily subjecting the patient to two separate, invasive procedures. Bon Secours' virtually non-existent utilization rates over the last several years are a testament to the fact that Roper aligned physicians recognize that referral to a comprehensive cardiac cath program is in the patient's best interest. There is no

reason to believe that the physicians' referral patterns would change upon the opening of a diagnostic only cardiac cath program at a small, 50-bed community hospital, such as Roper-Berkeley.

17. Roper-Berkeley claims that Roper Hospital will transfer some of its existing diagnostic caseload to Roper-Berkeley. However, again, there is no evidence that patients or physicians will choose Roper-Berkeley rather than continue to utilize the comprehensive cardiac cath services provided at Roper Hospital. Roper-Berkeley attempts to bolster its projected utilization under the premise that it will absorb some of the volume from Roper Hospital; however, the fact that Bon Secours' diagnostic cardiac cath program was virtually non-existent demonstrates that this premise is meritless and unsupportable.

18. Roper-Berkeley's CON application fails to meet the State Health Plan requirement that a new diagnostic cath service can only be approved "if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year." *Id.* at p. VIII-5, ¶ 3. Roper-Berkeley and the Department apparently misinterpreted this provision as requiring existing facilities to have provided 500 diagnostic equivalents per lab in the most recent year, despite the plain language of the State Health Plan. See Exhibit A, p. 2. Only one facility, Trident, met the threshold of 500 diagnostic procedures for each of its two labs. See Exhibit E, p. 6. Roper Hospital, MUSC, and Bon Secours fell well below this threshold.

19. The State Health Plan states that

An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic *equivalent* procedures annually within three years of initiation of services, without reducing the utilization of existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization *procedures* per laboratory.

State Health Plan, p. VIII-5, ¶ 4 (emphasis added). In addition to the fact that Roper-Berkley's service area cannot support its utilization projections, Roper-Berkeley's projections are seriously flawed in that Roper-Berkeley's claims that it will absorb volume from Roper Hospital are unsupportable. Yet, Roper-Berkeley presumes that it will absorb eighty (80%) percent of Roper Hospital's Berkeley County cases, sixty-five (65%) percent of its Dorchester County cases, and fifty (50%) percent of its Charleston County cases. Such dramatic shifts in market share are not supported by the facts.

20. Rather than absorbing Roper Hospital's cardiac cath patient base, the more likely scenario is that Roper-Berkeley's Proposed Project will redirect patients from Trident. Trident is currently a major provider of diagnostic and therapeutic catheterization services to residents in Berkeley and Dorchester Counties. Yet, the Department gave no consideration to the potential adverse impact the Proposed Project would have on Trident. The Department stated that "[a]s one lab in the service area is being closed as a result of this approval. . . no unnecessary duplication of services is expected." See Exhibit A, p. 3. Bon Secours' utilization was *de minimis*, and the closure of its cardiac cath program will have no material impact on utilization at Roper-Berkeley. The absorption of the less than five diagnostic cath cases annually performed at Bon Secours will not keep Roper-Berkeley in operation. Roper-Berkeley will have to redirect significant market share from Trident to achieve its projected volumes. Nevertheless, both Roper-Berkeley and the Department dismissed the issue of adverse impact, despite the fact that Trident is located only seven miles from the Roper-Berkeley campus.

21. Roper-Berkeley's utilization projections are also based on the assumption that Roper Hospital's historical diagnostic cardiac cath volume will grow in conjunction with the projected rate of population growth. However, this assumption is inconsistent with Roper

Hospital's recent historical experience, as well as the experience of all other area service providers. Every provider in the service area has seen a decline in diagnostic cath procedures since 2011, and utilization of diagnostic cardiac cath services through the service area declined by twenty (20%) percent between 2011 through 2015. See Exhibit D, p. 8. There is no reason to believe that this trend will not continue.

22. Essentially all of Roper-Berkeley's patients will likely originate from its primary service area. As such, Roper-Berkeley cannot meet the required 500 diagnostic catheterization equivalents annually, even assuming the redirection of patients from Roper Hospital. In all likelihood, Roper-Berkeley will operate a low volume program, while redirecting market share from Trident, adversely impacting Trident's utilization. Yet, the Department never questioned the legitimacy of Roper-Berkeley's utilization projections. See Exhibit A, p. 2.

23. There is no community need for Roper-Berkeley's Proposed Project. As noted above, Roper-Berkeley utilized an unrealistic service area to bolster its utilization projections. In its approval letter, the Department stated that all labs within the planning area operate between seventy-nine (79%) percent and nearly ninety-four (94%) percent capacity. The Department then concludes that Roper-Berkeley has sufficiently demonstrated community need. *Id.* However, the CON project review criteria for community need requires that the Proposed Project:

meet an identified (documented) need of the target population. The assumptions and methods used to determine the level of need should be specified in the application and *based on a reasonable approach* as judged by the review body.

S.C. Code Ann. Regs. 61-15, § 802.2.c. (emphasis added). The project review criteria further provides that "[c]urrent and/or projected utilization should be sufficient to justify the expansion or implementation of a proposed service." *Id.* at § 802.2.e. There is nothing reasonable about Roper-Berkeley's assumptions with respect to community need or projected utilization. The

actual utilization that Roper-Berkeley will realize will be much lower than projected and is insufficient to justify the implementation of the Proposed Project. The area is already well-served by Trident and other area providers, all of whom have capacity to meet the needs of the community, particularly given the fact that all providers have experienced declining utilization over the past several years.

24. Roper-Berkeley's Proposed Project will unnecessarily duplicate services without increasing accessibility to services. The Department's conclusion that there will be no duplication of services because Bon Secours would close its cardiac cath program upon approval of the CON is illogical. Bon Secours' cardiac cath program existed in name only. The absorption of less than five diagnostic procedures annually will not support the operation of Roper-Berkeley's Proposed Project, and it is unlikely that any significant number of patients will be redirected from Roper Hospital. The presumption that utilization volumes will grow with the population contravenes the declining utilization trends in the service area, which has experienced significant population growth in the last decade. The likely scenario is that Roper-Berkeley will rely on the redirection of market share from Trident, adversely impacting Trident's utilization. There is no need for the Proposed Project. It does nothing to increase accessibility to services, and it is an unnecessary duplication of services.

25. The Proposed Project is not financially feasible. The project review criteria require an applicant to project "both the immediate and long-term financial feasibility of the proposal. Such projections should be reasonable and based upon accepted accounting procedures." S.C. Code Ann. Regs. 61-15, § 802.15. The assumptions underlying Roper-Berkeley's projections are unreasonable and unsupportable and cannot be realized. More reasonable assumptions would have produced dramatically lower projected utilization and,

therefore, dramatically lower financial projections. In reality, the Proposed Project is unlikely to demonstrate an excess of revenue over expenses.

26. The Proposed Project does not promote cost containment. The Proposed Project has a total project cost of almost \$2.9 million for an unneeded service, which will likely be underutilized. The Proposed Project will adversely impact Trident and other area providers and will increase health care costs in the service area.

27. In sum, the Proposed Project does not comply with the requirements of the State Health Plan or the project review criteria set forth in the CON regulations, and the Department's decision to approve Roper-Berkeley's CON application should be reversed.

LEGAL ARGUMENTS

28. In response to the Department's decision (i) to grant a CON to Roper-Berkeley for the addition of cardiac catheterization services at a total project cost of \$2,873,366; and (ii) the Board's decision not to hold a final review conference on this matter, rendering the Department's Staff Decision the final agency decision (hereinafter, collectively, "Department's Decision"), in accordance with S.C. Code Ann. § 44-1-60(G), and reserving its right to raise any and all issues presented to and considered by the Department below, Trident respectfully requests that the Court reverse the Department's Decision for the following reasons:

a. The Department's Decision is arbitrary, capricious, and affected by other error of law or fact, because Roper-Berkeley's CON application fails to comply with the requirements for the establishment of a new diagnostic cardiac cath lab set forth in the State Health Plan in that Roper-Berkeley failed to demonstrate that "all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year." State Health Plan, p. VIII-5, ¶ 3. Roper-Berkeley and the

Department conveniently discounted Bon Secours' virtually non-existent utilization on Roper-Berkeley's assertion that Bon Secours' would cease operation after approval of the CON. Bon Secours' subsequent closure is irrelevant and does not cure the fact that Roper-Berkeley did not meet this State Health Plan criteria at the time the Department was reviewing its CON application. Notwithstanding, even discounting Bon Secours' utilization rates, Roper-Berkeley still failed to meet this State Health Plan criteria because the only provider in the service area that met the 500 diagnostic cath *procedures* (not equivalents) threshold was Trident. The Department unjustly and indefensibly created a new set of standards for Roper-Berkeley when it could not meet the State Health Plan standards. Because Roper-Berkeley's CON application failed to meet this State Health Plan criteria, it cannot be approved. S.C. Code Ann. § 44-7-210(B); S.C. Code Ann. Regs. 61-15, § 307.

b. The Department's Decision is arbitrary, capricious, and affected by other error of law or fact, because Roper-Berkeley's CON application fails to comply with the 45 minute drive time, service area standard set forth in the State Health Plan. State Health Plan, p. VIII-4, ¶ 2. Roper-Berkeley instead relies on an unrealistic service area encompassing four counties in an effort to create sufficient utilization to justify its Proposed Project. The Department argues that an applicant is not required to comply with the 45 minute drive time standard; however, this assertion contravenes the purpose of both CON standards and projections of need and is more evidence of the Department's willingness to create new requirements for Roper-Berkeley because it cannot meet the applicable requirements of the State Health Plan. See State Health Plan, p. I-2. The State Health Plan requirements are based on reasonable projections of need, but there is nothing reasonable about Roper-Berkeley's service area or the utilization projections upon which they are based. Because Roper-Berkeley's CON application

failed to meet this State Health Plan criteria, it cannot be approved. S.C. Code Ann. § 44-7-210(B); S.C. Code Ann. Regs. 61-15, § 307.

c. The Department's Decision is arbitrary, capricious, and affected by other error of law or fact, because Roper-Berkeley's CON application fails to comply with the State Health Plan requirement that an applicant for a new diagnostic service "must project that the proposed service will perform a minimum of 500 diagnostic equivalents annually within three years of initiation of services, without reducing the utilization of existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory." State Health Plan, p. VIII-5. Roper-Berkeley's projections are unsupportable and based upon unrealistic assumptions.

In addition to Roper-Berkeley's use of an unrealistically broad service area, Roper-Berkeley assumes that it will absorb diagnostic cath cases from its sister facility, Roper Hospital. The facts do not support this assumption. There is no reason to believe that either patients or physicians would choose a diagnostic-only lab over a comprehensive cath lab, thereby running the risk that the patient may need to be transferred to another facility or need to schedule a second invasive procedure. The fact that Bon Secours' diagnostic cath program has essentially existed in name only is a testament to the fact that Roper-Berkeley cannot rely upon the absorption of diagnostic cath cases from Roper Hospital.

Roper-Berkeley also assumes that Roper Hospital's diagnostic cath volume will grow in conjunction with the projected rate of population growth; however, this assumption is inconsistent with both Roper Hospital's historical experience and the historical experience of all other area providers. Diagnostic cardiac cath procedures actually declined in the service area by

twenty (20%) percent between 2011 and 2015, while the population grew, and there is no reason to believe the trend will not continue.

Had Roper-Berkeley used reasonable assumptions in generating its projected utilization, the projections would have been far lower. The facts do not support Roper-Berkeley's projections. Because Roper-Berkeley's CON application fails to meet this State Health Plan criteria, it cannot be approved. S.C. Code Ann. § 44-7-210(B); S.C. Code Ann. Regs. 61-15, § 307.

d. The Department's Decision is arbitrary, capricious, and affected by other error of law or fact, because Roper-Berkeley's CON application fails to demonstrate community need. S.C. Code Ann. Regs. 61-15, § 802.2. The CON regulations require that the Proposed Project meet an identified need based upon reasonable assumptions and methods. *Id.* at § 802.2.c. The CON regulations also require that the applicant project utilization sufficient to justify the expansion or implementation of the Proposed Project. *Id.* at § 802.2.e. As demonstrated herein, there is nothing reasonable about either Roper-Berkeley's assumptions identifying community need or its projected utilization. The facts demonstrate that Roper-Berkeley's utilization will actually be much lower than projected and insufficient to justify the Proposed Project. Because Roper-Berkeley's CON application fails to meet the requirements of S.C. Code Ann. Regs. 61-15, § 802.2, it cannot be approved.

e. The Department's Decision is arbitrary, capricious, and affected by other error of law or fact, because Roper-Berkeley's Proposed Project is an unnecessary duplication of services. Roper-Berkeley and the Department illogically conclude that as a result of the closure of Bon Secours' diagnostic cath program there will be no unnecessary duplication of services. Bon Secours' program was virtually non-existent, as there were never more than ten (10)

diagnostic cardiac catheterization cases performed in the Bon Secours lab in the last five years. The absorption of approximately five cardiac cath procedures annually will not support the operation of Roper-Berkeley's Proposed Project, and it is unlikely that Roper-Berkeley will absorb any substantial number of diagnostic cardiac cath cases from Roper Hospital. The more realistic scenario is that Roper-Berkeley's Proposed Project will redirect patients from Trident, adversely impacting Trident's utilization volumes. There is no need for Roper-Berkeley's Proposed Project. The Proposed Project is an unnecessary duplication of services and does nothing to increase accessibility to services. Because Roper-Berkeley's Proposed Project fails to meet the requirements of S.C. Code Ann. Regs. 61-15, § 802.3, it cannot be approved.

f. The Department's Decision is arbitrary, capricious, and affected by other error of law or fact, because Roper-Berkeley's Proposed Project is not financially feasible. The CON project review criteria require that the applicant project immediate and long-term financial feasibility of the Proposed Project based upon reasonable projections. S.C. Code Ann. Regs. 61-15, § 802.15. As demonstrated herein, the assumptions underlying Roper-Berkeley's financial projections are not reasonable and cannot be realized. More reasonable assumptions would have resulted in dramatically lower utilization projections and, consequently, dramatically lower financial projections. In reality, the Proposed Project is unlikely to generate an excess of revenue over expenses. Because Roper-Berkeley's CON application fails to meet the requirements of S.C. Code Ann. Regs. 61-15, § 802.15, it cannot be approved.

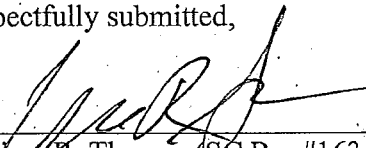
g. The Department's Decision is arbitrary, capricious, and affected by other error of law or fact, because Roper-Berkeley's Proposed Project does not promote cost containment. The Proposed Project has a total project cost of almost \$2.9 million for a service that is not needed, that will be underutilized, and that will adversely impact Trident and other

area providers. Roper-Berkeley's Proposed Project will increase health care costs in the service area and, therefore, will do nothing to promote cost containment. Because Roper-Berkeley's CON application fails to meet the requirements of S.C. Code Ann. Regs. 61-15, § 802.16, it cannot be approved.

WHEREFORE, based on the foregoing, Trident respectfully requests that the Court issue an Order:

- A. Reversing the Department's Decision to approve Roper-Berkeley's CON application for the addition of cardiac catheterization services at Roper St. Francis Hospital – Berkeley at a total project cost of \$2,873,366;
- B. Finding the Department's Decision to be arbitrary, capricious, and affected by other error of law or fact; and
- C. Denying Roper-Berkeley's CON application.

Respectfully submitted,



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*Attorneys for Petitioner
Trident Medical Center, LLC, d/b/a Trident Medical
Center*

Columbia, South Carolina
October 21, 2016.

Exhibit A

To Petition for Administrative Review and
Request for Contested Case Hearing



July 25, 2016

VIA CERTIFIED MAIL

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 760
Charleston, SC 29403

Re: **Decision Granting Application for a Certificate of Need**
Roper St. Francis Hospital – Berkeley
Addition of Cardiac Catheterization services to Roper St. Francis Hospital - Berkeley
at a total project cost of \$2,873,366.
Case No.: 2340
Berkeley County, South Carolina

Dear Ms. Cantwell:

The South Carolina Department of Health and Environmental Control (Department) has reviewed the above-referenced Certificate of Need (CON) Application. After consideration of the entire administrative record in this matter, the Department concludes the Applicant has presented substantial evidence the Project materially complies with the relevant project review criteria and is consistent with the South Carolina Health Plan enacted August 13, 2015 (Plan). Specifically, the Project satisfies the requirements set forth in Section 802 of Regulation 61-15 pertaining to Community Need Documentation, Distribution (Accessibility), Financial Feasibility, and Cost Containment. Accordingly, it is the decision of the Department that a Certificate of Need be granted to Roper St. Francis Hospital – Berkeley.

The Department's decision is based on the following findings:

Compliance with the State Health Plan

In addition to the declarative Certificate of Need Standards #1 and #2 outlined in the Plan for cardiac catheterization services, the following Standards for the Project apply:

3. New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year.

A review of relevant Joint Annual Report (JAR) data for all diagnostic catheterization labs within the 45-minute drive time service area showed that all diagnostic catheterization labs met or exceeded the 500 procedure threshold outlined in the Plan with one notable exception. The

diagnostic cardiac catheterization lab located at Roper St. Francis Xavier Hospital in West Ashley performed no more than nine (9) procedures per year in any year from 2010 to 2014, according to available JAR data. The Department explained this inconsistency to the Applicant as an agent for both Roper St. Francis Hospital – Berkeley and Bon Secours St. Francis Xavier Hospital. As such an agent, the Applicant agreed to shutter its diagnostic catheterization lab upon approval of the instant application, regardless of the timing of the new lab installation or any potential opposition to the instant application, thus allowing the department to discount the utilization figures of the lab at the Bon Secours St. Francis Xavier location. As such, the Department concludes that other diagnostic catheterization labs within the service area operate at such an equivalent capacity as to not preclude the addition of the diagnostic catheterization lab contemplated by the Applicant.

4. An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services; without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.

The Applicant projects a minimum of 510 procedures by the close of the third reporting year, and no evidence is provided which shows utilization at other existing diagnostic catheterization labs will drop below the 500 minimum procedure threshold as a result of approving the Project.

Certificate of Need Standards #5 and #6 do not apply to the contemplated Project as it is not an expansion of current cardiac catheterization services and is not a mobile diagnostic catheterization laboratory.

The Department notes that Trident Medical Center has filed as an Affected Person and in opposition to the application. A letter of opposition detailing the opposition's argument was received on July 21, 2016. After consideration of all information presented therein, the Department has determined that Trident's opposition does not present a sufficient reason to deny the Application.

Accordingly, the Department concludes the Applicant has sufficiently complied with the Standards outlined in the Plan, Chapter VIII-4 and Chapter VIII-5.

Community Need Documentation

While the planning area for diagnostic catheterization services is defined as an area within a 45-minute, one-way drive from the Applicant's facility, the Applicant further considers its service area to include Berkeley County as well as parts of Dorchester, Charleston, and Colleton Counties. Within the planning area, there are a total of 11 existing catheterization labs which are open and able to perform the services contemplated by the Applicant's Project. With the notable exception discussed previously, all labs within the planning area operate between 79% and nearly 94% capacity.

Accordingly, the Department concludes Applicant has sufficiently projected Community Need to satisfy the requirements of Section 802.2, Reg: 61-15.

Distribution (Accessibility)

Patients will be admitted regardless of age, race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, or gender identity or expression. Applicant has budgeted an appropriate amount of gross revenue for the treatment of indigent patients. As one lab in the service area is being closed as a result of this approval, and as another lab which is to be approved is in the extreme southern portion of the service area relative to this Applicant's proposed location, no unnecessary duplication of services is expected to occur.

The Department concludes that Applicant has satisfied the requirements of Distribution (Accessibility) pursuant to Section 802.3, Reg. 61-15.

Financial Feasibility

Applicant provided three year budget projections demonstrating financial feasibility. Julie Graudin, CPA for Roper St. Francis Healthcare, attests that the Project will be funded by utilizing existing bond proceeds issued for the development of the larger hospital project.

The Department concludes that Applicant has satisfied the requirements of Financial Feasibility pursuant to Section 802.15, Reg. 61-15.

Cost Containment

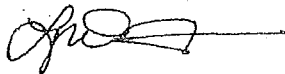
Integrating the contemplated laboratory into the pre-construction phase of the new Roper St. Francis Hospital – Berkeley realizes certain economies of practice which are otherwise lost during later renovation. Quality of cardiac care is increased through the provision of diagnostic services wherein early intervention prevents later invasive treatments at a much higher cost to the patient.

The Department concludes that Applicant has satisfied the requirements of Cost Containment pursuant to Section 802.16, Reg. 61-16.

The Department has determined the findings required by S.C. Code Reg. 61-15 §501 are not applicable to this Project.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Mr. Aaron Gantt (803.545.4400); Division of Health Facilities Construction, Mr. William McCallum (803.545.4215); Division of Health Licensing, Ms. Gwendolyn Thompson, (803.545.4370); and Bureau of Certification, Ms. MaryJo Roué (803.545.4293).

Sincerely,



Louis Eubank
Director
Certificate of Need Program

cc: William R. Thomas, Esq. (email/Certified Mail)

Enclosures: Guide to Board Review

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@dhcc.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

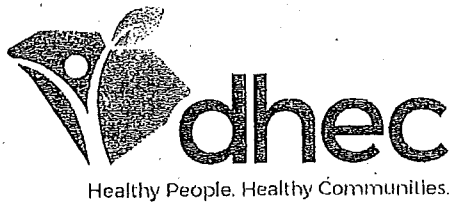
1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
 - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
 - Type of decision (permit, enforcement, etc.) and description of the 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.

Exhibit B

To Petition for Administrative Review and
Request for Contested Case Hearing



Allen Amster, *Chairman*
Mark S. Lutz, *Vice Chairman*
Ann B. Kirol, DDS, *Secretary*
R. Kenyon Wells

Board:
Charles M. Joye II, P.E.
I. Clarence Batts, Jr.
David W. Gillespie, MD
William Lee Hewitt, III

September 21, 2016

Via U.S. Mail - Certified

9214 8969 0099 9790 1406 0717 83
William R. Thomas
Parker Poe Adams & Bernstein, LLP
Post Office Box 1509
Columbia, SC 29202

Via U.S. Mail

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 760
Charleston, SC 29403

Via Electronic Mail Delivery

Ashley C. Biggers
SCDHEC - Office of General Counsel
2600 Bull Street
Columbia, SC 29201

RE: Docket No. 16-RFR-61, Roper St. Francis - Berkeley - Approval of Certificate of Need Application for the addition of cardiac catheterization services.

Dear Counsel of Record and Ms. Cantwell:

The South Carolina Board of Health and Environmental Control will not conduct a Final Review Conference on the above-referenced matter.

CONTESTED CASE GUIDANCE

S.C. Code Section 44-1-60 provides that if the Board declines in writing to schedule a final review conference, the staff 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 (ALC) within thirty calendar days after notice is mailed to the applicant, permittee, licensee, and affected person that the Board declined to hold a final review conference.

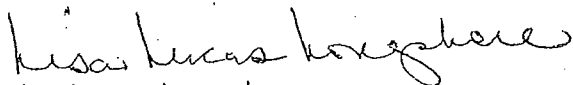
A request for a contested case hearing before the Administrative Law Court must be filed within the time allowed and in accordance with the Rules of the ALC, including payment of the ALC's filing fee, at the following address:

Clerk's Office
South Carolina Administrative Law Court
Edgar A. Brown Building
1205 Pendleton St., Suite 224
Columbia, SC 29201

The ALC's Notice of Request for Contested Case Hearing form and the Rules of the ALC can be found at the ALC's website: <http://www.scalc.net>. Further information on filing a request for a contested case hearing before the ALC may be obtained by calling the Clerk's Office at the Administrative Law Court (803-734-0550).

If a party files a request for a contested case hearing with the ALC, the party must serve a copy of the request on DHEC and any other parties at the same time the request is filed with the ALC. A copy of the request for a contested case hearing must be delivered or mailed to DHEC at the address at the top of this memorandum.

Sincerely,



Lisa Lucas Longshore
Clerk

The above information on filing a request for a contested case hearing before the Administrative Law Court is provided as a courtesy; parties before the ALC are responsible for complying with all applicable requirements of the Court.

Exhibit C

To Petition for Administrative Review and
Request for Contested Case Hearing



Catherine E. Heigel, Director

Promoting and protecting the health of the public and the environment

May 26, 2016

VIA CERTIFIED MAIL

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 760
Charleston, SC 29403

Article #: 92148969009997901404889441

Re: Roper St. Francis Hospital - Berkeley Inc. d/b/a Roper St. Francis Hospital -
Berkeley
Addition of Cardiac Catheterization services to Roper St. Francis Hospital -
Berkeley at a total project cost of \$2,873,366.
Matter No.: 2340

Dear Ms. Cantwell:

This is to notify you the South Carolina Department of Health and Environmental Control ("Department") has determined the aforementioned project to be complete for purposes of review by the Certificate of Need Program. Enclosed is an invoice for the required application fee. It may be paid by check made payable to the S.C. Department of Health and Environmental Control or by electronic check through the Department's website (www.scdhec.gov) using the "Pay Invoices" hyperlink at the bottom of each webpage. This is a secure website. If payment is not received within fifteen (15) days of your receipt of this invoice, the pending application will be considered withdrawn and this matter closed. Should this deadline fall on a weekend or State holiday, it will be extended to the next calendar day that is neither weekend nor holiday pursuant to Regulation 61-15, Section 303.

Should the Department receive your application fee within the fifteen (15) day deadline, the Department will render a decision no earlier than thirty (30) days, but no later than one-hundred (120) days from the date notice is provided to affected persons in the State Register, unless a public hearing is held pursuant to Regulation 61-15, Section 305.

The Department has determined the relative importance of the project review criteria, pursuant to Regulation 61-15, Section 304, which will be used to review your application. The specific criteria to be used are set forth below and are ranked according to their relative importance, with the most important being listed first. All other relevant criteria will be given equal importance.

Letter to Shannon Cantwell
May 26, 2016
Page 2

- a. Compliance with the State Health Plan – 1;
- b. Community Need Documentation – 2;
- c. Distribution (Accessibility) – 3;
- d. Financial Feasibility – 15; and
- e. Cost Containment – 16.

The aforementioned criteria are set forth in Regulation 61-15, Section 802. Should you wish to submit any additional information to the Department in support of your application, you have thirty (30) days from the receipt of this correspondence to do so.

If you have any questions, please contact me at 803.545.3652.

Sincerely,



Louis Eubank
Director
Certificate of Need Program

Enclosures: Application Fee Invoice

Exhibit D

To Petition for Administrative Review and
Request for Contested Case Hearing



William R. Thomas
 Partner
 Telephone: 803.253.8658
 Direct Fax: 803.255.8017
 willthomas@parkerpoe.com

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

June 24, 2016

VIA HAND DELIVERY AND EMAIL

Louis W. Eubank, MSW, MPH
 Director, Certificate of Need Program
 Bureau of Health Facilities and Services Development
 SC Department of Health and Environmental Control
 301 Gervais Street
 Columbia, South Carolina 29201

Re: Roper St. Francis Hospital – Berkeley Inc. d/b/a Roper St. Francis Hospital - Berkeley
Certificate of Need Application for the addition of cardiac catheterization services to Roper St. Francis Hospital – Berkeley at a total project cost of \$2,873,366
DHEC Matter No. 2340

TRIDENT MEDICAL CENTER'S AFFECTED PERSON STATUS AND OPPOSITION

Louis
 Dear Mr. Eubank:

Pursuant to S.C. Code Ann. §§44-7-130(1) and 44-7-210(C) and Regulation 61-15 §§103(1) and 305, I am writing on behalf of Trident Medical Center, LLC, d/b/a Trident Medical Center ("Trident"), an existing provider of similar services located in Charleston, South Carolina, which is in the same health service area and geographic area to be served by the applicant, to notify the Department that Trident is an "affected person" with respect to Roper St. Francis Hospital – Berkeley's CON application referenced above, and that it opposes the approval of Roper St. Francis Hospital – Berkeley's CON application. Trident is also requesting that a project review meeting be held by the Department prior to the Department making a decision on this CON application. More specifically, Trident opposes the above referenced CON application because, among other reasons, the project does not comport with the purposes of the CON Act; the project does not comply with the standards set forth in the 2015 *South Carolina Health Plan*; the project is not needed; the project will have an adverse impact on Trident's cardiac catheterization program and its open heart program; the project does not increase accessibility to catheterization services; and the project will not contain costs.

Please copy Trident on any future correspondence to or from the Department concerning this CON application. Thank you for your consideration of Trident's position, and please let me know if you have any questions or concerns.

Sincerely,

William R. Thomas

WRT/ccq

PPAB 3281931v1

Exhibit E

To Petition for Administrative Review and
Request for Contested Case Hearing

Sullivan Consulting Group, Inc.

2090 Bethany Way · Alpharetta, Georgia 30004 · (770) 753-4222 · Fax: (770) 753-4223

July 21, 2016

VIA E-MAIL

Louis Eubank, MSW, MPH
Director
Certificate of Need Program
Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

RE: CON Application 2340

Dear Mr. Eubank:

On behalf of Trident Medical Center ("Trident"), I am submitting this letter in opposition to the Certificate of Need ("CON") application filed by Roper St. Francis Hospital-Berkeley ("Roper-Berkeley") to develop a new diagnostic cardiac catheterization program at its approved but not yet constructed hospital to be located in Goose Creek, Berkeley County. The proposed program is scheduled to open in June 2019. The application also proposes to close the existing diagnostic cardiac catheterization program at Bon Secours St. Francis Hospital ("BSSFH"), which is of little consequence given that this program purposefully has only performed only a handful of diagnostic catheterization procedures over the past several years.

1. Summary of Trident's Objections to the Project

- The project does not represent a transfer of an existing diagnostic cardiac catheterization service but instead the initiation of a new service.
- Roper-Berkeley fails to satisfy the criteria in the 2015-2016 South Carolina Health Plan (Criterion 1).
- Roper-Berkeley fails to demonstrate a community need for the project (Criterion 3).
 - In particular, the application fails to define a reasonable service area for its diagnostic cardiac cath program at a new 50-bed hospital.
 - Moreover, the projections of utilization for the project are unreasonable for a number of reasons. Roper-Berkeley failed to consider the declining trend in diagnostic cardiac cath procedures in the service area. Its projections also assume unrealistic market shares from distant areas that would require patients to bypass existing comprehensive cardiac cath providers.

Mr. Louis Eubank

July 21, 2016

Page 2

- The historical utilization of the BSSFH diagnostic cath program demonstrates that patients and physicians prefer to utilize the comprehensive cardiac cath program at Roper Hospital rather than a diagnostic only program such as the one proposed for Roper-Berkeley.
- The project fails to demonstrate financial feasibility in light of these unrealistic utilization projections (Criterion 15).
- The project will not contribute to cost containment because it is unneeded, will likely be underutilized, and depends on patients traveling long distances to reach a start-up program at a small community hospital (Criterion 16).

The Project is not a Transfer of an Existing Service.

While the BSSFH diagnostic cath program will close upon approval of this CON application, there is no attempt in the Roper-Berkeley application to characterize this project as a "transfer" of the diagnostic cardiac cath service from BSSFH nor would the project, as explained more fully below, qualify as a transfer.

Compliance with the South Carolina Health Plan

Given the Roper-Berkeley application is proposing a new diagnostic cardiac cath service, the relevant standards for review are those for Cardiac Catheterization Services and specifically the criteria relating to Diagnostic Cardiac Catheterization. Roper-Berkeley does not address the Exception to Service Area Standards, which are considered when an applicant seeks to transfer beds or services between two related facilities. Given that these Exceptions are not addressed by the applicant, there is no basis to approve the project under these criteria. In an abundance of caution, however, this letter will address the reasons why the Roper Berkeley project fails to satisfy these Exceptions as well.

Cardiac Catheterization Standards

The Roper-Berkeley application unsuccessfully attempts to demonstrate conformity with the State Health Plan standards for new diagnostic cardiac cath services. Certain of these criteria are discussed below.

Mr. Louis Eubank

July 21, 2016
Page 3

2. *The service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes' one way automobile travel time; for comprehensive cardiac catheterization laboratories the service area is all facilities within 60 minutes' one way automobile travel time; a pediatric cardiac program should serve a population encompassing at least 30,000 births per year, or roughly two million people.*

Roper-Berkeley does not utilize a 45-minute one-way automobile travel time to define its service area. Instead, as shown in Exhibit 1, it defines its service area to include a wide ranging region across four counties.

Exhibit 1
Roper St. Francis Hospital-Berkeley
Proposed Diagnostic Cardiac Catheterization Service
Area

Primary Service Area

Berkeley County - All ZIP Codes

Dorchester County- 29420, 29472, 29483, 29485, 29456

Charleston County - 29406, 29410, 29418, 29420, 29456

Secondary Service Area

Remainder of Charleston County

Remainder of Dorchester County

Colleton County

Source: Roper-Berkeley Application, Exhibit 2

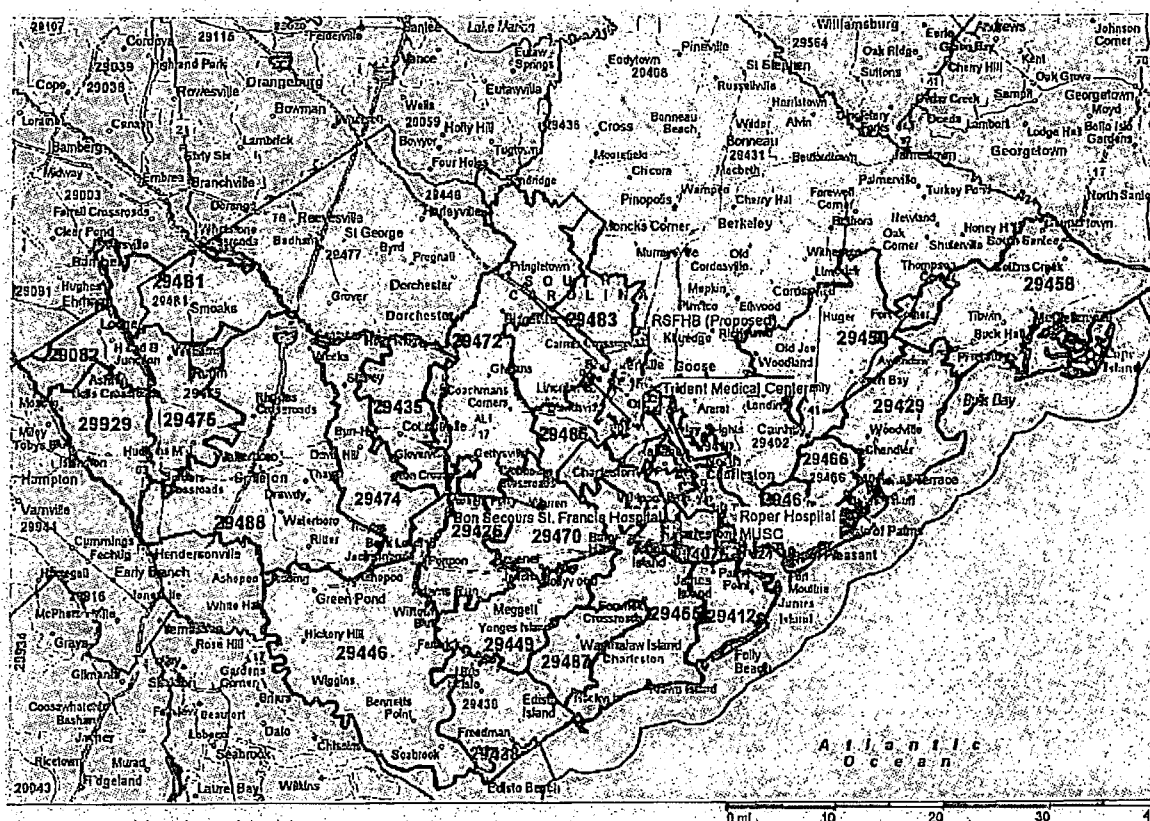
A map of this service area is presented in Exhibit 2 and demonstrates the breadth of the service area.

Mr. Louis Eubank

July 21, 2016

Page 4

Exhibit 2
Roper St. Francis Hospital-Berkeley Proposed Diagnostic Cardiac Cath Service Area



Many portions of Charleston and Colleton Counties are outside of a 45-minute one-way automobile travel time from the Roper-Berkeley site. More importantly, it is unlikely that a start-up diagnostic cardiac cath program at a 50-bed hospital would attract patients from such a large area for a number of reasons. The most important reason is that historically referring physicians in the Roper St. Francis system area have referred virtually all of their patients to the comprehensive cardiac cath program at Roper Hospital rather than the diagnostic-only program at BSSFH. In 2015 BSSFH performed only 2 diagnostic caths, which is consistent with its experience over the past several years.

BSSFH, with 204 inpatient beds, is a substantially larger and more established hospital than Roper-Berkeley, and there is no reason to expect that physicians affiliated with Roper St. Francis will change these historical referral patterns to utilize a 50-bed hospital with substantially fewer resources than BSSFH. There are valid clinical reasons for choosing a comprehensive cardiac cath program over a diagnostic-only program. Patients who are high risk are more appropriately served in a program with open heart surgery back-up. If a physician believes that there is a strong likelihood that a patient will require percutaneous coronary intervention ("PCT"), it is

Mr. Louis Eubank

July 21, 2016

Page 5

more appropriate to refer the patient to a comprehensive center where both the diagnostic cath and the PCI could be performed in a single cath lab session.

Another factor undermining the credibility of the Roper-Berkeley service area definition is the fact that many patients would have to drive past one or more existing cardiac cath programs to reach Roper-Berkeley. For example, Trident is located only 7 miles from Roper-Berkeley and is more proximate to areas south and west of Roper-Berkeley. These existing providers, with the exception of BSSFH, offer comprehensive ranges of cardiac interventions, which makes it highly unlikely that any material number of patients not residing in close proximity to Roper-Berkeley will seek cardiac cath services at the 50-bed facility.

An additional argument presented in the application is that Roper Hospital is well utilized and it could "off-load" some of its existing diagnostic cath volume to Roper-Berkeley to reduce current utilization levels. There is simply no evidence that patients and physicians will choose to go to Roper-Berkeley rather than utilize the comprehensive services at Roper Hospital, particularly if the patients do not live in areas near Roper-Berkeley. In fact, if this were the case, BSSFH would be a thriving program; however, it appears to be the most underutilized program in state.

The expansive Roper-Berkeley service area appears to have been cobbled together in an effort to bolster the utilization projections for the proposed program, as discussed in more detail below. The service area is not reasonable, and the projections that result from the use of this service area are unreliable.

Diagnostic and Mobile Catheterization Services

3. *New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year;*

All existing labs in the service area have not performed a minimum of 500 diagnostic catheterization procedures per laboratory in 2015. Roper-Berkeley misinterpreted this criterion in its application response by addressing the number of diagnostic cardiac catheterization equivalents per laboratory, which is inconsistent with the plain language of this criterion. Exhibit 3 displays 2015 cardiac cath utilization data for all providers in the service area. Only one provider, Trident, exceeded the standard of 500 diagnostic catheterizations per laboratory. Roper hospital averaged only 398 diagnostic catheterizations per laboratory.

Mr. Louis Eubank

July 21, 2016
Page 6

Exhibit 3
Roper St. Francis Hospital-Berkeley Service Area
2015 Diagnostic Catheterizations per Laboratory

Facility	Cath Labs	Diagnostic Caths	Diagnostic Caths Per Lab
MUSC*	6	1,804	301
Roper Hospital	3	1,193	398
Bon Secours St. Francis	1	4	4
Trident Medical Center	2	1,081	541
Total	12	4,082	340

*Includes adult and pediatric procedures

Source: Joint Annual Reports of Hospitals

Based on the most recent utilization data, the Roper-Berkeley project fails to satisfy this criterion.

4. *An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.*

Exhibit 4 on the following page recreates the utilization projections presented in the application. The problems with Roper-Berkeley's utilization projections begin with the unreasonable service area discussed above. Even putting aside the reasonableness of the service area, there are several other serious flaws with the projections presented.

The first assumption is that Roper-Berkeley will only serve patients who otherwise would have utilized diagnostic cath services at Roper Hospital. There is no basis to support this assumption. There is no reason to expect that patients would in many cases travel farther to receive a diagnostic cath at a small hospital with a limited range of services. Given the proximity of Roper-Berkeley to Trident and the fact that Trident is a major provider of diagnostic and therapeutic cath services to residents of Roper-Berkeley's primary service area, the more likely scenario is that Roper will redirect patients within its primary service area from Trident. No consideration was given by Roper-Berkeley to the shift in market shares that is probable when developing a program in a new location.

Exhibit 4

Roper St. Francis Hospital-Berkeley Projected Diagnostic Cardiac Cath Utilization

			Diagnostic Caths			% Shifted to Roper Berkeley			for Roper Berkeley		
	2015 Diagnostic Caths at RSF Labs	CAGR for Population	2019	2020	2021	2019	2020	2021	2019	2020	2021
Primary Service Area											
Berkeley County - All ZIPs	292	1.30%	307	311	316	45%	60%	80%	138	187	252
Dorchester County											
29420	27	1.83%	29	30	30	45%	55%	65%	13	16	20
29472	5	5.50%	6	7	7	45%	55%	65%	3	4	4
29483	62	1.81%	67	68	69	45%	55%	65%	30	37	45
29485	42	1.60%	45	45	46	45%	55%	65%	20	25	30
29456*	-	2.00%	-	-	-	45%	55%	65%	-	-	-
Charleston County											
29406	46	1.67%	49	50	51	30%	40%	50%	15	20	25
29410	-	1.11%	-	-	-	30%	40%	50%	-	-	-
29418	60	1.74%	64	65	67	30%	40%	50%	19	26	33
29420	-	1.83%	-	-	-	30%	40%	50%	-	-	-
29456*	-	2.00%	-	-	-	30%	40%	50%	-	-	-
Total PSA	534		568	576	585				238	315	410
Secondary Service Area											
Remainder of Charleston County	782	0.56%	800	804	809	2.5%	5.0%	7.5%	20	40	61
Remainder of Dorchester County	13	1.95%	14	14	15	5.0%	8.0%	10.0%	1	1	1
Colleton County	118	0.10%	118	119	119	5.0%	8.0%	10.0%	6	9	12
Total Secondary Service Area	913		932	937	942				27	51	74
In-Migration	121	7.89%				6.0%	6.0%	6.0%	17	23	31
Total Cath Patients	1,568		1,500	1,513	1,527				282	389	515
Actual In-migration		7.72%									
Source: Roper-Berkeley Application, Exhibit 13											

Mr. Louis Eubank

July 21, 2016
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Another fundamental assumption in the projections is that Roper Hospital's historical diagnostic cardiac catheterization volume will grow in the future at the rate of population growth. That assumption is inconsistent with Roper Hospital's recent historical experience as well as the experience of *all service area providers*. Exhibit 5 presents the trend in diagnostic cardiac cath volume at all service area providers.

- Roper Hospital has seen its diagnostic cath procedures decline from 1,776 in 2011 to 1,193 in 2015¹, a drop of 32.8 percent despite population growth in the Charleston area.
- The total diagnostic cath procedures performed by service area providers decreased from 5,103 in 2011 to 4,082 in 2015, a 20.0 percent reduction.

There is no reason to expect that there will be any growth in diagnostic caths over the next five years as Roper-Berkeley has projected. If Roper Hospital's 2015 diagnostic cath volumes were held constant, the projected utilization for Roper-Berkeley would have been 475 diagnostic caths in 2021, although this even figure is significantly overstated as discussed below.

Exhibit 5
Roper St. Francis Hospital-Berkeley Service Area
Trend in Diagnostic Catheterizations: 2011 to 2015

	2011	2012	2013	2014	2015	% Change 2011-15
Roper Hospital	1,776	1,785	1,651	1,578	1,193	-32.8%
Bon Secours St. Francis	7	9	3	4	4	-42.9%
MUSC*	1,994	1,996	1,954	1,982	1,804	-9.5%
Trident Medical Center	1,326	1,332	995	1,007	1,081	-18.5%
Total	5,103	5,122	4,603	4,571	4,082	-20.0%

*Includes adult and pediatric patients.

Source: Joint Annual Reports of Hospitals

¹ In the Roper-Berkeley application reports 1,568 diagnostic catheterizations performed by Roper Hospital, which is significantly higher than 1,193 reported on its 2015 JAR.

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The percentage of Roper Hospital's patients to be shifted to Roper-Berkeley is similarly unreasonable. As shown in Exhibit 4, 80 percent of Berkeley County cases, 65 percent of Dorchester County primary service area patients, and 50 percent of Charleston County primary service area patients are expected to be redirected from Roper Hospital to Roper-Berkeley. Such dramatic shifts in volume from a comprehensive program to a diagnostic-only program are not reasonable, particularly in light of Roper's experience of operating a diagnostic-only program at BSSFH. In the secondary service area, it is unlikely that there will be any material redirection of diagnostic caths from Roper Hospital to Roper-Berkeley given the distances these patients would have to travel and the more limited nature of the Roper-Berkeley services.

Given that virtually all of the patients will be drawn from Roper-Berkeley primary service area, Roper-Berkeley will not reach 500 diagnostic cath procedures annually, as its own projections indicate. Even with the unrealistically high assumed redirection of patients from Roper hospital to Roper-Berkeley, the primary service area is expected to provide only 405 diagnostic cath procedures in 2021. Under more realistic assumptions, the projected utilization would be far less. The likelihood is that Roper-Berkeley will operate a low volume diagnostic cath program, just as BSSFH has done for many years.

Exceptions to Service Area Standards

As discussed previously, Roper-Berkeley did not address the Exceptions to Service Area Standards, apparently recognizing that the closure of a program at BSSFH that has been effectively unutilized for many years and opening a new program nearly three years later in a new hospital did not constitute a transfer of the program. Even if the project were reviewed under these Exceptions, the project fails to satisfy the requirements for a transfer of a service.

1. *A transfer or exchange of service may be approved only if there is no overall increase in the number or amount of such services.*

Roper-Berkeley does not satisfy this criterion because there is an overall increase in the number of diagnostic cath services in the service area. There currently is no legitimate cath lab program at BSSFH, nor has there been since 2007, when Roper St. Francis made the decision to discontinue services at the lab. See Exhibit 6.

Exhibit 6 Bon Secours St. Francis Hospital Trend in Diagnostic Catheterizations

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	Total	Ave/Yr
Diagnostic Caths	0	0	0	2	7	9	3	4	2	27	3

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As the chart details, BSSFH has average only 3 diagnostic caths a year since 2007, and zero caths each year from 2007 to 2009. Roper-Berkeley is applying to open a new diagnostic cath service at its Goose Creek campus three years from now, while Roper St. Francis is maintaining a fictional program at BSSFH to foreclose any new applicants for diagnostic catheterization services in the tri-county region. New applicants cannot apply unless "all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year." 2015 State Health Plan, p. VIII-5. The Department should not recognize BSSFH's diagnostic catheterization program as an existing service merely because only (3) three diagnostic caths are performed on average each year, which is not indicative of an actual program.

3. *The facility receiving the service must demonstrate the need for the additional capacity based on both historical and projected utilization patterns.*

Roper-Berkeley fails to satisfy this criterion. There is simply no need for additional capacity in either the Roper St. Francis system or in the service area generally. As discussed above, the BSSFH diagnostic cath program has performed a *de minimus* number of procedures each year. If Roper needed additional capacity, it could have redirected patients to BSSFH. Given that Roper's diagnostic cardiac cath volume has declined by nearly 33 percent and the service area by 20 percent, there is no basis to conclude that a new cardiac cath laboratory is needed based on historical utilization patterns. A reasonable projection of future utilization would indicate that service area diagnostic cath procedures will not increase materially.

4. *The applicants must explain the impact of transferring the technology on the health care delivery system of the county and/or service area from which it is to be taken; any negative impact must be detailed, along with the perceived benefits of the proposal.*

Roper-Berkeley never addressed the impact of its proposed opening of a new diagnostic cath program in Berkeley County other to make the unreasonable and undocumented assumption that all of the patients served by Roper-Berkeley would otherwise have gone to Roper Hospital. As discussed above, the more likely scenario is that Roper-Berkeley would seek to capture the patients Trident is currently serving given Roper-Berkeley's proximity to Trident and its position in the middle of Trident's primary service area. This adverse impact on Trident should not be permitted for a project that is unneeded and will likely be underutilized.

For all of the foregoing reasons, the Roper-Berkeley project is not consistent with the either Cardiac Catheterization Standards or the Exceptions to Service Area Standards in the State Health Plan.

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Community Need

The Roper-Berkeley proposal to develop a diagnostic cath program meets no community need. As discussed in the preceding section, Roper St. Francis has available cardiac cath lab capacity within its own system given the miniscule volumes served by BSSFH in recent years. In addition, Roper Hospital's volumes have been declining as have the volumes of other providers in the Roper-Berkeley service area.

There is no demonstration that patients in Berkeley County or any other portion of Roper-Berkeley's service area require enhanced access to diagnostic cardiac cath services. Roper-Berkeley is located only 7 miles from Trident, which offers comprehensive cardiac care. Trident has and will continue to serve patients in need of diagnostic cath services in the Roper-Berkeley primary service area.

Roper-Berkeley has not defined a reasonable service area for its project. If patients were to indeed travel from distant parts of Charleston and Colleton Counties to Roper-Berkeley, they would have to pass by other providers who offer more comprehensive care. A more reasonably defined service area would not support the approval of another diagnostic cath provider.

The proposed closure of BSSFH's existing diagnostic-only program, contingent on the approval of the Roper-Berkeley proposal, has no relevance from a health planning standpoint. The BSSFH program has been serving so few patients that Roper St. Francis should have closed it many years ago. BSSFH's inability to attract diagnostic cath patients from the comprehensive program at Roper Hospital is also a strong indicator that the Roper-Berkeley program will similarly experience poor utilization.

Financial Feasibility

The financial projections for the project are presented in Attachment 6 of the application. These projections are based on the projected volumes, which as discussed above, are wholly unreasonable. More reasonable projections would result in dramatically lower volumes for the Roper-Berkeley program, and it is unlikely to generate an excess of revenues over expenses. Financial feasibility is not demonstrated.

Cost Containment

This project will not promote cost containment. It requires a capital expenditure of \$2,873,366 for a program that is not needed and will be underutilized. To achieve its projected utilization, patients will be required to travel long distances to reach a start-up program in a small community hospital.

Mr. Louis Eubank

July 21, 2016

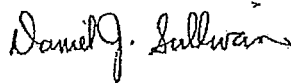
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Moreover, the proposed program will increase costs and time for the patients who otherwise would have received diagnostic cath services at Roper Hospital but will be redirected to Roper-Berkeley. Currently, when a patient presents to Roper Hospital for a diagnostic cath and it is determined that PCI is required, the PCI can be performed during the same cath lab session. Patients seen at Roper-Berkeley who are determined to need PCI will have to travel to Roper Hospital by ambulance or a present to Roper Hospital at a later scheduled appointment. A second cath procedure must be performed and a second catheter inserted into the patient, which increases the cost as well as the physical discomfort to the patient.

The diagnostic cath program at Roper-Berkeley will unnecessarily duplicate existing services. Trident is located squarely within Roper-Berkeley's primary service area, offers a more comprehensive range of cardiac services, and has ample available capacity to serve additional cardiac cath patients in the future.

We appreciate the opportunity to submit this comments and will be happy to provide any additional information you require.

Sincerely,



Daniel J. Sullivan

Exhibit F

To Petition for Administrative Review and
Request for Contested Case Hearing



William R. Thomas
 Partner
 Telephone: 803.253.8658
 Direct Fax: 803.255.8017
 willthomas@parkerpoe.com

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

August 9, 2016

RECEIVED

AUG 09 2016

Via E-mail (LUCASLM@dhec.sc.gov) & Hand Delivery

The Honorable Lisa Lucas Longshore
 Clerk
 SC Board of Health and Environmental Control
 2600 Bull Street
 Columbia, SC 29201-1708

**SC Department of
 Health and Environmental
 Control**

Re: **Request for Final Review**
Department decision granting application for a Certificate of Need to Roper
St. Francis Hospital - Berkeley for the addition of cardiac catheterization
services at a total project cost of \$2,873,366
CON Case No.: 2340

Dear Ms. Longshore:

Pursuant to S.C. Code Ann. § 44-1-60(E); the State Certification of Need and Health Facility Licensure Act (S.C. Code Ann. §§ 44-7-110 *et seq.*) ("CON Act"); S.C. Code Ann. Regs. 61-15 ("CON Regulations"); and Article I, Section 22 of the South Carolina State Constitution; on behalf of our client, Trident Medical Center, LLC, d/b/a Trident Medical Center ("Trident"), I am writing to request that the Department Board conduct a final review conference of the Department's July 25, 2016 decision to approve Roper St. Francis Hospital-Berkeley's¹ ("Roper - Berkeley") Certificate of Need ("CON") application for the addition of diagnostic cardiac catheterization services at a total project cost of \$2,873,366 ("Proposed Project"). **Exhibit A.** Trident respectfully requests that the Department Board reverse the Department's decision to approve the Proposed Project and sets forth its arguments in support of its position herein.

Also, enclosed with this Request for Final Review, please find a check in the amount of \$100.00 as payment of the filing fee.

BACKGROUND

On May 9, 2016, Roper-Berkeley submitted its CON application for its Proposed Project. On May 26, 2016, the CON application was deemed complete. **Exhibit B.** By letter dated, June 24, 2016, Trident notified the Department of its status as an "affected person," as that term

¹ The Department approved this project even though the Roper-Berkeley Hospital is not scheduled to open until the year 2019. Thus, if any provider in the service area were to apply for a CON to add diagnostic services to its facility, Roper-Berkeley could assert that the Department should not approve the CON until such time as Roper-Berkeley's diagnostic catheterization lab is up and running.

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is defined by the CON Act and the CON Regulations, stated its opposition to the Proposed Project, and requested a Project Review Meeting. **Exhibit C.** Subsequently, on July 21, 2016, Trident submitted a letter from its consultant, Sullivan Consulting Group, Inc., detailing its reasons for opposing Roper-Berkeley's Proposed Project. **Exhibit D.** On July 25, 2016, the Department issued its letter to Roper-Berkeley, notifying Roper-Berkeley that its CON application was approved. The Department declined to hold a Project Review Meeting on the basis that Roper-Berkeley's project was subject to the State Health Plan's Chapter II transfer provision, but according to the approval letter, that was not the case. As the approval letter states, the Department reviewed Roper-Berkeley's CON application based on the applicable project review criteria for a new cardiac catheterization lab, rather than an intra-system transfer of a catheterization lab. If Trident knew that the Department was not going to review Roper-Berkeley's CON application using the transfer provision, it would have requested a formal Public Hearing instead of a Project Review Meeting.²

As set forth in detail below and as will be more fully explained at a final review conference held on this matter, Trident respectfully requests that the Board overturn the Department's decision to approve Roper-Berkeley's CON application because it (i) fails to satisfy the criteria set forth in the South Carolina Health Plan enacted August 13, 2015 ("State Health Plan"); (ii) fails to demonstrate community need for the Proposed Project; (iii) is not financially feasible; (iv) will not promote cost containment; and (v) will adversely impact other area providers, including Trident.

ARGUMENTS

Compliance with the State Health Plan

Bon Secours' Non-Existent Diagnostic Cardiac Catheterization Program

Roper-Berkeley's CON application states that upon approval of the application, Bon Secours St. Francis Xavier Hospital ("Bon Secours"), Roper - Berkeley's sister facility, will close its existing diagnostic catheterization lab. See CON Application, § B11. Roper - Berkeley then

² The CON Regulations provide that

[a] public hearing must be requested in writing by an 'affected person' as defined in these regulations within thirty (30) calendar days of the notification of the beginning of a review. Where such a hearing is requested, prior notice of the hearing will be provided to 'affected persons.' The written notification of the hearing shall include the proposed schedule for the review time, date, and place of such hearing. The public hearing shall provide an opportunity for any person to present information relevant to the application.

S.C. Code Ann. Regs. 61-15, § 306. To avoid the complications associated with a public hearing, the Department established the informal Project Review Meeting back in the 1990s. The Project Review Meeting gives the applicant and affected persons the ability to meet with and present its position to the Department's staff in a forum that allows the opposing side to address the Department's staff. The Department's staff also can also question each side and here the opposing party's response. The process is very transparent, and it gives the Department an opportunity to learn more about the application. By denying Trident's request for a Project Review Meeting under false pretenses, the Department denied Trident its due process right to a Public Hearing, and it summarily dismissed Trident's arguments in opposition to the Proposed Project as insufficient to deny the application. See Exhibit A, p. 2.

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claims, "[a]s a result, this project will not result in an increase in diagnostic cardiac catheterization capacity in the service area." *Id.* Roper-Berkeley's CON application cannot be approved because the State Health Plan provides that a new diagnostic service cannot be approved unless "all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year." State Health Plan, p. VIII-5, ¶ 3 (emphasis added). Bon Secours has not achieved the 500 procedure threshold in the last several years, and in fact, has been averaging less than 10 caths per year for the last four years. According to the State Health Plan, in 2013, the most recent year utilized for State health planning purposes, Bon Secours performed a total of three diagnostic caths in 2013. See State Health Plan, p. XIII-34. In 2015, Bon Secours performed a total of four diagnostic caths. See Exhibit B, p. 6.

Neither the Department nor Roper-Berkeley treat the instant CON application as a transfer of services from Bon Secours, presumably because Roper-Berkeley is aware that it cannot meet the State Health Plan criteria for transferring a health service. See generally State Health Plan, p. II-2. For example, Roper-Berkeley could not demonstrate need for additional capacity based on historical and projected utilization patterns, as required. *Id.* at ¶ 3. Yet, Roper-Berkeley's Proposed Project could not be treated as the establishment of a new service either merely because it proposes that Bon Secours will close its program upon approval of Roper-Berkeley's Proposed Project. The Department's decision to grant Roper-Berkeley's CON application as a "new service" allows Roper-Berkeley to skirt compliance with the State Health Plan by creating its own procedural process, because Roper-Berkeley cannot meet the requirements for either the transfer of a health service or the establishment of a new service. It is fundamentally unjust to create a separate set of standards merely because a provider cannot meet the applicable standards of the State Health Plan. Roper-Berkeley's CON application must be denied because Bon Secours' diagnostic cardiac catheterization program has not met the requisite threshold of 500 annual diagnostic catheterizations procedures to permit approval of a new diagnostic catheterization service provider.³

Setting aside the fact that Roper-Berkeley's CON application cannot be approved because of the low utilization of Bon Secours' program, Roper-Berkeley's CON application fails to meet many of the remaining applicable standards and criteria of the State Health Plan and the project review criteria set forth in the CON Regulations and cannot be approved.

Unrealistic Service Area

The State Health Plan provides that "[t]he service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes one way automobile travel time. . . ." *Id.* at p. VIII-4. Roper-Berkeley's service area is much broader than the 45 minute one way automobile travel time standard. Roper-Berkeley's service area is defined to encompass four counties: Berkeley, Dorchester, Charleston, and Colleton. Many portions of Charleston and Colleton Counties lie well outside of the 45 minute drive time service area established in the

³ In fact, Trident learned that DHEC issued an approval letter to East Cooper Regional Medical Center on the same day it approved Roper-Berkeley's diagnostic catheterization lab. For this to occur, Bon Secours hospital had to discontinue its cardiac catheterization program before East Cooper could have been approved because all diagnostic catheterization labs in the service area have to be operating at above 500 diagnostic catheterization procedures per year. However, upon information and belief, DHEC approved Roper-Berkeley's CON application and East Cooper's CON application while Bon Secours' diagnostic catheterization lab was operating with a CON, which is a violation of the State Health Plan standards.

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State Health Plan. More importantly, however, Roper-Berkeley's service area is simply unrealistic.

Roper-Berkeley's sister facility, Roper Hospital, is located in downtown Charleston. Roper Hospital aligned physicians historically refer all patients to the comprehensive cardiac catheterization program at Roper Hospital, not the diagnostic-only catheterization program at Bon Secours. Consequently, as noted above, Bon Secours' diagnostic program is essentially non-existent. Bon Secours performed only four diagnostic catheterizations in 2015. Physicians who believe there is a likelihood that a patient will require percutaneous coronary intervention ("PCI") will naturally refer that patient to a comprehensive cardiac catheterization program where both procedures can be performed during the same visit. It is in the patient's best interest to be referred to a facility that can provide comprehensive services in one setting rather than refer the patient to a diagnostic-only program where the patient may need PCI and require transfer to another facility, or require that the patient be scheduled for a procedure on another day, unnecessarily subjecting the patient to two separate, invasive procedures. Bon Secours' virtually non-existent cardiac catheterization utilization in the past several years reflects that Roper Hospital aligned physicians recognize that referral to a comprehensive cardiac catheterization program is far preferable and in the best interest of the patients. There is simply no reason to believe that the physicians' referral patterns would change upon the opening of a diagnostic-only cardiac catheterization program at a small, 50 bed community hospital, such as Roper-Berkeley.

Furthermore, Roper-Berkeley's service area is unrealistic, because it illogically assumes that patients would travel greater distances past other providers with existing cardiac catheterization programs to have the procedure performed at Roper-Berkeley. It is highly unlikely that any material number of patients who do not reside in close proximity to Roper-Berkeley would bypass other providers, many of which operate comprehensive cardiac catheterization programs, to seek services at Roper-Berkeley.

Roper-Berkeley also asserts that Roper Hospital will transfer some its existing diagnostic caseload to Roper-Berkeley. However, again, there is no evidence that patients or physicians will choose Roper-Berkeley, rather than continue to utilize the comprehensive cardiac catheterization services provided at Roper Hospital, just as they have always done. Roper-Berkeley attempts to bolster its projected utilization under the premise that it will absorb some of the volume from Roper Hospital; however, the fact that the utilization of Bon Secours' diagnostic cardiac catheterization program is virtually non-existent, and has been so for the past several years demonstrates that this premise is meritless and unsupportable.

Roper-Berkeley has abandoned the 45 minute drive time standard for a much broader service area to generate better utilization projections for its Proposed Project, but the facts demonstrate that the service area is unrealistic, and the utilization projections are unsupportable. Roper-Berkeley's CON application fails to meet the service area standard as set forth in the State Health Plan, which means the CON application cannot be approved. See State Health Plan, p. VIII-4, ¶ 2.

Diagnostic Cath Utilization Standards for New Services

Assuming that Roper-Berkeley's Proposed Project can be considered the establishment of a new service, notwithstanding the extremely low utilization of Bon Secours' program, the State Health Plan provides that new diagnostic catheterization services can only be approved "if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization

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procedures per laboratory during the most recent year." *Id.* at p. VIII-5, ¶ 3 (emphasis added). Roper-Berkeley's CON application fails to meet this standard. Roper-Berkeley and the Department apparently misinterpreted this provision of the State Health Plan as requiring existing facilities to have provided 500 diagnostic equivalents per lab in the most recent year; however, the State Health Plan clearly states that the standard is procedures. In its decision letter, the Department states that after excluding Bon Secours, which it should not have done, "the Department concludes that other diagnostic catheterization labs within the service area operate at such an *equivalent* capacity as to not preclude the addition of the diagnostic catheterization lab contemplated by the Applicant." Exhibit A, p. 2 (emphasis added). Again, pursuant to the clear language of the State Health Plan, diagnostic equivalents are not the standard, diagnostic procedures are. Only one facility, Trident, met the threshold of 500 diagnostic procedures for each of its two catheterization labs. See Exhibit D, p. 6. Roper Hospital, MUSC, and, of course, Bon Secours all fell well below the threshold. Consequently, Roper-Berkeley's CON application fails to meet this criteria and is not in compliance with the State Health Plan as required for CON approval.

Projected Utilization

The State Health Plan states that

An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.

State Health Plan, p. VIII-5, ¶ 4. Without regard for the fact that Roper-Berkeley's utilization projections are based on an unrealistic, over-sized service area, as addressed above, the utilization projections are unsupportable as a result of several additional, serious flaws. Again, Roper-Berkeley has assumed that it will absorb diagnostic catheterizations from Roper Hospital; however, there is no credible basis to support such an assumption. Why would patients travel, in many cases, greater distances to a smaller hospital that offers a more limited range of services? Why would Roper aligned physicians refer patients to a smaller hospital with a more limited range of services and risk that the patient would require transfer to another hospital if the patient requires PCI, or require the patient to make another appointment for a second, separate, invasive procedure? As noted above, there is no reason to believe that Roper aligned physicians would refer patients to Roper-Berkeley, because they currently do not refer patients to Bon Secours, a larger, more established hospital with a greater range of services. Yet, Roper-Berkeley assumes that eighty (80%) percent of Roper Hospital's Berkeley County cases, sixty-five (65%) percent of its Dorchester County cases, and fifty (50%) percent of its Charleston County cases will be redirected to Roper-Berkeley. Such dramatic shifts in market share between the two facilities is simply not supported by the facts.

The more likely scenario is that Roper will redirect patients currently being served by Trident, because Trident is a major provider of diagnostic and therapeutic catheterization services to residents in Berkeley and Dorchester Counties. It appears that no consideration was given to this likely shift in market share as a result of the Proposed Project. The Department does not address the potential adverse impact on Trident. Instead, the Department states, "[a]s one lab in the service area is being closed as a result of this approval, and as another lab which is to be approved is in the extreme southern portion of the service area relative to this Applicant's proposed location, no unnecessary duplication of services is

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expected." See Exhibit A, p. 3. Bon Secours utilization is *de minimis*, at best; therefore, the closure of Bon Secours will have no material impact on utilization at Roper-Berkeley. The absorption of the less than five diagnostic catheterization cases annually performed at Bon Secours will not keep Roper-Berkeley in operation. Roper-Berkeley will have to redirect significant market share from Trident to achieve its volume projections. Nevertheless, both Roper-Berkeley and the Department dismiss this issue despite the fact that Trident is located only seven miles from the Roper-Berkeley campus.

Roper-Berkeley's utilization projections are also based on the assumption that Roper Hospital's historical diagnostic cardiac catheterization volume will grow in conjunction with the projected rate of population growth. However, this assumption is inconsistent with Roper Hospital's recent historical experience, as well as the experience of *all other area service providers*. Every provider in the service area has seen a decline in diagnostic catheterization procedures since 2011, and utilization of diagnostic cardiac catheterization services throughout the service area has declined by twenty (20%) percent between 2011 through 2015. See Exhibit D, p. 8. There is no reason to believe that this trend will not continue.

Essentially all of Roper-Berkeley's patients will likely originate from its primary service area. As such, Roper-Berkeley cannot meet the required 500 diagnostic catheterization equivalents annually, even assuming the redirection of Trident's patients from Roper Hospital. In all likelihood, Roper-Berkeley will operate a low volume program, while redirecting market share from Trident, adversely impacting Trident's utilization. Despite these facts, the Department did not call into question Roper-Berkeley's utilization projections. See Exhibit A, p. 2.

Compliance with the CON Regulations

Community Need

The Department acknowledges that the service area for diagnostic catheterization services is defined by the State Health Plan as an area within a 45 minute one way drive time from the proposed location of the services. See *id.* at p. 2. It further acknowledges that Roper-Berkeley's defined service area is much larger, encompassing four counties. *Id.* However, the Department ignores the fact that Roper-Berkeley's service far exceeds the 45 minute drive time standard because Roper-Berkeley could not project utilization sufficient to meet the State Health Plan requirements without artificially expanding its service area. An applicant should not be allowed to create a fictional service area to bolster its utilization projections and a community need for which there is no basis in fact.

The Department states that all labs within the planning area operate between seventy-nine (79%) percent and nearly ninety-four (94%) percent capacity, and then concludes that the Applicant has sufficiently demonstrated community need. *Id.* The CON project review criteria for community need requires that the Proposed Project:

meet an identified (documented) need of the target population. The assumptions and methods used to determine the level of need should be specified in the application and *based on a reasonable approach* as judged by the review body.

S.C. Code Ann. Regs. 61-15, § 802.2.c. (emphasis added). The project review criteria further provides that "[c]urrent and/or projected utilization should be sufficient to justify the expansion or implementation of a proposed service." *Id.* at § 802.2.e. There is nothing reasonable about

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Roper-Berkeley's assumptions identifying community need or projected utilization. The actual utilization that Roper-Berkeley's Proposed Project will realize is much lower than projected and insufficient to justify the implementation of the Proposed Project.

The service area is already well served by other area providers, including Trident, and other area providers have the capacity to meet the residents' needs, particularly in light of the fact that all area providers have experienced declining utilization of these services over the past several years.

Distribution (Accessibility)

As noted above, the Department concludes that because Roper-Berkeley proposes that Bon Secours will close upon approval of Proposed Project, there is no unnecessary duplication of services. See Exhibit A, p. 3. This conclusion is illogical. Bon Secours' cardiac catheterization program existed essentially only in name. The absorption of less than five diagnostic procedures annually will not support the operation of Roper-Berkeley's Proposed Project. It is unlikely that significant numbers of patients will be redirected from Roper Hospital, and the presumption that utilization volumes will grow with the population contravenes the declining utilization trends in the service area. The likely scenario, based on the facts, is that Roper-Berkeley will rely on the redirection of market share from Trident, adversely impacting Trident's utilization volumes. There is no need for Roper-Berkeley's Proposed Project, and consequently, the Proposed Project is an unnecessary duplication of services. It does nothing to increase accessibility to services, and it does not meet the project review criteria set forth in Section 802.3 of the CON Regulations.

Financial Feasibility

The project review criteria require that the applicant project "both the immediate and long-term financial feasibility of the proposal. Such projection should be reasonable and based upon accepted accounting procedures." S.C. Code Ann. Regs. 61-15, § 802.15. Roper-Berkeley's CON application fails to meet this requirement because the financial projections are based upon unreasonable underlying assumptions that cannot be realized. More reasonable assumptions would have resulted in dramatically lower utilization projections and, therefore, dramatically lower financial projections. The Proposed Project is unlikely to demonstrate an excess of revenues over expenses, and Roper-Berkeley has failed to demonstrate financial feasibility as required for CON approval.

Cost Containment

Contrary to the Department's conclusion, the Proposed Project does not promote cost containment, regardless of any economies of scale realized by the integration of the Proposed Project into Roper-Berkeley's hospital pre-construction phase. See Exhibit A, p. 3. The Proposed Project has a total project cost of almost \$ 2.9 million for a service that is not needed and will likely be underutilized. It will adversely impact Trident and other area providers and will increase health care costs in the service area.

CONCLUSION

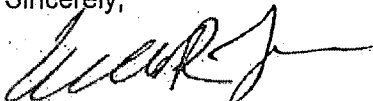
Trident respectfully requests that the Board reverse the Department's decision to approve Roper-Berkeley's CON application, because (i) the Proposed Project does not meet the applicable standards and criteria of the State Health Plan; (ii) there is no community need

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for the Proposed Project because the area is already well served by other area providers; (iii) the service area is unrealistic and the utilization projections will not be realized; (iv) the Proposed Project will adversely impact Trident and other area providers; (v) the Proposed Project is not financially feasible; and (vi) the Proposed Project will not promote cost containment. "The Department may not issue a Certificate of Need unless an application is in compliance with the South Carolina Health Plan, Project Review Criteria, and other regulations." S.C. Code Ann. §§ 44-7-210(B). Based upon the foregoing, Roper-Berkeley's CON application must be denied.

Trident welcomes the opportunity to present its arguments in support of its position in greater detail and to address any questions or concerns the Board may have at the final review conference held on this matter.

Sincerely,

A handwritten signature in dark ink, appearing to read 'W. R. Thomas', with a stylized flourish extending from the end.

William R. Thomas

WRT:jbc

Exhibit A

To Request for Final Review



July 25, 2016

VIA CERTIFIED MAIL

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 760
Charleston, SC 29403

Re: **Decision Granting Application for a Certificate of Need
Roper St. Francis Hospital – Berkeley**
Addition of Cardiac Catheterization services to Roper St. Francis Hospital - Berkeley
at a total project cost of \$2,873,366.
Case No.: 2340
Berkeley County, South Carolina

Dear Ms. Cantwell:

The South Carolina Department of Health and Environmental Control (Department) has reviewed the above-referenced Certificate of Need (CON) Application. After consideration of the entire administrative record in this matter, the Department concludes the Applicant has presented substantial evidence the Project materially complies with the relevant project review criteria and is consistent with the South Carolina Health Plan enacted August 13, 2015 (Plan). Specifically, the Project satisfies the requirements set forth in Section 802 of Regulation 61-15 pertaining to Community Need Documentation, Distribution (Accessibility), Financial Feasibility, and Cost Containment. Accordingly, it is the decision of the Department that a Certificate of Need be granted to Roper St. Francis Hospital – Berkeley.

The Department's decision is based on the following findings:

Compliance with the State Health Plan

In addition to the declarative Certificate of Need Standards #1 and #2 outlined in the Plan for cardiac catheterization services, the following Standards for the Project apply:

3. New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year.

A review of relevant Joint Annual Report (JAR) data for all diagnostic catheterization labs within the 45-minute drive time service area showed that all diagnostic catheterization labs met or exceeded the 500 procedure threshold outlined in the Plan with one notable exception. The

diagnostic cardiac catheterization lab located at Roper St. Francis Xavier Hospital in West Ashley performed no more than nine (9) procedures per year in any year from 2010 to 2014, according to available JAR data. The Department explained this inconsistency to the Applicant as an agent for both Roper St. Francis Hospital – Berkeley and Bon Secours St. Francis Xavier Hospital. As such an agent, the Applicant agreed to shutter its diagnostic catheterization lab upon approval of the instant application, regardless of the timing of the new lab installation or any potential opposition to the instant application, thus allowing the department to discount the utilization figures of the lab at the Bon Secours St. Francis Xavier location. As such, the Department concludes that other diagnostic catheterization labs within the service area operate at such an equivalent capacity as to not preclude the addition of the diagnostic catheterization lab contemplated by the Applicant.

4. An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.

The Applicant projects a minimum of 510 procedures by the close of the third reporting year, and no evidence is provided which shows utilization at other existing diagnostic catheterization labs will drop below the 500 minimum procedure threshold as a result of approving the Project.

Certificate of Need Standards #5 and #6 do not apply to the contemplated Project as it is not an expansion of current cardiac catheterization services and is not a mobile diagnostic catheterization laboratory.

The Department notes that Trident Medical Center has filed as an Affected Person and in opposition to the application. A letter of opposition detailing the opposition's argument was received on July 21, 2016. After consideration of all information presented therein, the Department has determined that Trident's opposition does not present a sufficient reason to deny the Application.

Accordingly, the Department concludes the Applicant has sufficiently complied with the Standards outlined in the Plan, Chapter VIII-4 and Chapter VIII-5.

Community Need Documentation

While the planning area for diagnostic catheterization services is defined as an area within a 45-minute, one-way drive from the Applicant's facility, the Applicant further considers its service area to include Berkeley County as well as parts of Dorchester, Charleston, and Colleton Counties. Within the planning area, there are a total of 11 existing catheterization labs which are open and able to perform the services contemplated by the Applicant's Project. With the notable exception discussed previously, all labs within the planning area operate between 79% and nearly 94% capacity.

Accordingly, the Department concludes Applicant has sufficiently projected Community Need to satisfy the requirements of Section 802.2, Reg. 61-15.

Distribution (Accessibility)

Patients will be admitted regardless of age, race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, or gender identity or expression. Applicant has budgeted an appropriate amount of gross revenue for the treatment of indigent patients. As one lab in the service area is being closed as a result of this approval, and as another lab which is to be approved is in the extreme southern portion of the service area relative to this Applicant's proposed location, no unnecessary duplication of services is expected to occur.

The Department concludes that Applicant has satisfied the requirements of Distribution (Accessibility) pursuant to Section 802.3, Reg. 61-15.

Financial Feasibility

Applicant provided three year budget projections demonstrating financial feasibility. Julie Graudin, CPA for Roper St. Francis Healthcare, attests that the Project will be funded by utilizing existing bond proceeds issued for the development of the larger hospital project.

The Department concludes that Applicant has satisfied the requirements of Financial Feasibility pursuant to Section 802.15, Reg. 61-15.

Cost Containment

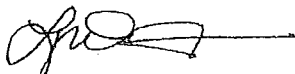
Integrating the contemplated laboratory into the pre-construction phase of the new Roper St. Francis Hospital – Berkeley realizes certain economies of practice which are otherwise lost during later renovation. Quality of cardiac care is increased through the provision of diagnostic services wherein early intervention prevents later invasive treatments at a much higher cost to the patient.

The Department concludes that Applicant has satisfied the requirements of Cost Containment pursuant to Section 802.16, Reg. 61-16.

The Department has determined the findings required by S.C. Code Reg. 61-15 §501 are not applicable to this Project.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Mr. Aaron Gantt (803.545.4400); Division of Health Facilities Construction, Mr. William McCallum (803.545.4215); Division of Health Licensing, Ms. Gwendolyn Thompson, (803.545.4370); and Bureau of Certification, Ms. MaryJo Roué (803.545.4293).

Sincerely,



Louis Eubank
Director
Certificate of Need Program

cc: William R. Thomas, Esq. (email/Certified Mail)

Enclosures: Guide to Board Review

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.

Exhibit B

To Request for Final Review



Catherine E. Heigel, Director

Promoting and protecting the health of the public and the environment

May 26, 2016

VIA CERTIFIED MAIL

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 760
Charleston, SC 29403

Article #: 92148969009997901404889441

Re: Roper St. Francis Hospital - Berkeley Inc. d/b/a Roper St. Francis Hospital -
Berkeley
Addition of Cardiac Catheterization services to Roper St. Francis Hospital -
Berkeley at a total project cost of \$2,873,366.
Matter No.: 2340

Dear Ms. Cantwell:

This is to notify you the South Carolina Department of Health and Environmental Control ("Department") has determined the aforementioned project to be complete for purposes of review by the Certificate of Need Program. Enclosed is an invoice for the required application fee. It may be paid by check made payable to the S.C. Department of Health and Environmental Control or by electronic check through the Department's website (www.scdhec.gov) using the "Pay Invoices" hyperlink at the bottom of each webpage. This is a secure website. If payment is not received within fifteen (15) days of your receipt of this invoice, the pending application will be considered withdrawn and this matter closed. Should this deadline fall on a weekend or State holiday, it will be extended to the next calendar day that is neither weekend nor holiday pursuant to Regulation 61-15, Section 303.

Should the Department receive your application fee within the fifteen (15) day deadline, the Department will render a decision no earlier than thirty (30) days, but no later than one-hundred (120) days from the date notice is provided to affected persons in the State Register, unless a public hearing is held pursuant to Regulation 61-15, Section 305.

The Department has determined the relative importance of the project review criteria, pursuant to Regulation 61-15, Section 304, which will be used to review your application. The specific criteria to be used are set forth below and are ranked according to their relative importance, with the most important being listed first. All other relevant criteria will be given equal importance.

Letter to Shannon Cantwell
May 26, 2016
Page 2

- a. Compliance with the State Health Plan – 1;
- b. Community Need Documentation – 2;
- c. Distribution (Accessibility) – 3;
- d. Financial Feasibility – 15; and
- e. Cost Containment – 16.

The aforementioned criteria are set forth in Regulation 61-15, Section 802. Should you wish to submit any additional information to the Department in support of your application, you have thirty (30) days from the receipt of this correspondence to do so.

If you have any questions, please contact me at 803.545.3652.

Sincerely,



Louis Eubank
Director
Certificate of Need Program

Enclosures: Application Fee Invoice

Exhibit C

To Request for Final Review



William R. Thomas

Partner

Telephone: 803.253.8658

Direct Fax: 803.255.8017

willthomas@parkerpoe.com

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

June 24, 2016

SCDHEC
Received

VIA HAND DELIVERY AND EMAIL

Louis W. Eubank, MSW, MPH
Director, Certificate of Need Program
Bureau of Health Facilities and Services Development
SC Department of Health and Environmental Control
301 Gervais Street
Columbia, South Carolina 29201

JUN 24 2016
Certificate of Need Program

Re: Roper St. Francis Hospital – Berkeley Inc. d/b/a Roper St. Francis Hospital - Berkeley
Certificate of Need Application for the addition of cardiac catheterization services to Roper St. Francis Hospital – Berkeley at a total project cost of \$2,873,366
DHEC Matter No. 2340

TRIDENT MEDICAL CENTER'S AFFECTED PERSON STATUS AND OPPOSITION

Dear Mr. Eubank:

Pursuant to S.C. Code Ann. §§44-7-130(1) and 44-7-210(C) and Regulation 61-15 §§103(1) and 305, I am writing on behalf of Trident Medical Center, LLC, d/b/a Trident Medical Center ("Trident"), an existing provider of similar services located in Charleston, South Carolina, which is in the same health service area and geographic area to be served by the applicant, to notify the Department that Trident is an "affected person" with respect to Roper St. Francis Hospital – Berkeley's CON application referenced above, and that it opposes the approval of Roper St. Francis Hospital – Berkeley's CON application. Trident is also requesting that a project review meeting be held by the Department prior to the Department making a decision on this CON application. More specifically, Trident opposes the above referenced CON application because, among other reasons, the project does not comport with the purposes of the CON Act; the project does not comply with the standards set forth in the 2015 *South Carolina Health Plan*; the project is not needed; the project will have an adverse impact on Trident's cardiac catheterization program and its open heart program; the project does not increase accessibility to catheterization services; and the project will not contain costs.

Please copy Trident on any future correspondence to or from the Department concerning this CON application. Thank you for your consideration of Trident's position, and please let me know if you have any questions or concerns.

Sincerely,

William R. Thomas

WRT/ccq

PPAB 3281931v1

Exhibit D

To Request for Final Review

Sullivan Consulting Group, Inc.

2090 Bethany Way · Alpharetta, Georgia 30004 · (770) 753-4222 · Fax: (770) 753-4223

July 21, 2016

VIA E-MAIL

Louis Eubank, MSW, MPH
Director
Certificate of Need Program
Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

RE: CON Application 2340

Dear Mr. Eubank:

On behalf of Trident Medical Center ("Trident"), I am submitting this letter in opposition to the Certificate of Need ("CON") application filed by Roper St. Francis Hospital-Berkeley ("Roper-Berkeley") to develop a new diagnostic cardiac catheterization program at its approved but not yet constructed hospital to be located in Goose Creek, Berkeley County. The proposed program is scheduled to open in June 2019. The application also proposes to close the existing diagnostic cardiac catheterization program at Bon Secours St. Francis Hospital ("BSSFH"), which is of little consequence given that this program purposefully has only performed only a handful of diagnostic catheterization procedures over the past several years.

1. Summary of Trident's Objections to the Project

- The project does not represent a transfer of an existing diagnostic cardiac catheterization service but instead the initiation of a new service.
- Roper-Berkeley fails to satisfy the criteria in the 2015-2016 South Carolina Health Plan (Criterion 1).
- Roper-Berkeley fails to demonstrate a community need for the project (Criterion 3).
 - In particular, the application fails to define a reasonable service area for its diagnostic cardiac cath program at a new 50-bed hospital.
 - Moreover, the projections of utilization for the project are unreasonable for a number of reasons. Roper-Berkeley failed to consider the declining trend in diagnostic cardiac cath procedures in the service area. Its projections also assume unrealistic market shares from distant areas that would require patients to bypass existing comprehensive cardiac cath providers.

Mr. Louis Eubank

July 21, 2016

Page 2

- The historical utilization of the BSSFH diagnostic cath program demonstrates that patients and physicians prefer to utilize the comprehensive cardiac cath program at Roper Hospital rather than a diagnostic only program such as the one proposed for Roper-Berkeley.
- The project fails to demonstrate financial feasibility in light of these unrealistic utilization projections (Criterion 15).
- The project will not contribute to cost containment because it is unneeded, will likely be underutilized, and depends on patients traveling long distances to reach a start-up program at a small community hospital (Criterion 16).

The Project is not a Transfer of an Existing Service.

While the BSSFH diagnostic cath program will close upon approval of this CON application, there is no attempt in the Roper-Berkeley application to characterize this project as a "transfer" of the diagnostic cardiac cath service from BSSFH nor would the project, as explained more fully below, qualify as a transfer.

Compliance with the South Carolina Health Plan

Given the Roper-Berkeley application is proposing a new diagnostic cardiac cath service, the relevant standards for review are those for Cardiac Catheterization Services and specifically the criteria relating to Diagnostic Cardiac Catheterization. Roper-Berkeley does not address the Exception to Service Area Standards, which are considered when an applicant seeks to transfer beds or services between two related facilities. Given that these Exceptions are not addressed by the applicant, there is no basis to approve the project under these criteria. In an abundance of caution, however, this letter will address the reasons why the Roper Berkeley project fails to satisfy these Exceptions as well.

Cardiac Catheterization Standards

The Roper-Berkeley application unsuccessfully attempts to demonstrate conformity with the State Health Plan standards for new diagnostic cardiac cath services. Certain of these criteria are discussed below.

Mr. Louis Eubank

July 21, 2016
Page 3

2. *The service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes' one way automobile travel time; for comprehensive cardiac catheterization laboratories the service area is all facilities within 60 minutes' one way automobile travel time; a pediatric cardiac program should serve a population encompassing at least 30,000 births per year, or roughly two million people.*

Roper-Berkeley does not utilize a 45-minute one-way automobile travel time to define its service area. Instead, as shown in Exhibit 1, it defines its service area to include a wide ranging region across four counties.

Exhibit 1
Roper St. Francis Hospital-Berkeley
Proposed Diagnostic Cardiac Catheterization Service
Area

Primary Service Area

Berkeley County - All ZIP Codes

Dorchester County- 29420, 29472, 29483, 29485, 29456

Charleston County - 29406, 29410, 29418, 29420, 29456

Secondary Service Area

Remainder of Charleston County

Remainder of Dorchester County

Colleton County

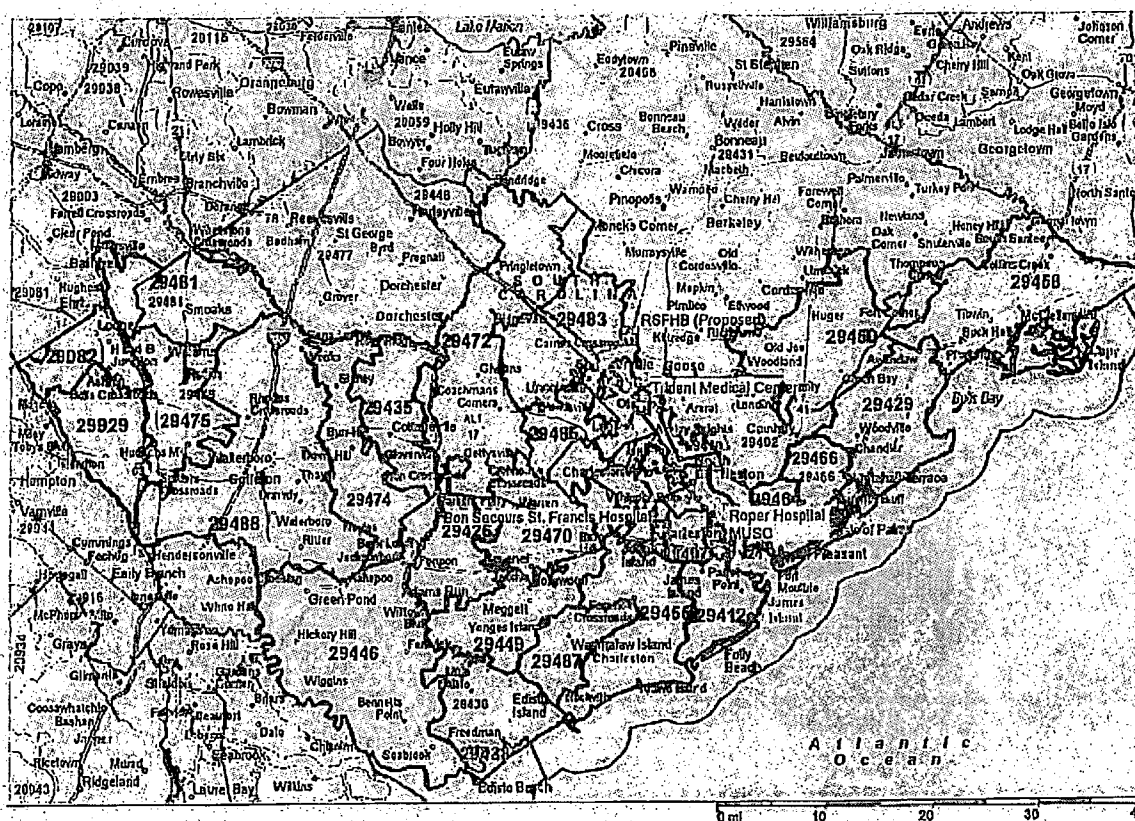
Source: Roper-Berkeley Application, Exhibit 2

A map of this service area is presented in Exhibit 2 and demonstrates the breadth of the service area.

Mr. Louis Eubank

July 21, 2016

Page 4

Exhibit 2**Roper St. Francis Hospital-Berkeley Proposed Diagnostic Cardiac Cath Service Area**

Many portions of Charleston and Colleton Counties are outside of a 45-minute one-way automobile travel time from the Roper-Berkeley site. More importantly, it is unlikely that a start-up diagnostic cardiac cath program at a 50-bed hospital would attract patients from such a large area for a number of reasons. The most important reason is that historically referring physicians in the Roper St. Francis system area have referred virtually all of their patients to the comprehensive cardiac cath program at Roper Hospital rather than the diagnostic-only program at BSSFH. In 2015 BSSFH performed only 2 diagnostic caths, which is consistent with its experience over the past several years.

BSSFH, with 204 inpatient beds, is a substantially larger and more established hospital than Roper-Berkeley, and there is no reason to expect that physicians affiliated with Roper St. Francis will change these historical referral patterns to utilize a 50-bed hospital with substantially fewer resources than BSSFH. There are valid clinical reasons for choosing a comprehensive cardiac cath program over a diagnostic-only program. Patients who are high risk are more appropriately served in a program with open heart surgery back-up. If a physician believes that there is a strong likelihood that a patient will require percutaneous coronary intervention ("PCI"), it is

Mr. Louis Eubank

July 21, 2016

Page 5

more appropriate to refer the patient to a comprehensive center where both the diagnostic cath and the PCI could be performed in a single cath lab session.

Another factor undermining the credibility of the Roper-Berkeley service area definition is the fact that many patients would have to drive past one or more existing cardiac cath programs to reach Roper-Berkeley. For example, Trident is located only 7 miles from Roper-Berkeley and is more proximate to areas south and west of Roper-Berkeley. These existing providers, with the exception of BSSFH, offer comprehensive ranges of cardiac interventions, which makes it highly unlikely that any material number of patients not residing in close proximity to Roper-Berkeley will seek cardiac cath services at the 50-bed facility.

An additional argument presented in the application is that Roper Hospital is well utilized and it could "off-load" some of its existing diagnostic cath volume to Roper-Berkeley to reduce current utilization levels. There is simply no evidence that patients and physicians will choose to go to Roper-Berkeley rather than utilize the comprehensive services at Roper Hospital, particularly if the patients do not live in areas near Roper-Berkeley. In fact, if this were the case, BSSFH would be a thriving program; however, it appears to be the most underutilized program in state.

The expansive Roper-Berkeley service area appears to have been cobbled together in an effort to bolster the utilization projections for the proposed program, as discussed in more detail below. The service area is not reasonable, and the projections that result from the use of this service area are unreliable.

Diagnostic and Mobile Catheterization Services

3. *New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year;*

All existing labs in the service area have not performed a minimum of 500 diagnostic catheterization procedures per laboratory in 2015. Roper-Berkeley misinterpreted this criterion in its application response by addressing the number of diagnostic cardiac catheterization equivalents per laboratory, which is inconsistent with the plain language of this criterion. Exhibit 3 displays 2015 cardiac cath utilization data for all providers in the service area. Only one provider, Trident, exceeded the standard of 500 diagnostic catheterizations per laboratory. Roper hospital averaged only 398 diagnostic catheterizations per laboratory.

Mr. Louis Eubank

July 21, 2016

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Exhibit 3**Roper St. Francis Hospital-Berkeley Service Area
2015 Diagnostic Catheterizations per Laboratory**

Facility	Cath Labs	Diagnostic Caths	Diagnostic Caths Per Lab
MUSC*	6	1,804	301
Roper Hospital	3	1,193	398
Bon Secours St. Francis	1	4	4
Trident Medical Center	2	1,081	541
Total	12	4,082	340

*Includes adult and pediatric procedures

Source; Joint Annual Reports of Hospitals

Based on the most recent utilization data, the Roper-Berkeley project fails to satisfy this criterion.

4. *An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.*

Exhibit 4 on the following page recreates the utilization projections presented in the application. The problems with Roper-Berkeley's utilization projections begin with the unreasonable service area discussed above. Even putting aside the reasonableness of the service area, there are several other serious flaws with the projections presented.

The first assumption is that Roper-Berkeley will only serve patients who otherwise would have utilized diagnostic cath services at Roper Hospital. There is no basis to support this assumption. There is no reason to expect that patients would in many cases travel farther to receive a diagnostic cath at a small hospital with a limited range of services. Given the proximity of Roper-Berkeley to Trident and the fact that Trident is a major provider of diagnostic and therapeutic cath services to residents of Roper-Berkeley's primary service area, the more likely scenario is that Roper will redirect patients within its primary service area from Trident. No consideration was given by Roper-Berkeley to the shift in market shares that is probable when developing a program in a new location.

Exhibit 4

Roper St. Francis Hospital-Berkeley Projected Diagnostic Cardiac Cath Utilization

			Diagnostic Caths			% Shifted to Roper Berkeley			for Roper Berkeley		
	2015 Diagnostic Caths at RSF Labs	CAGR for Population	2019	2020	2021	2019	2020	2021	2019	2020	2021
Primary Service Area											
Berkeley County - All ZIPs	292	1.30%	307	311	316	45%	60%	80%	138	187	252
Dorchester County											
29420	27	1.83%	29	30	30	45%	55%	65%	13	16	20
29472	5	5.50%	6	7	7	45%	55%	65%	3	4	4
29483	62	1.81%	67	68	69	45%	55%	65%	30	37	45
29485	42	1.60%	45	45	46	45%	55%	65%	20	25	30
29456*	-	2.00%	-	-	-	45%	55%	65%	-	-	-
Charleston County											
29406	46	1.67%	49	50	51	30%	40%	50%	15	20	25
29410	-	1.11%	-	-	-	30%	40%	50%	-	-	-
29418	60	1.74%	64	65	67	30%	40%	50%	19	26	33
29420	-	1.83%	-	-	-	30%	40%	50%	-	-	-
29456*	-	2.00%	-	-	-	30%	40%	50%	-	-	-
Total PSA	534		568	576	585				238	315	410
Secondary Service Area											
Remainder of Charleston County	782	0.56%	800	804	809	2.5%	5.0%	7.5%	20	40	61
Remainder of Dorchester County	13	1.95%	14	14	15	5.0%	8.0%	10.0%	1	1	1
Colleton County	118	0.10%	118	119	119	5.0%	8.0%	10.0%	6	9	12
Total Secondary Service Area	913		932	937	942				27	51	74
In-Migration	121	7.89%				6.0%	6.0%	6.0%	17	23	31
Total Cath Patients	1,568		1,500	1,513	1,527				282	389	515
Actual In-migration											
		7.72%									
Source: Roper-Berkeley Application, Exhibit 13											

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Another fundamental assumption in the projections is that Roper Hospital's historical diagnostic cardiac catheterization volume will grow in the future at the rate of population growth. That assumption is inconsistent with Roper Hospital's recent historical experience as well as the experience of *all service area providers*. Exhibit 5 presents the trend in diagnostic cardiac cath volume at all service area providers.

- Roper Hospital has seen its diagnostic cath procedures decline from 1,776 in 2011 to 1,193 in 2015¹, a drop of 32.8 percent despite population growth in the Charleston area.
- The total diagnostic cath procedures performed by service area providers decreased from 5,103 in 2011 to 4,082 in 2015, a 20.0 percent reduction.

There is no reason to expect that there will be any growth in diagnostic caths over the next five years as Roper-Berkeley has projected. If Roper Hospital's 2015 diagnostic cath volumes were held constant, the projected utilization for Roper-Berkeley would have been 475 diagnostic caths in 2021, although this even figure is significantly overstated as discussed below.

Exhibit 5
Roper St. Francis Hospital-Berkeley Service Area
Trend in Diagnostic Catheterizations: 2011 to 2015

	2011	2012	2013	2014	2015	% Change 2011-15
Roper Hospital	1,776	1,785	1,651	1,578	1,193	-32.8%
Bon Secours St. Francis	7	9	3	4	4	-42.9%
MUSC*	1,994	1,996	1,954	1,982	1,804	-9.5%
Trident Medical Center	1,326	1,332	995	1,007	1,081	-18.5%
Total	5,103	5,122	4,603	4,571	4,082	-20.0%

*Includes adult and pediatric patients.

Source: Joint Annual Reports of Hospitals

¹ In the Roper-Berkeley application reports 1,568 diagnostic catheterizations performed by Roper Hospital, which is significantly higher than 1,193 reported on its 2015 JAR.

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The percentage of Roper Hospital's patients to be shifted to Roper-Berkeley is similarly unreasonable. As shown in Exhibit 4, 80 percent of Berkeley County cases, 65 percent of Dorchester County primary service area patients, and 50 percent of Charleston County primary service area patients are expected to be redirected from Roper Hospital to Roper-Berkeley. Such dramatic shifts in volume from a comprehensive program to a diagnostic-only program are not reasonable, particularly in light of Roper's experience of operating a diagnostic-only program at BSSFH. In the secondary service area, it is unlikely that there will be any material redirection of diagnostic caths from Roper Hospital to Roper-Berkeley given the distances these patients would have to travel and the more limited nature of the Roper-Berkeley services.

Given that virtually all of the patients will be drawn from Roper-Berkeley primary service area, Roper-Berkeley will not reach 500 diagnostic cath procedures annually, as its own projections indicate. Even with the unrealistically high assumed redirection of patients from Roper hospital to Roper-Berkeley, the primary service area is expected to provide only 405 diagnostic cath procedures in 2021. Under more realistic assumptions, the projected utilization would be far less. The likelihood is that Roper-Berkeley will operate a low volume diagnostic cath program, just as BSSFH has done for many years.

Exceptions to Service Area Standards

As discussed previously, Roper-Berkeley did not address the Exceptions to Service Area Standards, apparently recognizing that the closure of a program at BSSFH that has been effectively unutilized for many years and opening a new program nearly three years later in a new hospital did not constitute a transfer of the program. Even if the project were reviewed under these Exceptions, the project fails to satisfy the requirements for a transfer of a service.

1. *A transfer or exchange of service may be approved only if there is no overall increase in the number or amount of such services.*

Roper-Berkeley does not satisfy this criterion because there is an overall increase in the number of diagnostic cath services in the service area. There currently is no legitimate cath lab program at BSSFH, nor has there been since 2007, when Roper St. Francis made the decision to discontinue services at the lab. See Exhibit 6.

Exhibit 6 Bon Secours St. Francis Hospital Trend in Diagnostic Catheterizations

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	Total	Ave/Yr
Diagnostic Caths	0	0	0	2	7	9	3	4	2	27	3

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As the chart details, BSSFH has average only 3 diagnostic caths a year since 2007, and zero caths each year from 2007 to 2009. Roper-Berkeley is applying to open a new diagnostic cath service at its Goose Creek campus three years from now, while Roper St. Francis is maintaining a fictional program at BSSFH to foreclose any new applicants for diagnostic catheterization services in the tri-county region. New applicants cannot apply unless "all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year." 2015 State Health Plan, p. VIII-5. The Department should not recognize BSSFH's diagnostic catheterization program as an existing service merely because only (3) three diagnostic caths are performed on average each year, which is not indicative of an actual program.

3. *The facility receiving the service must demonstrate the need for the additional capacity based on both historical and projected utilization patterns.*

Roper-Berkeley fails to satisfy this criterion. There is simply no need for additional capacity in either the Roper St. Francis system or in the service area generally. As discussed above, the BSSFH diagnostic cath program has performed a *de minimus* number of procedures each year. If Roper needed additional capacity, it could have redirected patients to BSSFH. Given that Roper's diagnostic cardiac cath volume has declined by nearly 33 percent and the service area by 20 percent, there is no basis to conclude that a new cardiac cath laboratory is needed based on historical utilization patterns. A reasonable projection of future utilization would indicate that service area diagnostic cath procedures will not increase materially.

4. *The applicants must explain the impact of transferring the technology on the health care delivery system of the county and/or service area from which it is to be taken; any negative impact must be detailed, along with the perceived benefits of the proposal.*

Roper-Berkeley never addressed the impact of its proposed opening of a new diagnostic cath program in Berkeley County other to make the unreasonable and undocumented assumption that all of the patients served by Roper-Berkeley would otherwise have gone to Roper Hospital. As discussed above, the more likely scenario is that Roper-Berkeley would seek to capture the patients Trident is currently serving given Roper-Berkeley's proximity to Trident and its position in the middle of Trident's primary service area. This adverse impact on Trident should not be permitted for a project that is unneeded and will likely be underutilized.

For all of the foregoing reasons, the Roper-Berkeley project is not consistent with the either Cardiac Catheterization Standards or the Exceptions to Service Area Standards in the State Health Plan.

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Community Need

The Roper-Berkeley proposal to develop a diagnostic cath program meets no community need. As discussed in the preceding section, Roper St. Francis has available cardiac cath lab capacity within its own system given the miniscule volumes served by BSSFH in recent years. In addition, Roper Hospital's volumes have been declining as have the volumes of other providers in the Roper-Berkeley service area.

There is no demonstration that patients in Berkeley County or any other portion of Roper-Berkeley's service area require enhanced access to diagnostic cardiac cath services. Roper-Berkeley is located only 7 miles from Trident, which offers comprehensive cardiac care. Trident has and will continue to serve patients in need of diagnostic cath services in the Roper-Berkeley primary service area.

Roper-Berkeley has not defined a reasonable service area for its project. If patients were to indeed travel from distant parts of Charleston and Colleton Counties to Roper-Berkeley, they would have to pass by other providers who offer more comprehensive care. A more reasonably defined service area would not support the approval of another diagnostic cath provider.

The proposed closure of BSSFH's existing diagnostic-only program, contingent on the approval of the Roper-Berkeley proposal, has no relevance from a health planning standpoint. The BSSFH program has been serving so few patients that Roper St. Francis should have closed it many years ago. BSSFH's inability to attract diagnostic cath patients from the comprehensive program at Roper Hospital is also a strong indicator that the Roper-Berkeley program will similarly experience poor utilization.

Financial Feasibility

The financial projections for the project are presented in Attachment 6 of the application. These projections are based on the projected volumes, which as discussed above, are wholly unreasonable. More reasonable projections would result in dramatically lower volumes for the Roper-Berkeley program, and it is unlikely to generate an excess of revenues over expenses. Financial feasibility is not demonstrated.

Cost Containment

This project will not promote cost containment. It requires a capital expenditure of \$2,873,366 for a program that is not needed and will be underutilized. To achieve its projected utilization, patients will be required to travel long distances to reach a start-up program in a small community hospital.

Mr. Louis Eubank

July 21, 2016

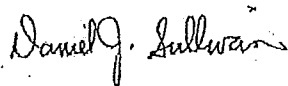
Page 12

Moreover, the proposed program will increase costs and time for the patients who otherwise would have received diagnostic cath services at Roper Hospital but will be redirected to Roper-Berkeley. Currently, when a patient presents to Roper Hospital for a diagnostic cath and it is determined that PCI is required, the PCI can be performed during the same cath lab session. Patients seen at Roper-Berkeley who are determined to need PCI will have to travel to Roper Hospital by ambulance or a present to Roper Hospital at a later scheduled appointment. A second cath procedure must be performed and a second catheter inserted into the patient, which increases the cost as well as the physical discomfort to the patient.

The diagnostic cath program at Roper-Berkeley will unnecessarily duplicate existing services. Trident is located squarely within Roper-Berkeley's primary service area, offers a more comprehensive range of cardiac services, and has ample available capacity to serve additional cardiac cath patients in the future.

We appreciate the opportunity to submit this comments and will be happy to provide any additional information you require.

Sincerely,



Daniel J. Sullivan

Exhibit G

To Petition for Administrative Review and
Request for Contested Case Hearing

SEP 16 2016

Clerk, Board of Health
and Environmental Control

STAFF RESPONSE TO REQUEST FOR FINAL REVIEW

Requestor: Trident Medical Center
In Re: **Docket No. 16-RFR-61** – Grant of Certificate of Need Application to Roper St. Francis Hospital – Berkeley for the addition of Cardiac Catheterization services at a total project cost of \$2,873,366.

INTRODUCTION

The Department received a Certificate of Need (“CON”) application from Roper St. Francis Hospital – Berkeley (“Roper-Berkeley”) for the addition of Cardiac Catheterization services at that facility at a total project cost of \$2,873,366 (“Project”). Roper-Berkeley submitted an application in May 2016 under the South Carolina Health Plan enacted August 13, 2015 (“Plan”). Trident Medical Center (“Trident”) opposed the Project. Trident requested a project review meeting in this matter. Staff declined to hold a project review meeting and, instead, invited Trident to submit written arguments in opposition to the Project. Trident did submit written arguments in support of its opposition, which staff considered prior to rendering its decision granting the CON for the Project.

By letter dated May 26, 2016, the Department notified Roper-Berkeley that the application was deemed complete (“Deemed Complete Letter”) and listed the relative importance of the project review criteria to be used in reviewing the application (“Relative Importance Criteria”): Compliance with the State Health Plan (Section 802(1)); Community Need Documentation (Section 802(2)); Distribution (Accessibility) (Section 802(3)); Financial Feasibility (Section 802(15)); and Cost Containment (Section 802(16)). After consideration of the entire administrative record, Department staff concluded that a CON should be issued for the proposed Project because Roper-Berkeley presented substantial evidence that the Project complies with the Relative Importance Criteria.

Based upon the above, staff issued its decision granting the CON on July 25, 2016 (“Decision”) (attached as Exhibit 1). The Decision made specific findings as to all Relative Importance Criteria. Trident filed its request for final review (“RFR”) on August 9, 2016. Department staff respectfully request that the Board decline to conduct a final review conference in this matter.

RELEVANT LAW¹

The purposes of the *State Certification of Need and Health Facility Licensure Act* (“the CON Act”), S.C. Code Ann. Sections 44-7-110 *et seq.*, are to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State. S.C. Code Ann. § 44-7-120.

¹ Excerpts of referenced Statutes and Regulations are attached at Exhibits 2 and 3. Excerpts of the Plan are attached at Exhibit 4.

The CON Act requires a person or health care facility to obtain a CON from the Department before undertaking certain projects. S.C. Code Ann. § 44-7-160; 3 S.C. Code Ann. Regs. 61-15 § 102(1). The Department may not issue a CON unless an application complies with the South Carolina Health Plan and project review criteria, which must be identified by the Department. S.C. Code Ann. § 44-7-210(B). Upon determination by the Department that an application is complete, the Department must notify the applicant of the relative importance of the project review criteria to be used in reviewing the application. 3 S.C. Code Ann. Regs. 61-15 § 304(1). A project need not comply with every project review criterion in order to be approved, but no project may be approved unless it is consistent with the South Carolina Health Plan. 3 S.C. Code Ann. Regs. 61-15 § 801(3).

Additionally, Chapter VIII of the Plan states a Certificate of Need is required to establish catheterization services in a hospital setting. In order to evaluate a proposal for the addition of such services reviewed under the Certificate of Need program, the following criteria must be applied to it:

(1) The capacity of a fixed cardiac catheterization laboratory shall be 1,200 diagnostic equivalents per year. Adult diagnostic catheterizations shall be weighted as 1.0 equivalents, while therapeutic catheterizations shall be weighted as 2.0 equivalents. For pediatric and adult congenital catheterization labs, diagnostic catheterizations shall be weighted as 2.0 equivalents, therapeutic catheterizations shall be weighted as 3.0 equivalents, electrophysiology (EP) studies shall be weighted as 2.0 equivalents, and biopsies performed after heart transplants shall be weighted as 1.0 equivalents. The capacity of mobile cardiac catheterization labs will be calculated based on the number of days of operation per week.

(2) The service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes' one way automobile travel time; for comprehensive cardiac VIII-5 catheterization laboratories the service area is all facilities within 60 minutes' one way automobile travel time; a pediatric cardiac program should serve a population encompassing at least 30,000 births per year, or roughly two million people.

(3) New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year.

(4) An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.

Id. at pp. VIII-4 and VIII-5.

BACKGROUND INFORMATION

Trident states in the "Background" section of its RFR that, by letter dated June 24, 2016, the Department was notified of Trident's status as an "affected person" regarding the Project and its

stated opposition to the Project. Trident further states that, on July 21, 2016, a letter from Sullivan Consulting Group was submitted to the Department detailing Trident's opposition. Further, Trident explains that the Department declined to hold a project review meeting "on the basis that Roper-Berkeley's project was subject to the State Health Plan Chapter II transfer provision, but according to the approval letter, that was not the case." *See* RFR, p. 2. Supportive of same, Trident states that it was deprived of its due process right to a Public Hearing when the Project Review Meeting request was denied. *See* RFR, p.2 n.2. While there is no right in statute or regulation to a project review meeting, Trident could have, but did not, request a Public Hearing on the application pursuant to 3 S.C. Code Ann. Regs. 61-15 § 306. Because Trident did not timely request a Public Hearing, and because there is no legal right to a project review meeting, Trident was not deprived of due process. Further, Trident has availed itself of the opportunity to request final review before the Board, and may, should it choose, also request a contested case hearing before the Administrative Law Court, both of which will allow Trident due process.

RESPONSE TO REQUEST FOR REVIEW

1. Trident claims that the Project fails to satisfy the criteria set forth in the Plan. *See* RFR, pp. 2 and 3. Specifically, Trident contends that the Project cannot be approved because the Plan "provides that a new diagnostic service cannot be approved unless 'all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year'". This contention is the crux of Trident's opposition as they claim the catheterization laboratory at Roper St. Francis Xavier ("Xavier") has performed fewer than 10 diagnostic procedures in the most recent year. *See* RFR p. 3. As to this issue, the Decision noted that upon approval of the Project, the Xavier lab would be shuttered. *See* Decision, p. 2. Moreover, by letter dated August 17, 2016, Roper St. Francis notified the Department that the Xavier laboratory had been permanently closed on August 1, 2016². Department staff concluded this closure would be sufficient to meet the spirit and letter of the Plan standards for establishment of an additional diagnostic cardiac catheterization laboratory in the 45-minute, one-way drive time service area.
2. Trident claims that Roper-Berkeley failed to demonstrate community need for the Project. Trident contends that the service area outlined by Roper-Berkeley in the instant CON application does not comport with the 45-minute, one-way drive time service area established in the Plan. In fact, the service area described in the instant CON application is inclusive of the 45-minute, one-way drive time service area outlined in the Plan as well as areas where no catheterization labs currently exist. Department staff found the Project-defined service area to be reasonable for the projected utilization established in the instant CON application. Neither the Plan nor applicable law require an applicant to limit its projected utilization to only those individuals residing in the Plan-defined service area. Trident's contention that the Department should have taken only the Plan-defined service area into consideration when rendering a decision on the Project is therefore misplaced.
3. Trident claims that Roper-Berkeley failed to demonstrate the financial feasibility of the Project. Department staff found no information contained in the instant CON application which would call the financial feasibility of the project into question. Roper-Berkeley provided the

² A copy of the Roper St. Francis closure letter, dated August 17, 2016, is attached at Exhibit 5.

required financial projections which Department staff found to be reasonable based upon accepted accounting principles. Accordingly Department staff found in favor of the Applicant. *See* Decision, p. 3.

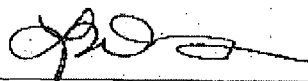
4. Trident claims that the Project does not foster cost containment as it is not needed, in their opinion. *See* RFR p. 7. As outlined in the Decision, the project does foster cost containment as it is part of a larger construction project. *See* Decision, p. 3.

5. Trident claims that the Project will adversely impact other providers in the area, including Trident Medical Center. Adverse Impact was not a project review criteria for this Project. However, the Plan allows Department staff to equally weigh improved accessibility to cardiac catheterization services against any adverse impact to other providers. In contemplating its Decision, Department staff found that the improved accessibility realized by the addition of a single diagnostic catheterization laboratory in a county where none exists, and where population growth is strong, was warranted and would not substantively impact any other provider in the 45-minute, one-way drive time service area.

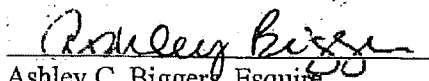
REQUESTED ACTION

For the foregoing reasons, staff respectfully requests that the Board deny Trident's request to conduct a final review conference and uphold staff's decision.

Respectfully submitted:



Louis Eubank
Director, Certificate of Need Program



Ashley C. Biggers, Esquire
Chief Counsel for Health Regulation

- Exhibit 1 – Decision Letter
- Exhibit 2 – Excerpts of CON Act
- Exhibit 3 – Excerpts of CON Regulation
- Exhibit 4 – Excerpts of the Plan
- Exhibit 5 – Letter regarding Xavier laboratory closure

EXHIBIT 1

Shannon Cantwell Article #:
92148969009997901405474639

William Thomas Article #:
92148969009997901405477203



July 25, 2016

VIA CERTIFIED MAIL

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 760
Charleston, SC 29403

Re: **Decision Granting Application for a Certificate of Need**
Roper St. Francis Hospital – Berkeley
Addition of Cardiac Catheterization services to Roper St. Francis Hospital - Berkeley
at a total project cost of \$2,873,366.
Case No.: 2340
Berkeley County, South Carolina.

Dear Ms. Cantwell:

The South Carolina Department of Health and Environmental Control (Department) has reviewed the above-referenced Certificate of Need (CON) Application. After consideration of the entire administrative record in this matter, the Department concludes the Applicant has presented substantial evidence the Project materially complies with the relevant project review criteria and is consistent with the South Carolina Health Plan enacted August 13, 2015 (Plan). Specifically, the Project satisfies the requirements set forth in Section 802 of Regulation 61-15 pertaining to Community Need Documentation, Distribution (Accessibility), Financial Feasibility, and Cost Containment. Accordingly, it is the decision of the Department that a Certificate of Need be granted to Roper St. Francis Hospital – Berkeley.

The Department's decision is based on the following findings:

Compliance with the State Health Plan

In addition to the declarative Certificate of Need Standards #1 and #2 outlined in the Plan for cardiac catheterization services, the following Standards for the Project apply:

3. New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year.

A review of relevant Joint Annual Report (JAR) data for all diagnostic catheterization labs within the 45-minute drive time service area showed that all diagnostic catheterization labs met or exceeded the 500 procedure threshold outlined in the Plan with one notable exception. The

diagnostic cardiac catheterization lab located at Roper St. Francis Xavier Hospital in West Ashley performed no more than nine (9) procedures per year in any year from 2010 to 2014, according to available JAR data. The Department explained this inconsistency to the Applicant as an agent for both Roper St. Francis Hospital – Berkeley and Bon Secours St. Francis Xavier Hospital. As such an agent, the Applicant agreed to shutter its diagnostic catheterization lab upon approval of the instant application, regardless of the timing of the new lab installation or any potential opposition to the instant application, thus allowing the department to discount the utilization figures of the lab at the Bon Secours St. Francis Xavier location. As such, the Department concludes that other diagnostic catheterization labs within the service area operate at such an equivalent capacity as to not preclude the addition of the diagnostic catheterization lab contemplated by the Applicant.

4. An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.

The Applicant projects a minimum of 510 procedures by the close of the third reporting year, and no evidence is provided which shows utilization at other existing diagnostic catheterization labs will drop below the 500 minimum procedure threshold as a result of approving the Project.

Certificate of Need Standards #5 and #6 do not apply to the contemplated Project as it is not an expansion of current cardiac catheterization services and is not a mobile diagnostic catheterization laboratory.

The Department notes that Trident Medical Center has filed as an Affected Person and in opposition to the application. A letter of opposition detailing the opposition's argument was received on July 21, 2016. After consideration of all information presented therein, the Department has determined that Trident's opposition does not present a sufficient reason to deny the Application.

Accordingly, the Department concludes the Applicant has sufficiently complied with the Standards outlined in the Plan, Chapter VIII-4 and Chapter VIII-5.

Community Need Documentation

While the planning area for diagnostic catheterization services is defined as an area within a 45-minute, one-way drive from the Applicant's facility, the Applicant further considers its service area to include Berkeley County as well as parts of Dorchester, Charleston, and Colleton Counties. Within the planning area, there are a total of 11 existing catheterization labs which are open and able to perform the services contemplated by the Applicant's Project. With the notable exception discussed previously, all labs within the planning area operate between 79% and nearly 94% capacity.

Accordingly, the Department concludes Applicant has sufficiently projected Community Need to satisfy the requirements of Section 802.2, Reg. 61-15.

Distribution (Accessibility)

Patients will be admitted regardless of age, race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, or gender identity or expression. Applicant has budgeted an appropriate amount of gross revenue for the treatment of indigent patients. As one lab in the service area is being closed as a result of this approval, and as another lab which is to be approved is in the extreme southern portion of the service area relative to this Applicant's proposed location, no unnecessary duplication of services is expected to occur.

The Department concludes that Applicant has satisfied the requirements of Distribution (Accessibility) pursuant to Section 802.3, Reg. 61-15.

Financial Feasibility

Applicant provided three year budget projections demonstrating financial feasibility. Julie Graudin, CPA for Roper St. Francis Healthcare, attests that the Project will be funded by utilizing existing bond proceeds issued for the development of the larger hospital project.

The Department concludes that Applicant has satisfied the requirements of Financial Feasibility pursuant to Section 802.15, Reg. 61-15.

Cost Containment

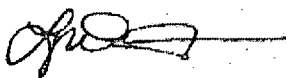
Integrating the contemplated laboratory into the pre-construction phase of the new Roper St. Francis Hospital – Berkeley realizes certain economies of practice which are otherwise lost during later renovation. Quality of cardiac care is increased through the provision of diagnostic services wherein early intervention prevents later invasive treatments at a much higher cost to the patient.

The Department concludes that Applicant has satisfied the requirements of Cost Containment pursuant to Section 802.16, Reg. 61-16.

The Department has determined the findings required by S.C. Code Reg. 61-15 §501 are not applicable to this Project.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Mr. Aaron Gantt (803.545.4400); Division of Health Facilities Construction, Mr. William McCallum (803.545.4215); Division of Health Licensing, Ms. Gwendolyn Thompson, (803.545.4370); and Bureau of Certification, Ms. MaryJo Roué (803.545.4293).

Sincerely,



Louis Eubank
Director
Certificate of Need Program

cc: William R. Thomas, Esq. (email/Certified Mail)

Enclosures: Guide to Board Review

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@dhcc.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.

EXHIBIT 2

**TITLE 44 – HEALTH
CHAPTER 7
ARTICLE 3**

State Certification of Need and Health Facility Licensure Act

SECTION 44-7-110. Short title.

This article may be cited as the "State Certification of Need and Health Facility Licensure Act".

SECTION 44-7-120. Declaration of purpose.

The purpose of this article is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State. To achieve these purposes, this article requires:

- (1) the issuance of a Certificate of Need before undertaking a project prescribed by this article;
- (2) adoption of procedures and criteria for submittal of an application and appropriate review before issuance of a Certificate of Need;
- (3) preparation and publication of a State Health Plan;
- (4) the licensure of facilities rendering medical, nursing, and other health care.

SECTION 44-7-160. Certificate of Need required under certain circumstances.

A person or health care facility as defined in this article is required to obtain a Certificate of Need from the department before undertaking any of the following:

- (1) the construction or other establishment of a new health care facility;
- (2) a change in the existing bed complement of a health care facility through the addition of one or more beds or change in the classification of licensure of one or more beds;
- (3) an expenditure by or on behalf of a health care facility in excess of an amount to be prescribed by regulation which, under generally acceptable accounting principles consistently applied, is considered a capital expenditure except those expenditures exempted in Section 44-7-170(B)(1). The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the development, acquisition, improvement, expansion, or replacement of any plant or equipment must be included in determining if the expenditure exceeds the prescribed amount;
- (4) a capital expenditure by or on behalf of a health care facility which is associated with the addition or substantial expansion of a health service for which specific standards or criteria are prescribed in the South Carolina Health Plan;
- (5) the offering of a health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan;
- (6) the acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of that prescribed by regulation.

SECTION 44-7-200. Application for Certificate of Need; notice; prohibited communications.

(A) An application for a Certificate of Need must be submitted to the department in a form established by regulation. The application must address all applicable standards and requirements set forth in departmental regulations, Project Review Criteria of the department, and the South Carolina Health Plan.

(B) Within twenty days before submission of an application, the applicant shall publish notification that an application is to be submitted to the department in a newspaper serving the area where the project is to

be located for three consecutive days. The notification must contain a brief description of the scope and nature of the project. No application may be accepted for filing by the department unless accompanied by proof that publication has been made for three consecutive days within the prior twenty-day period and payment of the initial application fee has been received.

(C) Upon publication of this notice and until a contested case hearing is requested pursuant to Section 44-1-60(G):

(1) members of the board and persons appointed by the board to hold a final review conference on staff decisions may not communicate directly or indirectly with any person in connection with the application; and

(2) no person shall communicate, or cause another to communicate, as to the merits of the application with members of the board and persons appointed by the board to hold a final review conference on staff decisions.

A person who violates this subsection is subject to the penalties provided in Section 1-23-360.

(D) After receipt of an application with proof of publication and payment of the initial application fee, the department shall publish in the State Register a notice that an application has been accepted for filing. Within thirty days of acceptance of the application, the department may request additional information as may be necessary to complete the application. The applicant has thirty days from the date of the request to submit the additional information. If the applicant fails to submit the requested information within the thirty-day period, the application is considered withdrawn.

(E) After a Certificate of Need application has been filed with the department, state and federal elected officials are prohibited from communicating with the department with regard to the Certificate of Need application at any time. This prohibition does not include written communication of support or opposition to an application. Such written communication must be included in the administrative record.

SECTION 44-7-210. Certificate of Need review procedures.

(A) After the department has determined that an application is complete, affected persons must be notified in accordance with departmental regulations. The notification to affected persons that the application is complete begins the review period; however, in the case of competing applications, the review period begins on the date of notice to affected persons that the last of the competing applications is complete and notice is published in the State Register. The staff shall issue its decision to approve or deny the application no earlier than thirty calendar days, but no later than one hundred twenty calendar days, from the date affected persons are notified that the application is complete, unless a public hearing is timely requested as may be provided for by department regulation. If a public hearing is properly requested, the staff's decision must not be made until after the public hearing, but in no event shall the decision be issued more than one hundred fifty calendar days from the date affected persons are notified that the application is complete. The staff may reorder the relative importance of the project review criteria no more than one time during the review period. The staff's reordering of the relative importance of the project review criteria does not extend the review period provided for in this section.

(B) The department may not issue a Certificate of Need unless an application complies with the South Carolina Health Plan, Project Review Criteria, and other regulations. Based on project review criteria and other regulations, which must be identified by the department, the department may refuse to issue a Certificate of Need even if an application complies with the South Carolina Health Plan. In the case of competing applications, the department shall award a Certificate of Need, if appropriate, on the basis of which, if any, most fully complies with the requirements, goals, and purposes of this article and the State Health Plan, Project Review Criteria, and the regulations adopted by the department.

(C) On the basis of staff review of the application, the staff shall make a staff decision to grant or deny the Certificate of Need and the staff shall issue a decision in accordance with Section 44-1-60(D). Notice of the decision must be sent to the applicant and affected persons who have asked to be notified. The decision becomes the final agency decision unless a timely written request for a final review is filed with the department as provided for in Section 44-1-60(E).

However, a person may not file a request for final review in opposition to the staff decision on a Certificate of Need unless the person provided written notice to the department during the staff review that he is an affected person and specifically states his opposition to the application under review.

(D) The staff's decision is not the final agency decision until the completion of the final review process provided for in Section 44-1-60(F).

(E) A contested case hearing of the final agency decision must be requested in accordance with Section 44-1-60(G). The issues considered at the contested case hearing considering a Certificate of Need are limited to those presented or considered during the staff review.

(F) Notwithstanding any other provision of law, including Section 1-23-650(C), in a contested case arising from the department's decision to grant or deny a Certificate of Need application, grant or deny a request for exemption under Section 44-7-170, or the issuance of a determination regarding the applicability of Section 44-7-160, the following apply:

- (1) each party may name no more than ten witnesses who may testify at the contested case hearing;
- (2) each party is permitted to take only the deposition of a person listed as a witness who may testify at the contested case hearing, unless otherwise provided for by the Administrative Law Court;
- (3) each party is permitted to serve only ten interrogatories pursuant to Rule 33 of the South Carolina Rules of Civil Procedure;
- (4) each party is permitted to serve only ten requests for admission, including subparts; and
- (5) each party is permitted to serve only thirty requests for production, including subparts.

The limitations provided for in this subsection are intended to make the contested case process more efficient, less burdensome, and less costly to the parties in Certificate of Need cases. Therefore, the Administrative Law Court may, by court order, lift these limitations beyond the parameters set forth in this subsection only in exceptional circumstances when failure to do so would cause substantial prejudice to the party seeking additional discovery.

(G) Notwithstanding any other provision of law, in a contested case arising from the department's decision to grant or deny a Certificate of Need application, grant or deny a request for exemption under Section 44-7-170, or the issuance of a determination regarding the applicability of Section 44-7-160, the Administrative Law Court shall file a final decision no later than eighteen months after the contested case is filed with the Clerk of the Administrative Law Court, unless all parties to the contested case consent to an extension or the court finds substantial cause otherwise.

EXHIBIT 3

REGULATION NO. 61-15**CERTIFICATION OF NEED FOR
HEALTH FACILITIES AND SERVICES**

Promulgated pursuant to Sections 44-7-110 et seq. of the Code of Laws of South Carolina, as amended.

CHAPTER 1 - PURPOSE, APPLICABILITY AND DEFINITIONS**Section 101. Purpose:**

The purpose of these Regulations is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State.

Section 102. Applicability:

1. A person or health care facility as defined in this Regulation is required to obtain a Certificate of Need from the Department of Health and Environmental Control before undertaking any of the following:

- a. The construction or other establishment of a new healthcare facility;
- b. A change in the existing bed complement of a health care facility through the addition of one or more beds or change in the classification of licensure of one or more beds;
- c. An expenditure by or on behalf of a health care facility in excess of two million dollars (\$2,000,000) which, under generally acceptable accounting principles consistently applied, is considered a capital expenditure except those expenditures exempted in Section 104. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the development, acquisition, improvement, expansion, or replacement of any plant or equipment must be included in determining if the expenditure exceeds the prescribed amount;
- d. A capital expenditure by or on behalf of a health care facility which is associated with the addition or substantial expansion of a health service for which specific standards or criteria are prescribed in the South Carolina Health Plan;
- e. If no capital expenditure is made, the offering of any health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan. For purposes of this section, operating costs include expenditures incurred by the health care facility and any person or other

entity on behalf of the health care facility to establish a new service. A person or other entity shall not be allowed to incur costs thereby attempting to enable a health care facility to avoid Certificate of Need review and establish a new service as described above;

f. The acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of six hundred thousand dollars (\$600,000);

2. An applicant may not split or combine one expenditure into two or more expenditures for the purpose of avoiding Certificate of Need review, nor may the Department be allowed to lump projects together arbitrarily to bring them under Certificate of Need review.

3. When any question exists, a potential applicant shall forward a letter requesting a formal determination by the Department as to the applicability of the Certificate of Need requirements to a particular project. Such a letter shall contain a detailed description of the project including the extent of modifications, changes in services and total costs. Additional information may be requested as may be reasonably necessary to make such applicability determination. The Department shall respond within sixty (60) calendar days of receipt of the necessary information.

4. These provisions do not apply to acquisitions or changes of ownership of health care facilities, services, and equipment that are already in existence, operational, and providing services in a particular service area, and which have undergone the review and obtained the approval that was appropriate under the law at the time they first entered the relevant service area, so long as the facility or service is not being relocated. For facilities, services, and equipment which have previously undergone Certificate of Need review, the Certificate of Need must be fulfilled prior to a change of ownership.

Section 103. Definitions:

1. Affected person means the applicant, a person residing within the geographic area served or to be served by the applicant, persons located in the health service area in which the project is to be located and who provide similar services to the proposed project, persons who before receipt by the Department of the proposal being reviewed have formally indicated an intention to provide similar services in the future, persons who pay for health services in the health service area in which the project is to be located and who have notified the Department in writing of their interest in Certificate of Need applications, the State Consumer Advocate and the State Ombudsman. Persons from another state who would otherwise be considered "affected persons" are not included unless that state provides for similar involvement of persons from South Carolina in its Certificate of Need process. A person may not file a request for final review in opposition to the staff decision on a Certificate of Need unless the person provided written notice to the Department during the staff review that he is an affected person and specifically states his opposition to the application under review. Affected persons may request in writing to be notified of a Department decision by regular mail or electronic mail in lieu of certified mail.

2. Ambulatory surgical facility means a distinct, free-standing, self-contained entity that is

involve the Department in the development of proposed projects prior to the submission of an application.

Section 302. Additional Information:

1. After receipt of an application with proof of publication in a local newspaper and the five hundred dollars (\$500) non-refundable filing fee, the Department shall publish in the State Register a notice that an application has been accepted for filing. The Department shall notify the applicant in writing when the application is not acceptable for filing.
2. Within thirty (30) calendar days from acceptance of an application, the Department will request any additional information pertinent to the project as may be deemed necessary to make the application complete. Should additional information be required for an application to be considered complete, the applicant will have thirty (30) calendar days from the date of the request to submit the requested information. If the applicant does not submit the requested information within thirty (30) calendar days, the application will be deemed to have been withdrawn.
3. Should the applicant within such thirty (30) calendar day period submit incomplete additional information, the Department will have thirty (30) calendar days in which to request further information. If the information requested is not received by the Department within thirty (30) calendar days of this second request, the application will be deemed to have been withdrawn.
4. If any deadline provided for in this section falls on a weekend or State holiday, the deadline will be extended until the next calendar day that is not a weekend or State holiday.

Section 303. Payment of Filing and Application Fees:

1. When the application is determined to be complete, the Department shall invoice the applicant, by certified mail, for the certificate of need application fee. The applicant shall have fifteen (15) calendar days from the date of receipt of the invoice to pay the fee by valid check made payable to the S.C. Department of Health and Environmental Control. Should the application fee not be received within fifteen (15) calendar days from receipt of the Department's invoice by the applicant, the application will be considered withdrawn.
2. If any deadline provided for in this section falls on a weekend or State holiday, the deadline must be extended until the next calendar day that is not a weekend or State holiday.

Section 304. Relative Importance Criteria:

1. Upon determination by the Department that an application is complete, the Department shall notify the applicant, by certified mail, of the relative importance of the project review criteria to be used in reviewing the application. The applicant will have thirty (30) calendar days from the date of receipt of this notice to submit any additional information. If, subsequent to this notice, the Department determines that the relative importance of the review criteria has changed, the Department must again notify the applicant by certified mail. The applicant will have thirty (30) calendar days from receipt of the revised notice to submit any additional information.

2. The staff may reorder the relative importance of the project review criteria no more than one time during the review period. The staff's reordering of the relative importance of the project review criteria does not extend the review period.
3. When an application has been appealed, the Department may not change the weight of the importance of the project review criteria.

Section 305. Review Time Frames:

1. Upon determination by the Department that the application is complete, and receipt of the application fee, the Department shall publish in the State Register a notice that the review cycle for the project has begun. Any affected person who has notified the Department in writing that they desire to be notified of the beginning of the review period be sent a copy of the notification.
2. The Department will make a decision on the complete application no earlier than thirty (30) calendar days but no later than 120 calendar days of the date of publication in the State Register unless a public hearing is held. Notice of a Department decision must be sent by certified mail, return receipt requested to the applicant and affected persons who have requested in writing to be notified.
 - a. If a public hearing is held pursuant to Section 306, the Department will render its decision no later than 150 calendar days from the date the affected persons are notified that the application is complete.
 - b. [Reserved]

Section 306. Public Hearing:

A public hearing must be requested in writing by an "affected person" as defined in these regulations within thirty (30) calendar days of the notification of the beginning of a review. Where such a hearing is requested, prior notice of the hearing will be provided to "affected persons. The written notification of the hearing shall include the proposed schedule for the review, time, date, and place of such hearing. The public hearing shall provide an opportunity for any person to present information relevant to the application.

Section 307. Department Review:

1. The Department may not issue a Certificate of Need unless an application is in compliance with the South Carolina Health Plan as described in this regulation, project review criteria, and other regulations which must be identified by the Department. The Department may refuse to issue a Certificate of Need even if an application is in compliance with the South Carolina Health Plan but is inconsistent with project review criteria or departmental regulations. The Department must identify any regulation that is used as a basis for denying an application that is in compliance with the South Carolina Plan.

e. A program and/or service narrative describing the final project configuration; and

f. An explanation of any deviation from the approved application with justification, or a signed statement from the applicant that the project was implemented as outlined in the application.

4. Records relating to the project shall be maintained by the applicant for seven (7) years following the completion of the project and these records shall be made available to the Department's auditors for inspection as needed.

5. The Department may audit any project for consistency with the information provided in the Certificate of Need application. Undertaking a project that is not in accordance with the approved application or conditions or amendments subsequently agreed to by the applicant and the Department may be considered a violation of this article.

CHAPTER 7 - PENALTIES FOR NON-COMPLIANCE

Section 701. Penalties:

Undertaking any activity requiring certificate of need review, as defined in Section 102 of these regulations, without prior approval of the Department or failing to comply with any of the above stated regulations shall be grounds for the denial, suspension, or revocation of the Certificate of Need, or other penalties, under the provisions of Sections 44-7-320 through 44-7-340 of the Code of Laws of South Carolina, as amended. Any violation of this regulation is subject to provisions set forth in the statute.

Section 702. [Reserved]

CHAPTER 8 - PROJECT REVIEW CRITERIA

Section 801. Applicability and Weighting:

1. The criteria listed in Section 802 are to be used in reviewing all projects under the Certification of Need program. These criteria have been grouped under the following general categories:

Need for the Proposed Project	(Section 802.1 through 802.4)
Economic Consideration	(Section 802.5 through 802.19)
Health System Resources	(Section 802.20 through 802.25)
Site Suitability	(Section 802.26 through 802.30)
Special Consideration	(Section 802.31 through 802.33)

2. The Department shall notify the applicant of the relative importance of the project review criteria to be used in reviewing the application. The relative importance assigned to each specific criterion is established by the Department depending upon the importance of the criterion applied to the specific project. The relative importance must be consistent for competing projects.

3. A project does not have to satisfy every criterion in order to be approved, but no project may be approved unless it is consistent with the South Carolina Health Plan. A project may be denied if the Department determines that the project does not sufficiently meet one or more of the criteria.

Section 802. Criteria for Project Review:

1. Need:

The proposal shall not be approved unless it is in compliance with the South Carolina Health Plan.

2. Community Need Documentation:

a. The target population should be clearly identified as to the size, location, distribution, and socioeconomic status (if applicable).

b. Projections of anticipated population changes should be reasonable and based upon accepted demographic or statistical methodologies, with assumptions and methodologies clearly presented in the application. The applicant must use population statistics consistent with those generated by the State Demographer, State Budget and Control Board.

c. The proposed project should provide services that meet an identified (documented) need of the target population. The assumptions and methods used to determine the level of need should be specified in the application and based on a reasonable approach as judged by the reviewing body. Any deviation from the population projection used in the South Carolina Health Plan should be explained.

d. In the case of a reduction, relocation, or elimination of a facility or service, the applicant should address the need that the population presently has for the service, the extent to which that need will be met by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination, or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, the elderly, handicapped persons, and other underserved groups, to obtain needed health care.

e. Current and/or projected utilization should be sufficient to justify the expansion or implementation of the proposed service.

3. Distribution (Accessibility):

a. Duplication and modernization of services must be justified. Unnecessary duplication of services and unnecessary modernization of services will not be approved.

- b. The proposed service should be located so that it may serve medically underserved areas (or an underserved population segment) and should not unnecessarily duplicate existing services or facilities in the proposed service area.
- c. The location of the proposed service should allow for the delivery of necessary support services in an acceptable period of time and at a reasonable cost.
- d. The proposed facility should not restrict admissions. If any restrictions are applied, their nature should be clearly explained.
- e. The applicant must document the means by which a person will have access to its services (e.g. outpatient services, admission by house staff, admission by personal physician)
- f. The applicant should address the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, the elderly, handicapped persons, and other medically underserved groups, are likely to have access to those services being proposed.
- g. The facility providing the proposed services should establish provisions to insure that individuals in need of treatment as determined by a physician have access to the appropriate service, regardless of ability to pay.
- h. Potential negative impact of the proposed project upon the ability and/or resources of existing providers to serve medically underserved groups must be considered.

4. Acceptability:

- a. The proposal and applicant should have the support of "affected persons" (including local providers and the target population). The lack of opposition should not be considered support for the purposes of these criteria.
- b. Where documented opposition exists to a proposal, such opposition will be considered along with the application.
- c. Possible transfer agreements should be confirmed and an intent to negotiate these arrangements should be documented by all parties.
- d. The applicant should document the initiation of any other required reviews or agency check-offs.

5. Financial Entries and Assumptions:

All financial entries and assumptions contained in the application must be provided by an

State and consistent with accepted good business practices in terms of assumption and retirement of debt:

- c. The applicant must document the impact the project will have on the facility's proposed level of patient charges.

11. Methods of Financing:

- a. Possible alternatives should be identified.
- b. Reasons for the selection of the proposed funding method should be stated and reasonable.

12. The applicant should demonstrate an ability to obtain the desired capital. The applicant must provide at least conditional commitment from an appropriate institution.

13. Record of the Applicant (Owner and/or Administrator):

- a. The applicant's record should be one of successful operation with adequate management experience.
- b. The applicant should have a demonstrated ability to obtain necessary capital financing.
- c. If the applicant has no prior experience, sources of assistance should be specified (i.e. technical assistance from specific individuals or organizations).
- d. The applicant's record or his representative's record of cooperation and compliance with State and Federal regulatory programs will be considered.

14. Ability to Complete the Project:

- a. The applicant should have demonstrated that the project can be initiated and completed within the proposed time frame specified in the application.
- b. The financial schedules and time frames contained in the application should be consistent with those usually experienced in the development of similar facilities or services.

15. Financial Feasibility:

The applicant must have projected both the immediate and long-term financial feasibility of the proposal. Such projection should be reasonable and based upon accepted accounting procedures.

16. Cost Containment (Minimizing Costs):

- a. The applicant should have identified and sought alternative sources and/or methods of funding and demonstrated that the method chosen was the most feasible option.
- b. If the applicant had the option of lease or purchase, with all other factors being equal, he should demonstrate that his choice is the least costly in the long run.
- c. The impact of the project upon the applicant's cost to provide services and the applicant's patient charges should be reasonable. The impact of the project upon the cost and charges of other providers of similar services should be considered if the data are available.

17. Efficiency:

The proposed project should improve efficiency by avoiding duplication of services, promoting shared services, and fostering economies of scale or size.

18. Physical Design:

The proposed project should foster economies of design by use of design characteristics such as improved access and circulation within the facility, the relationship of services within the facility, and the use of shared space for centralized supply, storage, and common activities.

19. Alternative Methods:

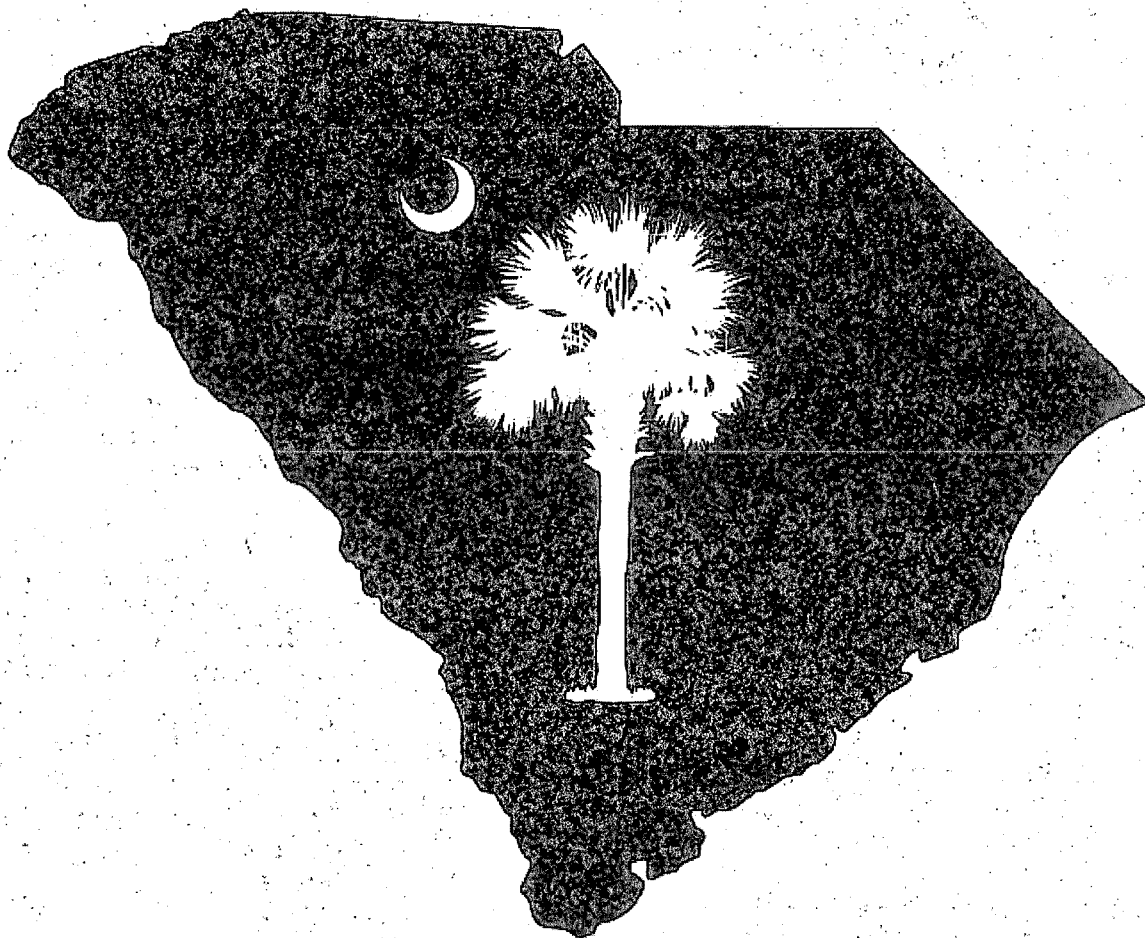
- a. The applicant should have considered any available or more effective alternatives which exist to the proposed service such as the use of less costly alternatives, outpatient services, shared services, or extended hours of service.
- b. For new construction projects, modernization of existing facilities should be considered as an alternative, and the rejection of this alternative by the applicant should be justified.

20. Staff Resources:

- a. The applicant should have a reasonable plan for the provision of all required staff (physicians, nursing, allied health and support staff, etc.).
- b. The applicant should demonstrate that sufficient physicians are available to insure proper implementation (e.g. utilization and/or supervision) of the project.
- c. If the applicant presently owns existing facilities or services, he should demonstrate a satisfactory staffing "track record."
- d. Alternative uses of resources for the provision of other health services should be identified and considered.

EXHIBIT 4

South Carolina Health Plan



Enacted 13 August 2015

CHAPTER VIII

CARDIOVASCULAR CARE¹

Diseases of the heart were responsible for as many deaths in South Carolina as cancer during 2013. Annually, heart disease and stroke are the leading cause of death in the State. Approximately one-third of all heart attacks are fatal. The amount of heart muscle damaged during a heart attack is an important determinant of whether patients live or die – and what their quality of life will be if they survive.

Diagnostic and therapeutic cardiac catheterizations and open heart surgery are tools in the treatment of heart disease. During a cardiac catheterization, a thin, flexible tube is inserted into a blood vessel in the arm or leg. The physician manipulates the tube to the chambers or vessels of the heart so that pressure measurements, blood samples and photographs can be taken. Injections of contrast material allow blockages or areas of weakness to appear on x-rays. Other diagnostic and therapeutic procedures may also be performed.

Percutaneous Coronary Interventions (PCIs) are therapeutic catheterization procedures used to revascularize occluded or partially occluded coronary arteries. These interventions include, but are not limited to: bare and drug-eluting stent implantation; Percutaneous Transluminal Coronary Angioplasty (PTCA); cutting balloon atherectomy; rotational atherectomy; directional atherectomy; excimer laser angioplasty; and extractional thrombectomy.

These procedures may be performed on an emergent or elective basis. “Emergent or Primary” means that a patient needs immediate PCI because, in the treating physician’s best clinical judgment, delay would result in undue harm or risk to the patient. An “Elective” PCI is scheduled in advance and performed on a patient with cardiac function that has been stable in the days prior to the procedure.

In 2011, the American College of Cardiology (ACC) and the American Heart Association (AHA) revised their Guidelines for PCI. The previous version of the Guidelines allowed the provision of Emergent/Primary PCIs in hospitals without an on-site open heart surgery program if certain criteria could be met, but, due to the risk of arterial damage and the resulting need for immediate open heart surgery, elective PCI was contraindicated for institutions without on-site surgical backup. The new Guidelines state that:

Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without

¹ Due to the October 1, 2015, transition from ICD-9 to ICD-10 coding for medical diagnoses and inpatient hospital procedures, all ICD-9 codes referenced in the South Carolina Health Plan shall be deemed to refer to the corresponding ICD-10 codes, as determined by CMS, once this transition takes place.

appropriate hemodynamic support capability for transfer.

Hospitals without an open heart surgery program shall be allowed to provide Emergent/Primary and/or Elective PCIs only if they comply with all sections of Standard 7 or 8 of the Standards for Cardiac Catheterization.

In 2013, the Society of Cardiovascular Angiography and Interventions (SCAI), AHA, and ACC updated their joint statement on clinical competence regarding coronary artery intervention procedures. The joint statement defined certain requirements for PCI operator competence and PCI facility volume requirements. The statement also noted an overall decrease in PCI volumes. This statement does not contain a material change in the Plan's existing Certificate of Need requirements.

Open heart surgery or cardiac surgery refers to an operation performed on the heart or intrathoracic great vessels. The operations include Coronary Artery Bypass Graft (CABG), where veins are extracted from the patient and grafted to bypass a constricted section of coronary artery, and Minimally Invasive Direct Coronary Artery Bypass (MIDCAB), where the surgeon operates through a smaller incision rather than breaking the breastbone to open the chest cavity and no bypass machine is used.

Both cardiac catheterization and open heart surgery programs require highly skilled staffs and expensive equipment. Appropriately equipped and staffed programs serving larger populations are preferable to multiple, minimum population programs. Underutilized programs may reflect unnecessary duplication of services in an area, which may seriously compromise quality and safety of procedures and increase the cost of care. Optimal performance requires a caseload of adequate size to maintain the skills and efficiency of the staff. Cardiac catheterization laboratories should perform a minimum of 500 diagnostic equivalents per year (diagnostic catheterizations are weighted as 1.0 equivalents, therapeutic catheterizations as 2.0). Emergent PCI providers should perform a minimum of 36 PCIs annually; all other therapeutic catheterization providers should perform a minimum of 300 therapeutic catheterizations annually. For pediatric catheterization and adult congenital catheterization labs, diagnostic catheterizations are weighted as 2.0-equivalents, therapeutic catheterizations as 3.0, EP studies as 2.0, biopsies performed after heart transplants as 1.0 equivalents, and adult concomitant congenital heart disease procedures performed in these labs are included in the utilization calculations. A minimum of 150 procedures per year is recommended; half of these should be on neonates or infants. There should be a minimum of 200 adult open heart surgery procedures performed annually per open heart surgery unit; improved results appear to occur in hospitals that perform a minimum of 350 cases annually. Pediatric open heart surgery units should perform 100 pediatric heart operations per year, at least 75 of which should be open heart surgery.

CARDIAC CATHETERIZATION

Relevant Definitions

"Cardiac Catheterization Procedure" is an invasive procedure where a thin, flexible catheter is

inserted into a blood vessel; the physician then manipulates the free end of the catheter into the chambers or vessels of the heart. All activities performed during one clinical session, including angiocardiology, coronary arteriography, pulmonary arteriography, coronary angioplasty and other diagnostic or therapeutic measures and physiologic studies shall be considered one procedure.

"Comprehensive Catheterization Laboratory" means a dedicated room or suite of rooms in which PCIs as well as diagnostic and therapeutic catheterizations are performed, in a facility with on-site open heart surgery backup.

"Diagnostic Catheterization" refers to a cardiac catheterization during which any or all of the following diagnostic procedures or measures are performed: Blood Pressure; Oxygen Content and Flow Measurements; Angiocardiology, Coronary Arteriography; and Pulmonary Arteriography. The following ICD-9-CM Procedure Codes refer to diagnostic catheterizations:

- 37.21 Right Heart Cardiac Catheterization
- 37.22 Left Heart Cardiac Catheterization
- 37.23 Combined Right and Left Heart Cardiac Catheterization

"Diagnostic Catheterization Laboratory" means a dedicated room in which only diagnostic catheterizations are performed.

"Percutaneous Coronary Intervention (PCI)" refers to a therapeutic procedure to relieve coronary narrowing, such as Percutaneous Transluminal Coronary Angioplasty (PTCA) or Coronary Stent Implantation. These procedures may be performed on an emergent or elective basis. "Emergent or Primary" means that a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient. An "Elective" PCI is scheduled in advance and performed on a patient with cardiac function that has been stable in the days prior to the procedure.

"Therapeutic Catheterization" refers to a PCI or cardiac catheterization during which, in addition to any diagnostic catheterization procedure, any or all of the following interventional procedures are performed: PTCA; Thrombolytic Agent Infusion; Directional Coronary Atherectomy; Rotational Atherectomy; Extraction Atherectomy; Coronary Stent Implants and Cardiac Valvuloplasty. The following ICD-9-CM Procedure Codes refer to therapeutic catheterizations:

- 00.66 Percutaneous Transluminal Coronary Angioplasty (PTCA)
- 17.55 Transluminal Coronary Atherectomy
- 35.52 Repair of Atrial Septal Defect with Prosthesis, Closed Technique
- 35.55 Repair of Ventricular Septal Defect with Prosthesis, Closed Technique
- 35.96 Percutaneous Valvuloplasty
- 36.06 Insertion of Non-Drug Eluting Coronary Artery Stent(s)
- 36.07 Insertion of Drug Eluting Coronary Artery Stent(s)
- 36.09 Other Removal of Coronary Artery Obstruction
- 37.34 Excision or Destruction of Other Lesion or Tissue of Heart, Endovascular Approach

Scope of Services

The following services should be available in both adult and pediatric catheterization laboratories:

1. Each cardiac catheterization lab should be competent to provide a range of angiographic (angiocardiography, coronary arteriography, pulmonary arteriography), hemodynamic, and physiologic (cardiac output measurement, intracardiac pressure, etc.) studies. These facilities should be available in one laboratory so that the patient need not be moved during a procedure.
2. The lab should have the capability of immediate endocardiac catheter pacemaking in cardiac arrest, a crash cart, and defibrillator.
3. A full range of non-invasive cardiac/circulatory diagnostic support services, such as the following, should be available within the hospital:
 - a. Nuclear Cardiology
 - b. Echocardiography
 - c. Pulmonary Function Testing
 - d. Exercise Testing
 - e. Electrocardiography
 - f. Cardiac Chest X-ray and Cardiac Fluoroscopy
 - g. Clinical Pathology and Blood Chemistry Analysis
 - h. Phonocardiography
 - i. Coronary Care Units (CCUs)
 - j. Medical Telemetry/Progressive Care
4. Each applicant shall document plans for providing cardiac rehabilitation services to its patients or plans for establishing referral agreements with facilities offering cardiac rehabilitation services.

CERTIFICATE OF NEED STANDARDS

1. The capacity of a fixed cardiac catheterization laboratory shall be 1,200 diagnostic equivalents per year. Adult diagnostic catheterizations shall be weighted as 1.0 equivalents, while therapeutic catheterizations shall be weighted as 2.0 equivalents. For pediatric and adult congenital catheterization labs, diagnostic catheterizations shall be weighted as 2.0 equivalents, therapeutic catheterizations shall be weighted as 3.0 equivalents, electrophysiology (EP) studies shall be weighted as 2.0 equivalents, and biopsies performed after heart transplants shall be weighted as 1.0 equivalents. The capacity of mobile cardiac catheterization labs will be calculated based on the number of days of operation per week.
2. The service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes' one way automobile travel time; for comprehensive cardiac

catheterization laboratories the service area is all facilities within 60 minutes' one way automobile travel time; a pediatric cardiac program should serve a population encompassing at least 30,000 births per year, or roughly two million people.

Diagnostic and Mobile Catheterization Services

3. New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year;
4. An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.
5. Expansion of an existing diagnostic catheterization service shall only be approved if the service has operated at a minimum use rate of 80% of capacity (i.e., 960 equivalents per laboratory) for each of the past two years and can project a minimum of 500 procedures per year on the additional equipment within three years of its implementation.
6. An applicant for a mobile diagnostic catheterization laboratory must be able to project a minimum of 100 diagnostic equivalents annually for each day of the week that the mobile lab is located at the applicant's facility by the end of the third year following initiation of the service, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic catheterization procedures per laboratory (i.e., an applicant wishing to have a mobile catheterization lab 2 days per week must project a minimum of 200 equivalents at the applicant's facility by the end of the third year of operation). In addition:
 - a. The applicant must document that the specific mobile unit utilized by the vendor will perform a combined minimum of 500 diagnostic equivalents per year;
 - b. The applicant must include vendor documentation of the complication rate of the mobile units operated by the vendor; and
 - c. If an application for a mobile lab is approved and the applicant subsequently desires to change vendors, the Department must approve such change in order to insure that appropriate minimum utilization can be documented.

Emergent and Elective PCI without On-Site Cardiac Backup

7. In 2005, the ACCF/AHA/SCAI Writing Committee determined that Emergency PCI (Primary PCI) is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished. Hospitals with diagnostic laboratories may be approved to perform emergency PCI without an on-site

EXHIBIT 5



2095 Henry Tecklenburg Drive, Charleston, SC 29414, Telephone: (843) 402-1006, Fax: (843) 402-1550

August 17, 2016

VIA EMAIL AND US MAIL

EUBANKLW@dhec.sc.gov

Louis Eubank
Director, Certificate of Need (C.O.N.) Program
South Carolina Department of Health & Environmental Control
301 Gervais Street
Columbia, SC 29201

Re: Proof of Closure – Bon Secours St. Francis Xavier Cardiac Catheterization Lab

Dear Mr. Eubank:

In response to your letter dated July 26, 2016, and in accordance with Roper St. Francis – Berkeley's Certificate of Need application for the addition of the cardiac catheterization service, which was approved by the South Carolina Department of Health and Environmental Control on July 25, 2016, please accept this letter as confirmation that Bon Secours St. Francis Xavier Hospital ("BSSFH") permanently closed its diagnostic cardiac catheterization lab on August 1, 2016. Please note that the area within BSSFH in which the now closed diagnostic catheterization lab was located, is being used to provide other medical services to patients consistent with BSSFH's license.

Please let me know if you have any questions regarding this matter.

Sincerely,

A handwritten signature in cursive script that reads "Allen Carroll".

Allen Carroll
Chief Executive Officer
Bon Secours St. Francis Xavier Hospital

cc: Ralph Barbier, Esq. (via email only)

SCDHEC

AUG 17 2016

Certificate of Need Program

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

Trident Medical Center, LLC, d/b/a Trident
Medical Center,

Petitioner,

vs.

South Carolina Department of Health and
Environmental Control and Roper St. Francis
Hospital - Berkeley, Inc., d/b/a Roper St.
Francis Hospital - Berkeley,

Respondents.

Docket No.: 2016-ALJ-07-0386-CC

**RESPONDENT ROPER ST. FRANCIS
HOSPITAL – BERKELEY’S MOTION TO
ALTER OR AMEND AND
MEMORANDUM IN SUPPORT**

Respondent Roper St. Francis Hospital – Berkeley, Inc. d/b/a Roper St. Francis Hospital – Berkeley (“Roper Berkeley”) hereby respectfully files this Motion pursuant to Rule 59(e) of the South Carolina Rules of Civil Procedure and Rule 68 of the Rules of Procedure for the Administrative Law Court to alter or amend the Final Order dated December 3, 2018, received by Roper Berkeley on December 4, 2018 and attached hereto as **Exhibit A**, which reversed the decision of the Respondent South Carolina Department of Health and Environmental Control (“DHEC” or “Department”) and denied the Certificate of Need (“CON”) granted to Roper Berkeley to establish diagnostic catheterization services in Berkeley County.

Roper Berkeley respectfully submits that the decision of the Court is contrary to the substantial evidence in the record that otherwise supports the decision of the Department to grant a CON to Roper Berkeley. Moreover, the Final Order’s failure to properly consider and apply the applicable laws and regulations to the evidence presented amounts to an error of law. As such, Roper Berkeley respectfully asks this Court to reconsider those findings and conclusions reversing the Department’s decision and to alter or amend its Final Order based on the arguments set forth herein.

FILED

DEC 13 2018

CENTRAL ISSUE

Having narrowed the issues in dispute, the sole question before the Court was whether DHEC's decision that Roper Berkeley's CON Application substantially complied with the *2015 South Carolina Health Plan* ("Health Plan") should be reversed based on Petitioner Trident Medical Center, LLC d/b/a Trident Medical Center's ("Trident") argument that the CON Application did not satisfy Standard 3. The Court was presented with sworn testimony from health planning experts on behalf of Trident and Roper Berkeley, and the Department's Chief of the Bureau of Healthcare Planning and Construction, and received documentary evidence in the form of exhibits.

ARGUMENTS

A. THE COURT ERRED IN INTERPRETING THE HEALTH PLAN CONTRARY TO THE INTERPRETATION OF DHEC.

It is undisputed that the Health Plan is DHEC's document and subject to interpretation by the Department in carrying out the statutory responsibilities of the agency. S.C. Code Ann. §§ 44-7-140, -180; *see also*, Sullivan Trial Tr. 123:16-124:5, 125:2-4. As the agency charged not only with the creation of the Health Plan but the overall responsibilities for the operation and control of the CON program, it is the Department's intent that prevails in interpreting the meaning of the Health Plan. *See* S.C. Code Ann. § 44-7-140; *see also* *Marlboro Park Hosp. v. S.C. Dept. of Health and Env'tl. Control*, 358 S.C. 573, 578-79, 595 S.E.2d 851, 854 (Ct. App. 2004).

The Court in the Final Order makes factual findings that interpret the meaning, purpose and intent of the Health Plan in a manner contrary to that of the Department. *See e.g.* Final Order pp. 5-6. For example, the Final Order finds that "[t]he purpose of the State Health Plan inventory for cardiac catheterization is to allow interested parties to identify existing providers in the service area and the historical utilization of each lab in a given area." *Id.* The testimony of the

Department's Chief, who at the time of the underlying decision was the Director of the CON Program, was that the Health Plan is a "planning tool" created by DHEC which "guides the development of certain healthcare facilities and services across the state." Eubank Trial Tr. 265:11-20. Mr. Eubank further testified that the Health Plan "allows the state to essentially adapt its healthcare planning practices to meet current needs." *Id.* at 266:3-6. The Final Order's finding that the Health Plan's cardiac catheterization lab inventory "allows a potential applicant to determine whether a new cardiac catheterization lab is needed in the service area," is unsupported by any evidence or testimony from the Department or other evidence in the record other than Trident's self-serving testimony. Instead, the Department's witness testified and explained that applications for covered services are reviewed regardless of the inventory, and given that any two potential applicants might read the same Health Plan provisions differently, the Department encourages providers to engage in discussions with the agency regarding potential and proposed projects. Eubanks Trial Tr. 294:16-295:11. Ms. Platt testified that the rigid inflexibility of Trident's theory of the inventory is unworkable and could prevent needed health services from coming to a community for many years. *See* Platt Trial Tr. 398:23-400:21.

Similarly, the Final Order's finding that the at-issue Standard 3 "calls for a retrospective view" of utilization is supported only by Trident's argument and is contrary to the substantial evidence in the record. As explained and is undisputed, the Health Plan is a *planning* tool, planning which necessarily requires prospective analysis. As explained by Roper Berkeley's expert in health planning, "the goal of Standard 3 is to look at what's currently available in the market. . . . It's an assessment of what's available in the market today in terms of capacity that's going to [be] available when you're looking to the future." Platt Trial Tr. 426:14-22. The testimony of the Department similarly evidences that the evaluation is of the impact a new provider will have on

other providers in the service area performing those services. Eubank Trial Tr. 268:5-269:6. The Court's finding that the Standard mandates retrospective review and prohibits prospective analysis is contrary to the substantial evidence in the record and wholly inapposite to the interpretation of the agency statutorily charged with drafting and implementing the Health Plan.

B. THE COURT ERRED IN EVALUATING THE CONCEPT OF EXISTING IN CONTEXTS OTHER THAN THE HEALTH PLANNING STANDARD.

Also contrary to and unsupported by the substantial evidence in the record is the Final Order's reliance on miscellaneous documents to find that the Bon Secours St. Francis Xavier catheterization laboratory was "existing," such documents or haphazard word usage having no bearing on the Department's interpretation of "existing lab" for purposes of health planning and Standard 3 in the Health Plan. Final Order pp. 7-8, 13. Seemingly based solely on Trident's argument and without any other evidentiary basis, the Court identifies multiple documents and communications in addressing whether the Bon Secours St. Francis Xavier catheterization laboratory was "existing" for purposes of satisfying Standard 3 of the Health Plan. This is error. Standard 3 is a health planning standard for evaluating the approvability of a proposed project in light of particular metrics; this evaluation of what is an "existing lab" is not tantamount to a metaphysical evaluation of whether a catheterization laboratory exists in the physical sense. Consequently, the Court attributing significance to the word "existing" in the CON Application or analyzing discussions of the laboratory's past performance and whether such discussions meant it was or was not "existing" is misplaced. Moreover, contrary to the findings in the Final Order, a determination of whether the Bon Secours St. Francis Xavier catheterization laboratory is an "existing lab" for purposes of Standard 3 is not for Roper Berkeley to make, thus the absence of affirmative statements in the CON Application or elsewhere that the laboratory is "non-operational" or "non-existent" is also immaterial to the question in dispute. Final Order p. 10.

C. THE COURT MISAPPREHENDS OR MISSTATES THE DEPARTMENT'S INTERPRETATION AND APPLICATION OF STANDARD 3.

In several respects, the Final Order misapprehends or misstates DHEC's analysis of what is an "existing lab" for purposes of Standard 3 and whether the Bon Secours St. Francis Xavier catheterization laboratory was an "existing lab" in review of the Roper Berkeley CON Application. Moreover, the Final Order inexplicably makes a finding that "although clearly aware that the lab had been operating in violation of Standard 3 since at least 2010, at no time did the Department undertake any enforcement action against Bon Secours." Final Order, p. 8. This finding is manifestly improper, as there is no volume requirement in Standard 3 so as to support a belief that a catheterization laboratory with volumes below the threshold is in *violation* of the planning standard. There again is a fundamental misunderstanding of the purpose of Standard 3 and the fact that Standard 3 only has significance when reviewing applications for diagnostic cardiac catheterization services. What is or is not an "existing lab" for any other reason in any other context is irrelevant.

The Final Order accurately reflects the Department's testimony that DHEC "did not consider Bon Secours to be an existing catheterization lab *for purposes of review of Standard 3* in 2016." Final Order p. 9 (emphasis added). That the Court proceeds to consider the inclusion of the utilization data for the Bon Secours St. Francis Xavier catheterization laboratory in the Health Plan's inventory as contradictory to this interpretation reflects the Court's misunderstanding of the central issue. Moreover, the Final Order inaccurately finds that the Department's letter approving Roper Berkeley's CON Application "does not imply that DHEC ever considered the Bon Secours catheterization lab as not existing." Final Order p. 12. To the contrary, the letter states: "there are 11 existing catheterization labs which are open and able to perform the services contemplated by the Applicant's Project." Joint Ex. 1 at 207. The Bon Secours St. Francis Xavier catheterization

laboratory was a 12th laboratory in the applicable service area. *See* Sullivan Trial Tr. 228:11-229:15. The first two pages of the decision directly address the underperforming laboratory and clearly reflects DHEC's interpretation and application of Standard 3 in the review of Roper Berkeley's CON Application. DHEC's decision in this instance is consistent with the 2010 position of Ms. Brandt that the agency could not "discount the existence" of an underperforming laboratory that would remain open and offering the service, because the position of the Department in 2016 was that the utilization of the underperforming laboratory was not relevant for purposes of planning new services under Standard 3 where the at-issue laboratory would be closed and would not remain open and offering the service. The Court's conclusion that the interpretation of Standard 3 challenged here and the prior unrelated discussion of historical utilization in 2010 are "at odds" is in error and directly contradicted by the record. *See e.g.* Platt Trial Tr. 454:4-23 (explaining Ms. Brandt was being asked to ignore the catheterization laboratory, to simply not include it, as opposed to the laboratory being closed).

E. THE COURT ERRED IN CONCLUDING PROVIDERS LACKED NOTICE OF THE PLANNED CLOSURE OF THE CATHETERIZATION LABORATORY.

The Final Order's conclusion that other providers would not be able to submit competing CON Applications based on not having knowledge that "one lab was about to be removed from the State Health Plan inventory" is contrary to the substantial evidence before the Court. Any interested provider would know from multiple public notices that new cardiac catheterization services were being proposed in the service area and would know of the planned closure of the Bon Secours St. Francis Xavier cardiac catheterization laboratory as was laid out in multiple publicly available documents, including the CON Applications of East Cooper Medical Center and Roper Berkeley. In addition to the statutorily required public notices published by the applicants, DHEC published multiple public notices in the State Register addressing the filed applications for

those services. The plan for the laboratory at Bon Secours St. Francis Xavier was laid out repeatedly in the CON Application filed by Roper Berkeley, and the Court's conclusion regarding knowledge of other providers is entirely contradicted by the documents and testimony in the record.

F. THE COURT ERRED IN FAILING TO CONSIDER THE POSITIONS OF TRIDENT BEFORE THE DEPARTMENT.

It is entirely inequitable and unfair to Roper Berkeley and DHEC to ignore and disregard the materially different positions taken by Trident during staff review of the Application. Despite attempts to minimize and deflect the significance of those positions, the opposition letter filed by Trident with the Department speaks for itself, and the Court should not disregard Trident's position below that "DHEC should not recognize BSSFH's diagnostic catheterization program as an existing service merely because only (3) three diagnostic caths are performed on average each year, which is not indicative of an actual program." Joint Ex. 1 at 199. The testimony of the Department was that this opposition letter and the arguments raised by Trident were considered prior to reaching the decision. *See* Eubank Trial Tr. 301:9-22. The outcome now challenged by Trident here, despite having actual notice of the plan with regard to the closure of the Bon Secours St. Francis Xavier laboratory, was never made to DHEC or asserted as an area of noncompliance with the Health Plan Standards. This inequity and unfairness is particularly harsh given that Roper St. Francis permanently closed the laboratory based on DHEC's interpretation of the Health Plan and exercise of its authority.

G. THE FINAL ORDER IS CONTROLLED BY ERRORS OF LAW.

- (1) *The Court fails to adhere to the applicable statutory construction principles.*

When interpreting a regulation, the ALC employs the same rules that govern the construction of statutes. *See Murphy v. S.C. Dept. of Health & Envtl. Control*, 396 S.C. 633, 639,

723 S.E.2d 191, 195 (2012). Likewise, statutory construction principles apply to the interpretation of the Health Plan. *Trident Med. Ctr., LLC v. S.C. Dept. of Health & Envtl Control*, 412 S.C. 341, 355, 772 S.E.2d 177, 184 (Ct. App. 2015) (“[W]e may interpret the State Health Plan using the rules of statutory construction applied to regulations with one caveat, each section of the State Health Plan must be read as a whole.”) Though interpreted using the same principles, the Health Plan is not approved by the General Assembly and the CON Act does not mandate a narrow or strict interpretation of the Health Plan. Section 44-7-210(C) merely states that “[t]he Department may not issue a Certificate of Need unless an application complies with the State Health Plan, Project Review Criteria, and other regulations.” S.C. Code Ann. § 44-7-210(C). Section 44-7-180(B) states that “nothing in this provision shall be construed as requiring the department to approve any project which is inconsistent with the South Carolina Health Plan.” *Id.* at § 44-7-180(B). It is undisputed that determining compliance requires judgment from the Department in its review of the application, as even Trident’s expert explained that there is no definition for what is means to “satisfy” the standards in the Health Plan, nor definitional guidance for what is “consistent with the Health Plan” or “compliance with the Health Plan.” Sullivan Trial Tr. 195:18-196:8.

In the statutory construction analysis, the Final Order completely fails to acknowledge that the inclusion in Standard 3 of the word “existing,” which is not defined in the Health Plan, must have some meaning and is subject to the Department’s reasonable interpretation and application. The case of *Murphy v. South Carolina Department of Health and Environmental Control*, 396 S.C. 633, 723 S.E.2d 191 (2012), is instructive and evidences the errors underlying the Final Order’s reversal of the agency. In *Murphy*, DHEC’s interpretation of the word “vicinity” in its regulations when evaluating the impact of a proposed activity “in the vicinity of the project” was specifically

challenged. 396 S.C. at 637-38, 723 S.E.2d 193-94. The Department testified that the applicable “vicinity” was determined on a case-by-case basis, taking into consideration the project at issue because every project was different. *See id.* at 640, 723 S.E.2d at 195. The opponent argued that “vicinity” meant the portion of the stream to be filled. *See id.* at 638, 723 S.E.2d at 194. The word “vicinity” was not defined in the regulation. *See id.* at 640, 723 S.E.2d at 195. The Supreme Court explained, “we interpret an undefined term in accordance with its usual and customary meaning.” *Id.* at 640, 723 S.E.2d at 195. Turning to Merriam-Webster Dictionary, the Supreme Court determined that the accepted meaning of vicinity “clearly includes more than the just the project; it logically incorporates the surrounding area.” *Id.* The Supreme Court then proceeded to address the deference due to the agency’s interpretation of the undefined term and held “[b]ecause this interpretation is both reasonable and consistent with the plain language of the regulation, we see no reason to deviate from DHEC’s construction and application.” *Id.* at 640-41, 723 S.E.2d at 195.

This Court’s adoption of an interpretation of Standard 3 that ignores the word existing in effect concludes that all labs in the service area are existing labs violates the well-known canon of statutory construction, *inclusion unius est exclusion alterius*, which is to say that including one excludes another. *See e.g. Hodges v. Rainey*, 341 S.C. 79, 86, 533 S.E.2d 578, 581 (2000) (citing Black’s Law Dictionary 602 (7th ed. 1999)). This interpretation is improper given that the Court is expected to reject a definition that renders a term meaningless or futile. *See Murphy*, 396 S.C. at 640, 723 S.E.2d at 195. Inexplicably, the Court finds that the “plain language” of Standard 3 is at odds with DHEC’s interpretation. The error of this finding is apparent given that the inclusion of the word “existing” in Standard 3 necessarily precludes a reading of the Standard that the plain language means “all labs” with no flexibility to interpret what is existing for planning health services in the future. Moreover, the presence of “existing” in Standard 3 but not within Standard

2 is strong evidence that the intent of the Department is to allow flexibility in evaluating utilization and capacity in a circumstance such as this, yet the Final Order makes no mention of this material difference in the terms used in Standard 2 versus Standard 3.

(2) *The Court fails to afford the appropriate level of deference to DHEC's interpretation of Standard 3.*

The Court's conclusions of law fail to adhere to the appropriate deference standards set forth by the Supreme Court. Final Order, p. 16. The matter of agency deference, and particularly the deference to DHEC with respect to its own regulations, was discussed at length in *Kiawah Development Partners, II v. South Carolina Department of Health and Environmental Control*, 411 S.C. 16, 766 S.E.2d 707 (2014). In *Kiawah II*, the Supreme Court detailed the two-step process for determining when agency deference is appropriate. "First, a court must determine whether the language of a statute or regulation directly speaks to the issue. If so, the court must utilize the clear meaning of the statute or regulation. If the statute or regulation is silent or ambiguous with respect to the specific issue, the court must give deference to the agency's interpretation of the statute or regulation, assuming the interpretation is worthy of deference." *Id.* at 32-33, 766 S.E.2d at 717 (internal quotations omitted) (citing *Brown v. Bi-Lo, Inc.*, 354 S.C. 436, 440, 581 S.E.2d 836, 838 (2003) and *Chevron, U.S.A. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984)). The Supreme Court further reiterated, "our deference doctrine provides that courts defer to an administrative agency's interpretations with respect to the statutes entrusted to its administration or its own regulations *unless there is a compelling reason to differ.*" *Kiawah II* at 34, 766 S.E.2d at 718 (internal quotation omitted) (emphasis added). Compelling reasons to differ exist only if the interpretation is "arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 36, 766 S.E.2d at 718 (quoting *Chevron*, 467 U.S. at 844).

In *Kiawah II*, DHEC's interpretation of the "area" to be considered in whether to permit

the construction of a bulkhead and reventment along the shoreline of Kiawah Island pursuant to a Department regulation was rejected by the ALC as being contrary to the meaning of “area” within the regulation. *Kiawah II* at 32, 766 S.E.2d at 717. In reversing the ALC, the Supreme Court held that “DHEC’s interpretation is neither arbitrary, capricious, nor manifestly contrary to the statute. To the contrary, DHEC’s interpretation is reasonable and consistent with its statutory authority.” *Id.* at 35, 766 S.E.2d at 719. The *Kiawah II* Court considered all of the authority vested in the agency to enforce and administer the coastal zone management program, as well as the stated policies behind the empowering Act to conclude the agency interpretation was sound. *See id.*

Here, the Court concludes that DHEC’s interpretation of “existing labs” in applying Standard 3 “is at odds with the plain language of Standard 3, which directs the Department to apply the utilization analysis retrospectively to measure the number of services performed by labs in the service area during the most recent year.” Final Order, p. 17. This conclusion is controlled by an error of law, in that as explained in *Kiawah II*, where a regulation “*is silent or ambiguous with respect to the specific issue*, the court must give deference to the agency’s interpretation of the statute or regulation, assuming the interpretation is worthy of deference.” *Kiawah II* at 32-33, 766 S.E.2d at 717) (emphasis added). It is undisputed that “existing” is an undefined term in the Health Plan and, quite clearly, what is an “existing lab” for purposes of Standard 3 is specifically at issue. Not only is the Court thus faced with silence by way of an undefined material term, but the meaning is otherwise ambiguous and subject to more than one reasonable interpretation. Trident’s own health planning expert testified that there is a “gap in the Standard,” because not being defined, it is ambiguous whether “existing lab” would or would not include an approved but not implemented laboratory. Sullivan Trial Tr. 143:14-144:11. Trident’s expert also opined that DHEC has the flexibility to address that gap and it is the job of the Department to interpret the Health Plan and

apply the standards reasonably. *Id.* at 484:16-23. Also substantial evidence of the ambiguity of the meaning of “existing” for purposes of Standard 3 is the Court’s use of a different dictionary than that used by the Supreme Court in *Murphy* to propose a “plain and ordinary meaning” of existing that offers a fundamentally different result than if the *Murphy* resource was used.

Other than Trident’s displeasure with the outcome, the Court was not presented with any **compelling reason** to differ with DHEC’s interpretation. In fact, the Final Order does not find or conclude that the Department acted arbitrarily, capriciously, or manifestly contrary to the statute, as would be necessary to reject DHEC’s interpretation of “existing” in Standard 3 of its Health Plan. *See Kiawah II* at 34, 766 S.E.2d at 718 (quoting *Chevron*, 467 U.S. at 844). In fact and tellingly, Trident’s displeasure and challenge to DHEC’s interpretation of Standard 3 was only as to Roper Berkeley’s CON Application and was not levied against the same interpretation of Standard 3 as reflected in the approval of East Cooper Medical Center’s CON Application. In both decisions, DHEC concluded that the laboratory at Bon Secours St. Francis Xavier was not an “existing lab” for purposes of Standard 3 and the approval of new diagnostic cardiac catheterization services in the service area.

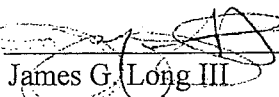
In evaluating deference to DHEC in the interpretation and application of Standard 3, the Court “must be mindful of the General Assembly’s entrustment of South Carolina’s health care marketplace to DHEC for cost containment, prevention of unnecessary duplication of services, serving public needs, and ensuring high quality of healthcare services.” *Trident Med. Ctr.* at 355, 772 S.E.2d at 184 (citing S.C. Code Ann. § 44-7-120). That the Court located a different definition of “existing” does render the definition used by DHEC arbitrary or capricious and the Court’s failure to undertake this second step of the deference doctrine is contrary to the requirements of

the law. *See Kiawah II* at 32-33, 766 S.E.2d at 717. Roper Berkeley respectfully submits this was error.

CONCLUSION

The Court's reversal of the Department's decision must be based on evidence showing by a preponderance of the evidence that the decision was in error, a burden born by Trident. *See Anonymous v. State Bd. of Med. Exam'rs*, 329 S.C. 371, 375, 496 S.E.2d 17, 19 (1998) (holding that the standard of proof in an administrative proceeding is generally the preponderance of the evidence); *Nat'l Health Corp. v. S.C. Dept. of Health and Envtl. Control*, 298 S.C. 373, 379, 380 S.E.2d 841, 844 (Ct. App. 1989) (holding that the preponderance of the evidence standard applies in CON disputes). As set forth herein, the substantial evidence before the Court supports affirmance of the agency's decision and does not reflect by a preponderance of the evidence that the Department erred in approving Roper Berkeley's CON Application. Therefore, Roper Berkeley respectfully requests this Court alter or amend its Final Order and affirm the decision of the Department to approve Roper Berkeley's CON Application.

RESPECTFULLY SUBMITTED,


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Hospital - Berkeley*

December 13, 2018
Columbia, South Carolina

EXHIBIT "A"
(Final Order – Dated 12/03/18)

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

Trident Medical Center, LLC, d/b/a Trident
Medical Center,

Petitioner,

vs.

South Carolina Department of Health and
Environmental Control, and Roper St. Francis
Hospital – Berkeley, Inc., d/b/a Roper St.
Francis Hospital – Berkeley County,

Respondents.

Docket No.: 16-ALJ-07-0386-CC

FINAL ORDER

Appearances:

For Petitioner Trident: William R. Thomas, Esq.

For Respondent Roper: Jennifer J. Hollingsworth, Esq.

For Respondent DHEC: Ashley C. Biggers, Esq.

STATEMENT OF THE CASE

This matter comes before the South Carolina Administrative Law Court (ALC or Court) upon the request of Petitioner Trident Medical Center, LLC, d/b/a Trident Medical Center (Trident) for a contested case hearing to review the decision of the South Carolina Department of Health and Environmental Control (DHEC or Department) granting a Certificate of Need (CON) to Roper St. Francis Hospital - Berkeley, Inc., d/b/a Roper St. Francis Hospital – Berkeley (Roper-Berkeley) for the addition of a new diagnostic cardiac catheterization lab¹ (Project) at its medical facility which is under construction in Berkeley County and is scheduled to open in the fall of 2019.

¹ Diagnostic catheterization is a tool used in the treatment of heart disease whereby a thin flexible tube is inserted into a blood vessel in the arm or leg allowing a doctor to examine the heart and associated blood vessels. See discussion of The Application *infra*.

FILED

DEC 03 2018

SC ADMIN. LAW COURT

Prior to a hearing on the merits, Petitioner filed a Motion for Summary Judgment that was denied by Order dated March 2, 2017. The parties thereafter conducted discovery and prepared the matter for a hearing. The contested case was heard on July 24 and July 25, 2018.²

FINDINGS OF FACT

Pursuant to Rule 25(C) of the Rules of Procedure for the Administrative Law Court (SCALC Rules), the parties submitted written stipulations of fact, which are hereby adopted by the Court and set forth below:

Roper-Berkeley filed a Certificate of Need (CON) Application on May 9, 2016, to construct a catheterization laboratory and provide diagnostic cardiac catheterization services at the Roper-Berkeley Hospital under construction in Berkeley County. The CON Application states that upon approval, the diagnostic catheterization laboratory at Bon Secours St. Francis Xavier Hospital (Bon Secours) will be permanently closed.

The applicable South Carolina Health Plan (State Health Plan) is the Health Plan enacted August 13, 2015.

By decision letter dated July 25, 2016, DHEC approved the CON Application. On August 17, 2016, Bon Secours notified the Department that it permanently closed its diagnostic cardiac catheterization lab effective August 1, 2016.

Trident timely filed a Request for Board Review with the DHEC Board that was denied without review on September 21, 2016.

Trident timely filed a contested case in the Administrative Law Court and is an affected person with standing to challenge DHEC's decision.

Chapter VIII of the State Health Plan is the Chapter addressing cardiovascular care services. Pages VIII-4 and VIII-5 contain the Standards for establishing a new diagnostic catheterization laboratory. Standards 1, 2, 3, and 4 apply to the CON Application. Standards 5 and 6 do not apply the CON Application.

² Prior to the contested case hearing, the parties informed the Court they had agreed to limit the issues before the Court as stated in the parties' stipulation of facts.

Standard 1 sets forth the capacity for cardiac catheterization laboratories in South Carolina based on the complexity of the services provided. Standard 2 sets forth the service area for cardiac catheterization laboratories based on the complexity of the services provided. Standard 3 sets forth the historical utilization threshold for approval of a new diagnostic catheterization laboratory in a service area. Standard 4 sets forth the minimum projected utilization for approval of a new diagnostic catheterization laboratory in a service area.

The facilities in the relevant service area with cardiac catheterization laboratories at the time of the CON Application's submission were Trident Medical Center, Roper Hospital, Medical University of South Carolina, and Bon Secours. All of the catheterization laboratories except Bon Secours were comprehensive catheterization laboratories. In 2014, Bon Secours reported in its Joint Annual Report to DHEC that 4 diagnostic catheterization procedures had been performed in its catheterization lab. In 2015, Bon Secours reported in its Joint Annual Report to DHEC that 2 diagnostic catheterizations had been performed.

The catheterization laboratories at Trident, Roper Hospital, and the Medical University satisfy the historical utilization threshold under Standard 3. The parties dispute whether the CON Application satisfies Standard 3 and, therefore, whether it complies with S.C. Code Ann. Regs. 61-15 § 802.1.

Initially, Trident challenged many aspects of the CON Application, but for efficiency and judicial economy, it has decided to withdraw its challenge to the CON Application in every respect with the exception of challenging whether the CON Application satisfies Standard 3. Trident asserts that because the CON Application does not satisfy Standard 3, the Application does not comply with the State Health Plan and, as such, is not consistent with the State Health Plan per Reg. 61-15 § 801.3 and S.C. Code Ann. § 44-7-210(B). Therefore, Trident contends that DHEC erred in approving the CON Application.

The parties recognize that Trident has withdrawn its challenges to the CON Application save the challenge concerning Standard 3, and while Trident may not agree with the following conclusions, the parties so stipulate to effectuate the contested case hearing for purposes of limiting the issues in dispute:

- (a) The CON Application satisfies Standard 4.

- (b) Reg. 61-15 is applicable to the CON Application.
- (c) The CON Application sufficiently projects Community Need to satisfy Section 802.2 of the Project Review Criteria (PRC).
- (d) The CON Application sufficiently meets the requirements for Distribution (Accessibility) set forth in Section 802.3 of the PRC.
- (e) The CON Application establishes financial feasibility set forth in Section 802.15 and related financial sections of the PRC.
- (f) The CON Application sufficiently meets the requirements of cost containment set forth in Section 802.16 of the PRC.
- (g) The CON Application will not have an adverse effect on other facilities as defined by Sections 802.23 and 802.24 of the PRC.
- (h) Any additional PRC applicable to the CON Application have been satisfied with the exception of Section 802.1, which relates to the parties' dispute as to Standard 3.
- (i) Section 500 of Reg. 61-15 is not applicable to the CON Application.

Dan Sullivan is qualified to testify as an expert witness pursuant to Rule 702 of the South Carolina Rules of Evidence (SCRE), under the designations of healthcare planning and the State Health Plan.

Kathy Platt is qualified to testify as an expert witness pursuant to Rule 702, SCRE, under the designations of healthcare planning and the State Health Plan.

In addition to these stipulations of fact, and having observed the witnesses and exhibits presented at the hearing and closely passed upon their credibility, taking into consideration the burden of proof upon the parties, I make these additional Findings of Fact by a preponderance of the evidence:

Parties

The Roper St. Francis Healthcare system consists of four hospitals: Roper Hospital on the Charleston Peninsula; Bon Secours in West Ashley; Mount Pleasant Hospital in Mount Pleasant; and Roper-Berkeley under construction in Berkeley County. At the time the CON Application was

filed in May 2016, Roper St. Francis Healthcare had four (4) licensed cardiac catheterization laboratories: three comprehensive catheterization laboratories at Roper Hospital and one diagnostic catheterization laboratory at Bon Secours in West Ashley.

Trident is an existing provider of cardiac catheterization services in Roper-Berkeley's proposed service area.

The Application

Roper-Berkeley filed a CON Application on May 9, 2016, proposing to establish diagnostic catheterization services at the Roper-Berkeley Hospital under construction in Goose Creek. DHEC reviewed the Application under the 2015 South Carolina Health Plan, which was enacted August 13, 2015.

Cardiovascular services subject to CON review include diagnostic catheterizations, therapeutic catheterizations, and percutaneous coronary interventions, as well as pediatric catheterizations and open-heart surgery.

A diagnostic catheterization is a procedure that involves threading a catheter through a vessel and using imaging equipment to photograph what is happening in those vessels. A therapeutic catheterization involves the same vessel imaging but also includes treatment procedures such as removing a blockage or inserting a stent.

Cardiac catheterizations are performed in a catheterization laboratory. Laboratories may be designated as providing only diagnostic catheterization services or may be designated as a comprehensive catheterization laboratory if both diagnostic and therapeutic catheterization services are provided in the laboratory. Roper-Berkeley's CON Application seeks to provide diagnostic catheterizations in a diagnostic catheterization laboratory.

The State Health Plan includes an inventory of cardiac catheterization services showing existing cardiac catheterization providers in the various regions of the state. The relevant region in this case is Region 4. In addition to the number of catheterization labs that each provider operates by region, the inventory also shows the historical utilization of those catheterization labs for certain years, in this case 2011, 2012, and 2013.

The purpose of the State Health Plan inventory for cardiac catheterization is to allow interested parties to identify existing providers in the service area and the historical utilization of each lab in

a given area. It also provides a reference point for applicants for health services to determine if existing providers are operating in conformity with the applicable standards, such as Standard 3. In doing so, the State Health Plan's cardiac catheterization lab inventory also allows a potential applicant to determine whether a new cardiac catheterization lab is needed in the service area.

CON applicants also obtain and review the relevant Joint Annual Reports (JAR) filed by the hospitals to analyze more recent utilization data. Moreover, it is standard practice for the Department to rely on the updated utilization data in the JAR when making a decision according to a State Health Plan that may be one or two years old.

Among the applicable standards in the Health Plan that must be satisfied for new diagnostic catheterization services, Trident only challenges Standard 3, which states that "[n]ew diagnostic catheterization services, including mobile services, shall be approved **only if all existing labs** in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year (emphasis added)."³

Standard 3 is a community-need standard that references utilization in the service area. In this case, the service area is a 45-minute drive time around the proposed Goose Creek location for new diagnostic catheterization services. Standard 3 is used to determine whether the existing labs in the service area are well utilized, which is of paramount importance for health planning. To measure the need for another cardiac catheterization lab one must know whether existing labs are being sufficiently utilized.

Standard 3 is an objective measure of utilization and uses the phrase "have performed," which calls for a retrospective view to determine if existing providers have satisfied the 500-procedure threshold. Standard 4, by contrast, is a prospective standard indicating what the Department expects the applicant to perform in the future.

Standard 3 also establishes whether there is a community need using objective measures. In tandem with the CON Act, the volume threshold set forth in Standard 3 seeks to avoid unnecessary duplication of catheterization labs, which can affect quality.

³ "The most recent year" refers to the completed year for which annual utilization data is available, in contrast to the current year.

Although Standard 3 does not directly reference quality, the Department does consider quality throughout the cardiovascular service chapter regarding case volume standards. In the context of Standard 3 and "quality," approving an unneeded lab could result in reducing the case volumes of existing providers. As stated in the 2015 State Health Plan, reduced case volumes diminish quality because "[o]ptimal performance requires a caseload of adequate size to maintain the skills and efficiency of the staff." (Cardiovascular Care, p. VIII-2)

Prior to its CON Application for Roper-Berkeley, Roper St. Francis did not notify the Department that it had closed or intended to close its catheterization lab at Bon Secours, although there were years when it reported the facility did not perform any catheterization procedures. Rather, the Department and Roper St. Francis **agreed** to the closure of Bon Secours' catheterization lab contingent upon and following approval of the CON Application for Roper-Berkeley.

It is clear from the record that as far back as 2010, DHEC Staff was aware of the substantial underperformance occurring in the catheterization lab at Bon Secours. In a May 27, 2010, letter involving a separate CON Application, the Department informed the Chief Operating Officer of East Cooper Medical Center that, "[b]ased on our review of the standards in the 2008-2009 South Carolina Health Plan and the CON law and regulations, we have determined that [the Department] does not currently have a mechanism in place that would allow the Department to discount the existence of the [Bon Secours] cardiac catheterization lab when computing the average utilization for the service area." The Department went on to "...recognize that continuing to inventory a service that has remained idle for three years can negatively impact the ability of other providers to offer that service." This letter was generated in the context of East Cooper Medical Center's desire to apply for a CON for new diagnostic catheterization services in 2010 while recognizing that Bon Secours' catheterization lab had been operating at very low or zero volumes in the previous years. The Department acknowledged that the appropriate remedy would be to amend the State Health Plan for 2010-2011 to allow adjustments for "unused" beds or equipment; however, no such steps were taken.⁴

DHEC Staff again became aware of the low catheterization utilization at Bon Secours following the Department's receipt of another East Cooper Medical Center CON Application on February 4,

⁴ See Joint Exhibit 2, p.081.

2016. In this application, East Cooper contended that the Bon Secours' catheterization lab should be considered non-operational for purposes of the Health Plan inventory because Bon Secours' lab was in violation of S.C. Reg. 61-15, Section 102(1)(e), which requires a person or facility to obtain a CON before offering any health service that was not offered in the preceding twelve-month period.⁵

Louis Eubank, the CON Program Director for DHEC, reviewed Roper-Berkeley's CON Application and made the decision on behalf of the Department to approve the Application. When applying CON Standard 3 to Roper-Berkeley's CON Application, he was aware that the diagnostic catheterization lab at Bon Secours was underutilized. Specifically, the JAR data showed that Bon Secours performed zero catheterization procedures in 2007, 2008, and 2009, resuming in 2010 with very low utilization.⁶

In fact, Mr. Eubank emailed counsel for Roper-Berkeley on April 14, 2016, a few weeks prior to Roper-Berkeley's submission of its CON Application, to inform him that the Department was considering enforcement action against Bon Secours for violating S.C. Reg. 61-15, Section 102(1)(e) by failing to obtain a new CON prior to performing diagnostic catheterization procedures beginning in 2010, after performing no catheterization procedures for the previous three years. Eubank wrote that the continued operation of the Bon Secours catheterization lab at such low volume was prohibiting the entry of any additional catheterization labs in the service area as outlined in State Health Plan standards for such services. Further, Eubank noted that the low volume would also likely prohibit the transfer of Bon Secours' catheterization lab from the operator's facility to another Roper St. Francis-owned facility under the service transfer criterion which requires adequate historic utilization figures. In the same email, the Department invited Roper to propose a solution within ten business days of the receipt of the email.⁷

Notably, although clearly aware that the lab had been operating in violation of Standard 3 since at least 2010, at no time did the Department undertake any enforcement action against Bon Secours.

⁵ S.C. Reg. 61-15, Section 102(1)(e) states "A person or health care facility as defined in this Regulation is required to obtain a [CON] from the [Department] before undertaking any of the following: ... the offering of any health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan."

⁶ This information is found in Joint Exhibit 2, at page 077 and in Petitioner's Exhibit 3, 007, 008, and 010, and in Petitioner's Exhibit 5, 011. Subsequent references in other documents, *infra*, allude to 2008 and 2009 only.

⁷ See Petitioner's Exhibit 5, p. 001.

Also, Mr. Eubank later testified that, given the period of not performing the required volume of catheterization procedures, he did not consider Bon Secours to be an existing catheterization lab for purposes of review of Standard 3 in 2016. Nevertheless, Bon Secours was included in the inventory of existing cardiac catheterization providers in the service area in the State Health Plan inventory.

In a letter to DHEC dated April 20, 2016, Bon Secours asked to be an affected person with respect to East Cooper's 2016 CON Application for a new diagnostic catheterization lab. As to East Cooper's claim that Bon Secours' catheterization lab was non-operational, Bon Secours wrote that East Cooper's position regarding the Bon Secours catheterization lab was inconsistent with the applicable CON laws and the State Health Plan. It further contended that until the CON Application for diagnostic catheterization services at Roper-Berkeley was approved, Bon Secours intended to operate its catheterization lab. However, at this time, Roper-Berkeley had not yet filed a CON Application for diagnostic catheterization services. Curiously, the letter makes clear that Roper St. Francis did not intend to close the Bon Secours lab if the Roper-Berkeley Application was not approved – only that the Bon Secours lab would be closed upon approval of the Project.

On April 22, 2016, two days after the Department received an affected person letter from Roper-Berkeley's legal counsel regarding East Cooper's CON Application, but more than two weeks prior to receiving Roper-Berkeley's CON Application, Mr. Eubank sent East Cooper's representative an email with the subject line "Notice from Roper/St. Francis" stating that, "I think everything will work out just fine for everyone."

Nineteen days after its affected person letter to DHEC regarding East Cooper's CON Application, Roper-Berkeley submitted its own CON Application stating that upon approval of the Application to establish diagnostic catheterization services at Roper-Berkeley, the diagnostic catheterization laboratory at Bon Secours would be permanently closed.

The CON Application includes relevant detail and documentation establishing the current and projected population growth for Berkeley, Dorchester, Colleton, and Charleston Counties, as well as data establishing the historical and projected utilization for all four of the Roper St. Francis system's cardiac catheterization laboratories.

The diagnostic catheterization laboratory at Bon Secours, discussed *infra*, was being underutilized even though the remaining cardiac catheterization laboratories in the applicable service area were well utilized.

DHEC approved the CON Application to add diagnostic catheterization services at Roper-Berkeley by decision letter dated July 25, 2016.⁸ On August 17, 2016, Bon Secours notified DHEC that it permanently closed its diagnostic catheterization laboratory on August 1, 2016.

Need for a Diagnostic Cardiac Catheterization Lab in the Service Area

The facilities in the relevant service area with cardiac catheterization laboratories at the time of the CON Application's submission were Trident Medical Center, Roper Hospital, Medical University of South Carolina, and Bon Secours. These catheterization laboratories, except Bon Secours' catheterization laboratory, were comprehensive catheterization laboratories. The eleven other catheterization laboratories at Trident, Roper Hospital, and the Medical University satisfy the historical utilization requirements under Standard 3.

In its CON Application, Roper-Berkeley classified Bon Secours as an existing lab and listed the volume for the Bon Secours diagnostic catheterization lab under Exhibit 14 entitled "Historical Utilization of Existing Labs in the Service Area." It also included utilization from 2012 to 2014, which showed that in no year was Bon Secours' catheterization volume over the 500-procedure threshold set forth in Standard 3. Following the table for Exhibit 14, the CON Application states, "[w]hile Bon Secours St. Francis Xavier Hospital is operating below the 500 diagnostic equivalents per year, the lab will be closed upon the approval of this project"

Nowhere in the CON Application does Roper-Berkeley state that the Bon Secours catheterization lab is non-operational or non-existent, only that it **will close** and, therefore, will not exist **after** the approval of the CON Application. The Application does not imply, or otherwise state, that the Department recognizes that Bon Secours is not offering diagnostic catheterization services.

In 2007, 2008, and 2009, Bon Secours reported in its JAR that no catheterization procedures were performed in its lab. The Department also had JAR data available as late as 2015 indicating that Bon Secours was operating well under the 500-catheterization-procedures standard. The Department, however, exercised its discretion not to take enforcement action under the CON

⁸ DHEC also approved East Cooper's CON Application for a diagnostic catheterization lab on the same day.

statute and regulation. The Department also did not suspend or fine Bon Secours, though such measures were available. Thus, Bon Secours' lab was not closed nor was it ever officially determined to be operating in violation of the law. Moreover, Bon Secours was not removed from the catheterization lab inventory of the State Health Plan even though the Department indicated as far back as 2010 that the appropriate remedy would be to amend the Plan.

Furthermore, Roper-Berkeley's legal counsel contended during the 2010 East Cooper application review process that Bon Secours **offered** catheterization services during two zero years (2008 and 2009). Indeed, Roper-Berkeley's position in its affected-person letter during the 2016 East Cooper application process emphasized that Bon Secours was an existing facility, had not lost its CON authorization, and would continue to operate its catheterization lab until Roper-Berkeley's CON Application was approved.

The most recent report available for DHEC review in considering the CON Application was the 2015 JAR. In it, Bon Secours reported that two diagnostic catheterization procedures had been performed in its lab; it reported four for 2014. Mr. Sullivan, on behalf of Trident, stated in his July 21, 2016, opposition letter to Roper-Berkeley's Catheterization Lab Project that "[a]ll existing labs in the service area have not performed a minimum of 500 diagnostic catheterization procedures per laboratory in 2015." Mr. Sullivan includes in his letter a chart, prepared from the relevant hospital JAR, also showing that four catheterization procedures were performed in Bon Secours' catheterization lab.⁹

Because Bon Secours' catheterization lab was still included in the 2015 State Health Plan inventory, it reported catheterization procedures, as required, to the Department in 2015, the year immediately preceding the Roper-Berkeley CON Application at issue.

At the hearing, Ms. Platt, who served as the health planning consultant for Roper-Berkeley, testified that she considered Bon Secours to be non-existing because it would not exist at the same time as Roper-Berkeley's proposed catheterization lab. However, Bon Secours is prominently included in the Roper-Berkeley CON Application exhibit entitled "Historical Utilization of Existing Labs in the Service Area."

⁹ The JAR actually states two diagnostic catheterizations, while "four" refers to a total of "other" procedures.

As mentioned above, Roper-Berkeley's CON Application provides that upon approval of the Application to establish diagnostic catheterization services at Roper-Berkeley, the diagnostic catheterization laboratory at Bon Secours would be permanently closed.

Typically, an applicant will agree to close a service upon the approval of a CON Application if it involves the transfer of the service. However, as Trident's expert, Mr. Sullivan, testified and stated in Trident's opposition letter to Roper-Berkeley's CON Application, Bon Secours did not have a historical utilization pattern that could merit a transfer. Indeed, the Department agreed with this position in the aforementioned April 14, 2016, email from Mr. Eubank to counsel for Roper-Berkeley stating that the low volume at Bon Secours' catheterization lab "prohibits the entry of any additional catheterization labs in the service area as outlined in SC Health Plan standards for such services" and would likely prohibit the transfer of the lab from Bon Secours to Roper-Berkeley. Nevertheless, despite taking such a position on April 14th and within days of receiving Trident's letter in opposition to the Roper-Berkeley Project, the Department issued the letter of July 25, 2016, approving the Roper-Berkeley CON Application.

In the decision letter approving the Roper-Berkeley Project, DHEC acknowledges that Bon Secours' catheterization lab fell below the 500 procedure-threshold mandated by the State Health Plan in discussing Standard 3. DHEC also noted that the applicant agreed to shut down its diagnostic catheterization lab upon approval of the Application under consideration for Roper-Berkeley. Purportedly, DHEC staff believed this prospective closing allowed the Department to discount the historical utilization levels of the Bon Secours lab. The Department states in its decision letter that with the agreed upon closure of the Bon Secours lab, the Department concludes that the other remaining diagnostic catheterization labs within the service area operate at a capacity that would not preclude the addition of the diagnostic catheterization lab at Roper-Berkeley.

The approval letter does not imply that DHEC ever considered the Bon Secours catheterization lab as not existing. In fact, the decision letter references Bon Secours' catheterization lab utilization during the years 2010-2014, all years in which Bon Secours reported few procedures performed. Even though the Department later claims to have used Bon Secours' zero-volume years (2007—2009) as a basis to find that its catheterization lab did not exist for purposes of Standard 3, its

approval letter does not refer to those years, nor does it state that Bon Secours was not offering diagnostic catheterization services during those years.¹⁰

On August 17, 2016, Bon Secours sent the Department a letter indicating it had “permanently closed its diagnostic cardiac catheterization lab on August 1, 2016,” which is seven days after the Roper-Berkeley Catheterization Lab Project was approved. It is clear that Bon Secours discontinued operations of its catheterization lab only after the Department issued its decision letter approving the Project.

CONCLUSIONS OF LAW

Based on the foregoing Stipulations and Findings of Fact, I conclude the following as a matter of law:

The ALC has jurisdiction over this matter pursuant to S.C. Const. art. I, § 22; S.C. Code Ann. §§ 1-23-320, -600(B), 44-1-60(F), and 44-7-210(E); 3 S.C. Code Ann. Regs. 61-15; and Rule 11 of the SCALC Rules. Trident timely filed its request for a contested case hearing regarding DHEC’s decision. *See* 3 S.C. Code Ann. Regs. 61-15 § 401. Because Trident is an existing provider of cardiac catheterization services in the service area, it is an “affected person” for the purposes of participating in a contested case related to DHEC’s decision. *See* S.C. Code Ann. § 44-7-130(1) (2018); 3 S.C. Code Ann. Regs. 61-15 § 103(1).

A contested case hearing conducted before this Court in a CON matter is a trial *de novo*, in which “the whole case is tried as if no trial whatsoever had been had in the first instance.” and the administrative law judge conducting the hearing is the sole finder of fact, who “must make sufficiently detailed findings supporting the denial or grant of a permit application.” *Marlboro Park Hosp. v. S.C. Dep’t of Health & Envtl. Control*, 358 S.C. 573, 579, 595 S.E.2d 851, 854 (Ct. App. 2004) (quoting *Blizzard v. Miller*, 306 S.C. 373, 412 S.E.2d 406 (1991) and *Converse Power Corp. v. S.C. Dep’t of Health & Envtl. Control*, 350 S.C. 39, 564 S.E.2d 341 (Ct. App. 2002)). The weight and credibility assigned to evidence presented at the hearing of a matter is within the province of the trier of fact. *S.C. Cable Television Ass’n v. S. Bell Tel. & Tel. Co.*, 308 S.C. 216, 222, 417 S.E.2d 586, 589 (1992). The trier of fact may also give an expert’s testimony the weight he or she determines it deserves, *Florence Cty. Dep’t of Soc. Servs. v. Ward*, 310 S.C. 69, 425

¹⁰ It is curious that the Department appears to negotiate the future closure of a facility (Bon Secours) that it considered to be non-existing at the time.

S.E.2d 61 (Ct. App. 1992), and may accept the testimony of one expert over that of another. *S.C. Cable Television Ass'n, supra*.

Finally, the CON Act states that “the Administrative Law Court ... shall consider the South Carolina Health Plan in place at the time the application was filed and may consider the current South Carolina Health Plan when making its decision.” S.C. Code Ann. § 44-7-225 (2018).

Regulatory Framework

This matter arises under the regulatory program by which the State of South Carolina issues CONs for the development of health care facilities and services. The regulatory scheme consists of the State Certification of Need and Health Facility Licensure Act (CON Act), S.C. Code Ann. § 44-7-110 *et seq.* (2018 & Supp. 2017); 3 S.C. Code Ann. Regs. 61-15 (Supp. 2017); and a State Health Plan, which is revised at least biannually. The purposes of the CON Act, and thus the regulatory program itself, are to “promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure high quality services are provided in health facilities in this State.” *See* S.C. Code Ann. § 44-7-120 (2018).

The CON Regulations require that:

On the basis of staff review of the record established by the Department, including but not limited to, the application, comments from affected persons and other persons concerning the application, data, studies, literature and other information available to the Department, the staff of the Department shall make a proposed decision to grant or deny the Certificate of Need.

3 S.C. Code Ann. Regs. 61-15 § 308 (Supp. 2017).

In determining whether to grant or deny an application for a CON, the Department evaluates the proposed project under the review criteria found in the CON Regulations and under the policies and standards set forth in the applicable State Health Plan. S.C. Code Ann. § 44-7-210(B) (2018). Pursuant to the CON Act, the Department may not issue a CON to an applicant “unless the application complies with the South Carolina Health Plan, Project Review Criteria, and other regulations.” *Id.*; *see also MRI at Belfair, LLC v. S.C. Dep’t of Health and Envtl. Control*, 379 S.C. 1, 9, 664 S.E.2d 471, 475 (2008) (holding that compliance with the State Health Plan and the Project Review Criteria (PRC) were independent requirements for approval of a CON). The Department can refuse to issue a CON based on PRC and other regulations it identifies even if an

application complies with the State Health Plan. S.C. Code Ann. § 44-7-210(B). But no project can be approved unless it is consistent with the State Health Plan. 3 S.C. Code Ann. Regs. 61-15 § 307(1). When CON applications are considered competing, "the [D]epartment shall award a [CON], if appropriate, on the basis of which, if any, most fully complies with the requirements, goals, and purposes of [the CON Act] and the State Health Plan, Project Review Criteria, and the regulations adopted by the department." S.C. Code Ann. § 44-7-210(B).

The PRC set forth in Regulation 61-15 include thirty-three separate criteria that fall into five general categories: (1) criteria related to the need for the proposed project; (2) criteria related to the economic considerations of the project; (3) criteria related to the project's impact on the resources of the health care system; (4) criteria related to the suitability of the site of the project; and (5) criteria related to certain special circumstances, such as the project's ability to serve medically underserved groups. *See* 3 S.C. Code Ann. Regs. 61-15 §§ 801(1), 802. Only the first criterion is at issue in this case.

As required by the CON Act, the State Health Plan contains the following statistics, standards, and findings with regard to the various facilities and services regulated by the CON Act:

- (1) an inventory of existing health care facilities, beds, specified health services, and equipment; (2) projections of need for additional health care facilities, beds, health services, and equipment; (3) standards for distribution of health care facilities, beds, specified health services, and equipment including scope of services to be provided, utilization, and occupancy rates, travel time, regionalization, other factors relating to proper placement of services, and proper planning of health care facilities; and (4) a general statement as to the project review criteria considered most important in evaluating Certificate of Need applications for each type of facility, service, and equipment, including a finding as to whether the benefits of improved accessibility to each such type of facility, service, and equipment may outweigh the adverse affects [sic] caused by the duplication of any existing facility, service, or equipment.

S.C. Code Ann. § 44-7-180(B). The State Health Plan section applicable to the establishment of Roper-Berkeley's Catheterization Lab Project is found in Chapter VIII, beginning at page VIII-1. The Standards applicable to the project begin at page VIII-4.

Standard 3 set forth in the Health Plan's section on new diagnostic catheterization services states that "[n]ew diagnostic catheterization services, including mobile services, shall be approved **only if all existing labs** in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year (emphasis added)[.]"

“Because the legislature has required these stringent requirements for the State Health Plan’s implementation, it is clear the legislature intended for the State Health Plan to be an enforceable document.” *Trident Med. Ctr. v. S.C. Dep’t of Health & Envtl. Control*, 412 S.C. 341, 350, 772 S.E.2d 177, 182 (Ct. App. 2015), *cert. denied* (Dec. 18, 2015). As such, the Court must interpret the Health Plan using the rules of statutory construction. *See id.* at 355, 772 S.E.2d at 184. “The question of statutory interpretation is one of law for the court to decide.” *Alltel Commc’ns, Inc. v. S.C. Dep’t of Revenue*, 399 S.C. 313, 316, 731 S.E.2d 869, 870 (2012). “Under the plain meaning rule, it is not the court’s place to change the meaning of a clear and unambiguous statute.” *Hodges v. Rainey*, 341 S.C. 79, 85, 533 S.E.2d 578, 581 (2000).

If a statute’s language is plain and unambiguous and conveys a clear and definite meaning, there is no occasion for employing rules of statutory interpretation and the court has no right to look for or impose another meaning. *Paschal v. State Election Comm’n*, 317 S.C. 434, 436, 454 S.E.2d 890, 892 (1995).

“The words of a regulation must be given their plain and ordinary meaning without resort to subtle or forced construction to limit or expand the regulation’s operation.” *Byerly v. Connor*, 307 S.C. 441, 444, 415 S.E.2d 795, 799 (1992).

A two-step process is required when interpreting and applying statutes and regulations administered by an agency. *Kiawah Dev. Partners, II v. S.C. Dep’t of Health & Envtl. Control*, 411 S.C. 16, 32, 766 S.E.2d 707, 717 (2014). “First, a court must determine whether the language of a statute or regulation directly speaks to the issue. If so, the court must utilize the clear meaning of the statute or regulation.” *Id.* (citing *Brown v. Bi-Lo, Inc.*, 354 S.C. 436, 440, 581 S.E.2d 836, 838 (2003)). Statutes and regulations that are silent or ambiguous are entitled to some level of deference. However, when an agency’s interpretation is arbitrary, capricious, or manifestly contrary to the statute or regulation at issue, the agency’s interpretation is not entitled to deference. *Id.* at 34, 766 S.E.2d at 718.

Approval of the Project

The Court must determine whether Roper-Berkeley’s Project should be approved under the CON Act, its regulations, and the State Health Plan. 3 S.C. Code Ann. Regs. 61-15 § 307(1).

While a project does not have to satisfy every Project Review Criterion to be approved, no project may be approved unless it is consistent with the State Health Plan. Here, the approval of the Project violates Standard 3 and is, thereby, inconsistent with the State Health Plan.

Standard 3 states that “[n]ew diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area **have performed** a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year (emphasis added) [.]” Roper-Berkeley would be a new diagnostic catheterization service. Therefore, each of the labs **existing** in the service area in which Roper-Berkeley would operate must have performed at least 500 diagnostic catheterization procedures per laboratory during the twelve months prior to the submission of Roper-Berkeley’s CON Application, when the review process begins. This determination of historical utilization is clearly retrospective, not prospective. There is no dispute that Bon Secours was not performing the minimum of 500 diagnostic catheterization procedures during the year prior to the filing of Roper-Berkeley’s CON Application.

The only remaining issue is whether Bon Secours was “existing.” DHEC and Ms. Platt take the position that “existing labs” means labs that will exist at or following the approval of the project. However, this interpretation is at odds with the plain language of Standard 3, which directs the Department to apply the utilization analysis retrospectively to measure the number of services performed by labs in the service area during the most recent year. Interestingly, this interpretation is also at odds with positions taken by the Department in both 2010 and earlier in 2016 when East Cooper submitted its CON Applications.

A court may look to a dictionary to determine the plain and ordinary meaning of statutory terms. *Liberty Mut. Ins. Co. v. S.C. Second Injury Fund*, 363 S.C. 612, 623-24, 611 S.E.2d 297, 302-03 (“Dictionaries can be helpful tools during the initial stages of legal research for the purpose of defining statutory terms... The words of a statute must be given their plain and ordinary meaning without resorting to subtle or forced construction[.]”) (Ct. App. 2005) (citations omitted). “Existing” may be defined as “in existence or operation at a current time.”¹¹ The Court interprets “existing” as used in Standard 3 to mean that a lab is open and is offering and has the capacity to provide catheterization services to patients, as Bon Secours did, at the time a CON Application is

¹¹ See <https://en.oxforddictionaries.com/definition/existing> (last visited on October 24, 2018).

filed. Given that Bon Secours offered cardiac catheterization services and reported a volume greater than zero during the most recent year prior to Roper-Berkeley's CON Application, it would be illogical to conclude that Bon Secours did not have an "existing lab" for the purposes of Standard 3.

The facts in this case also reflect that DHEC did not properly apply the term "existing" to the Bon Secours lab prior to approving Roper-Berkeley's CON Application.

In 2007, 2008, and 2009, Bon Secours reported that there were no catheterization procedures performed in its lab. The Department reviews these reports to determine utilization of **existing** providers. For 2015, Bon Secours reported that only two diagnostic catheterization procedures were performed. Bon Secours was not removed from the catheterization lab inventory and was included through 2015, the most recent year prior to Roper-Berkeley's CON Application. Roper itself, in its affected person's letter dated April 20, 2016, responding to East Cooper's CON Application, considered Bon Secours to be an existing facility that would continue to operate. Notwithstanding being out of compliance with the Standard 3 threshold, Bon Secours remained open and available to perform procedures up to and days after the approval of the Roper-Berkeley Application. For unknown reasons, the Department took no enforcement action to fine or suspend Bon Secours under the CON statute and regulations.

Further, the April 14, 2016, email from Mr. Eubank to counsel for Roper-Berkeley indicated that the low volume at Bon Secours' catheterization lab "prohibits the entry of any additional cath labs in the service area as outlined in SC Health Plan standards for such services" and would likely prohibit the transfer of the lab from Bon Secours to Roper-Berkeley. This statement confirms that DHEC considered Bon Secours to be an existing lab. Even in its approval letter, the Department does not refer to the years in which Bon Secours performed no catheterization procedures, nor does it indicate that Bon Secours did not offer diagnostic catheterization services during the years in which no procedures were reported. In the email, DHEC's invitation to Roper-Berkeley to propose a solution suggests that something needed to be done about Bon Secours as an existing facility in order for Roper-Berkeley to obtain a CON. However, although DHEC and Roper agreed to shut down Bon Secours before beginning operation, this future condition did not change the status of Bon Secours as an existing facility at the inception of the application process. Nor, did

the prospective agreement allow for other providers to submit competing CON Applications with the knowledge that one lab was about to be removed from the State Health Plan inventory.

There are simply no provisions or exceptions in the State Health Plan or in Reg. 61-15 that allow the Department to ignore the fact that a diagnostic catheterization lab is operating below the Standard 3 required threshold or, in the alternative, to agree on its future closing as a condition of approving a new application.

For the Department to allow an applicant to circumvent the requirements specified in the Health Plan by conditional actions, such as closing a lab upon the approval of an application, would allow an underperforming lab to serve as a "place-holder" to frustrate potential applicants who seek to provide a health service. A potential competitor reviews the inventory, finds a below-threshold provider, and concludes that no CON application could comply with Standard 3. On the contrary, a service provider should be able to rely on publicly available information, such as the State Health Plan and the most recent JAR, to find accurate and reliable data upon which to make business decisions in government-regulated areas such as those administered by DHEC.

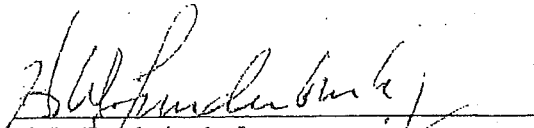
I find that Bon Secours was an existing lab offering and providing cardiac catheterization procedures in the service area in which Roper-Berkeley seeks to establish a new diagnostic catheterization lab, and that Bon Secours was not performing a minimum of 500 diagnostic catheterization procedures as Standard 3 requires for the twelve months prior to the filing of Roper-Berkeley's CON Application. Accordingly, Roper-Berkeley's CON Application to provide new diagnostic catheterization services in the service area is inconsistent with the State Health Plan.

ORDER

IT IS THEREFORE ORDERED that the Certificate of Need for Roper-Berkeley's proposed project for a diagnostic cardiac catheterization lab in Goose Creek, Berkeley County, South Carolina is **DENIED**.

AND IT IS SO ORDERED.

December 3, 2018
Columbia, South Carolina


H.W. Funderburk, Jr.
Administrative Law Judge

FILED

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SC ADMIN. LAW COURT

CERTIFICATE OF SERVICE

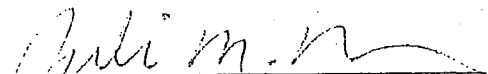
I, Julia M. Miller, hereby certify that I have this date served this Order upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, in the Interagency Mail Service, or by electronic mail to the address provided by the party(ies) and/or their attorney(s).

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December 3, 2018
Columbia, South Carolina


Julia M. Miller
Judicial Law Clerk

FILED

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SC ADMIN LAW COURT

FILED

DEC 03 2018

SC ADMIN. LAW COURT

Docket No.: 2016-ALJ-07-0386-CC

Petitioner,

vs.

South Carolina Department of Health and
Environmental Control and Roper St.
Francis Hospital – Berkeley, Inc., d/b/a
Roper St. Francis Hospital – Berkeley,

Respondents.

**PETITIONER'S RESPONSE TO
RESPONDENT ROPER ST. FRANCIS
HOSPITAL – BERKELEY'S MOTION TO
ALTER OR AMEND**

Petitioner Trident Medical Center, LLC, d/b/a Trident Medical Center (“Trident”), by and through its undersigned counsel, hereby responds to Respondent Roper St. Francis Hospital – Berkeley, Inc., d/b/a Roper St. Francis Hospital – Berkeley’s (“Roper”) Motion to Alter or Amend and respectfully requests that the Court deny Roper’s Motion for the reasons set forth herein.

A. THE COURT CORRECTLY INTERPRETED THE STATE HEALTH PLAN

Roper alleges that the Court erred in interpreting the South Carolina Health Plan, enacted August 13, 2015 (“State Health Plan”) in a manner contrary to that of the Department. This argument presumes that the Department’s interpretation of the State Health Plan is entitled to deference. In fact, Roper implies that the Court must defer to the Department’s interpretation merely because the Department drafts the Plan and oversees the Certificate of Need (“CON”) program. However, there is nothing in the State Certification of Need and Health Facility Licensure Act (S.C. Code Ann. §§ 44-7-110 *et seq.*) (“CON Act”) that supports Roper’s contention. Trident does not dispute that the Department is the “sole state agency [designated] for control and administration of the granting of Certificates of Need and licensure of health facilities.” S.C. Code Ann. § 44-7-140. *See* Mot., p. 2. Indeed, Trident does not disagree with

Roper's argument or the testimony of the former Director of the CON Program, Louis Eubank, that the State Health Plan is a planning tool utilized by the Department to guide the development of health care facilities and services across the State. *Id.* at p. 3. However, the Department's powers do not extend to include unfettered interpretation and application of the State Health Plan in a manner that is arbitrary and capricious and contradicts the plain language of the document itself.

Furthermore, the State Health Plan's purpose is not limited solely to use as a planning tool by the Department. Roper alleges that there is nothing to support the Court's finding that the State Health Plan, including its inventory provisions, allows health care providers to determine the need for additional services in a given area. *Id.* This is simply untrue. The State Health Plan provides,

In consultation with the Health Planning Committee, the Department formulated these standards to **guide medical providers throughout the State**. Inclusion of these standards in the application process is **designed to give applicants notice of its requirements and to elicit from them a commitment to incorporate these standards into both their applications and finished products**.

See State Health Plan, p. I-2 (emphasis added). In sum, the State Health Plan is every bit as much a planning tool for health care providers as it is for the Department, and providers must be able to rely upon the State Health Plan, as drafted, without being required to divine the possible capricious interpretations the Department may assign any given State Health Plan standard on any given day. This is precisely the reason the South Carolina General Assembly established a process for review of Department decisions, to ensure that Department decisions which are wholly unsupported by the governing laws do not stand.

Roper argues that the "Court's finding that [Standard 3] mandates retrospective review and prohibits prospective analysis is contrary to the substantial evidence in the record and wholly inapposite to the interpretation of the agency statutorily charged with drafting and implementing

the Health Plan.” Mot., p. 4. CON Standard 3, which governs the establishment of new diagnostic and mobile cardiac catheterization services, provides as follows:

New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area **have performed** a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year. . . .

State Health Plan, p. VIII-5 (emphasis added). The Court’s finding with respect to Standard 3 is wholly supported by the plain language of the State Health Plan itself. The Court must interpret the State Health Plan using the rules of statutory construction. *Trident Med. Ctr. v. S.C. Dept. of Health & Envtl. Control*, 412 S.C. 341, 350, 772 S.E.2d 177, 182 (Ct. App. 2014), *cert denied* (Dec. 18, 2015). “Under the plain meaning rule, it is not the court’s place to change the meaning of a clear and unambiguous statute.” *Hodges v. Rainey*, 341 S.C. 79, 85, 533 S.E.2d 578, 581 (2000). Consequently, there can be no deference to an agency’s interpretation of law that is contrary to the plain meaning of the statute or regulation. *See Kiawah Dev. Partners, II v. S.C. Dept. of Health & Envtl. Control*, 411 S.C. 16, 32, 766 S.E.2d 707, 717 (2014).

Furthermore, the Department’s former CON Program Director, Mr. Eubank, admitted at the hearing on this matter that Standard 3 required retrospective application:

Q: Okay. But it’s that have performed language that tells you, it tells you any other applicants or affected persons, that’s a retroactive look-back, so to speak. That’s kind of redundant, but **it’s a retroactive application that needs to be done, correct?**

A: **Correct. It’s past tense.**

See Trial Tr., 357:11 – 17 (emphasis added). Thus, the Department was well aware of the requirements of the State Health Plan; yet, chose to ignore those requirements when it decided to approve Roper’s CON application. Contrary to Roper’s arguments, the Court’s finding is supported by far more than just Trident’s arguments. Mot., p. 3. The Court’s finding is supported by a correct application of the law, as it should be.

B. THE COURT CORRECTLY DETERMINED THAT BON SECOURS' CARDIAC CATH PROGRAM EXISTED

Roper takes issue with the Court's "reliance on miscellaneous documents" in finding that Roper Bon Secours St. Francis Xavier Hospital's ("Bon Secours") cardiac catheterization program existed at the time Roper filed its CON application and, therefore, Bon Secours' failure to meet the minimum threshold established in CON Standard 3 prevented the Department from approving Roper's CON application. Mot., p. 4. Once again, Roper would have the Court disregard the plain language of the State Health Plan, which the Court cannot do. Because the State Health plan is subject to the rules of statutory construction, the primary goal in interpreting its provisions must be

to ascertain and effectuate the intent of the Legislature. Each provision, therefore, "should be given a reasonable construction[] consistent with the purpose and policy of the Act." Legislative intent "should be ascertained primarily from the plain language of the statute."

Furthermore, a primary rule of statutory interpretation is that **"words must be given their plain and ordinary meaning without resort to a subtle or forced construction which limits or expands the statute's operation."** Thus, when a statute contains "clear and unambiguous" terms, this Court "must apply those terms according to their literal meaning."

Abraham v. Palmetto Unified School Dist. No. 1, 343 S.C. 36, 48-49, 538 S.E.2d 656, 663 (Ct. App. 2000) (internal citations omitted) (emphasis added).

It is presumed that the State Health Planning Committee had a reason for including the word "existing" in CON Standard 3 when it approved the State Health Plan; therefore, the Court must give effect to that word and cannot ignore it. *Id.* at 48, 538 S.E.2d at 662. The existence of Bon Secours' catheterization lab is not the product of some metaphysical, intellectual exercise or a question of semantics. It existed and was in operation at the time that Roper filed its CON application. Neither the citation in the Final Order to correspondence from the Department to Roper regarding Bon Secours' existence nor the inclusion of Bon Secours' utilization in Roper's

CON application form the basis for the Court's decision. Rather, the Final Order's citation to those documents demonstrate that both the Department and Roper knew and understood that the Bon Secours catheterization lab existed and that its existence precluded the Department's approval of Roper's CON application. The plain language of the State Health Plan forms the basis for the Court's decision. However, Roper's and the Department's acknowledgement of the existence of Bon Secours' cath lab is relevant and instructive and demonstrates the arbitrary and capricious nature of the Department's decision.

C. THE COURT NEITHER MISAPPREHENDED NOR MISUNDERSTOOD THE DEPARTMENT'S INTERPRETATION AND APPLICATION OF CON STANDARD 3

Roper next takes issue with the finding in the Final Order that "although clearly aware that the lab had been operating in violation of Standard 3 since at least 2010, at no time did the Department undertake any enforcement action against Bon Secours." Mot., p. 5 (quoting Final Order, p. 8). Roper alleges that this "finding is manifestly improper, as there is no volume requirement in Standard 3 so as to support a belief that a catheterization laboratory with volumes below the threshold is in violation of the planning standard." *Id.* Roper further alleges that "Standard 3 only has significance when reviewing applications for diagnostic services. What is or is not an 'existing lab,' for any other reason in any other context is irrelevant." *Id.*

The State Health Plan provides that the inclusion of CON standards "is designed to give applicants notice of its requirements and to elicit from them a commitment to incorporate these standards into both their applications and finished products." State Health Plan, p. I-2. There may be no requirement that the Department take enforcement action against a health care provider for failing to continue to meet State Health Plan requirements after a CON project is fully implemented; however, the Department certainly had the authority to do so. Bon Secours failed to perform any cardiac catheterizations in 2008 and 2009. The CON Act and the "CON Regulations" (S.C. Code Ann. Regs. 61-15) require a provider to obtain a CON for a health care

service “which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan.” S.C. Code Ann. § 44-7-160(5). *See also* S.C. Code Ann. Regs. 61-15, § 102.1.e. Thus, when Bon Secours resumed providing cardiac catheterizations, the Department could have taken enforcement action against it but did not. *See* Trial Tr., 323:19 – 324: 11. Additionally, had the Department considered Bon Secours catheterization laboratory to be non-existent, it could have removed the lab from the inventory reflected in the State Health Plan. *Id.* at 315:9-12.

Contrary to Roper’s assertion, the Court clearly understood the issue and understood that the Department’s vacillating positions as to Bon Secours’ existence was contrary to the plain language of the State Health Plan. CON Standard 3 is a health care planning standard designed to ensure, *inter alia*, that new diagnostic catheterization services are not approved in a service area that has sufficient *capacity* to meet the needs of that area. The Department realized the implications of Bon Secours’ low utilization as far back as 2010 and knew that Bon Secours could not be discounted, despite its being minimally operational, as long as it remained open and offering services. *See* Pet. Ex. 3, p. 11. Roper Hospital understood this as well when it advocated for Bon Secours’ continued existence and refused to close Bon Secours’ cath lab absent the approval of its CON application. *See* Pet. Ex. 5, p. 3. Yet, Roper continues to argue for an interpretation of the State Health Plan that would render the inclusion of the word existence in CON Standard 3 superfluous. *See Abraham*, 343 S.C. at 48, 538 S.E.2d at 662 (“It is well settled, however, that statutes ‘should be so construed that no word, clause, sentence, provision or part shall be rendered surplusage or superfluous.’”). Roper and the Department’s tortuous reading of the State Health Plan is confounding in every respect but its self-serving nature.

E.¹ THE COURT CORRECTLY CONCLUDED THAT PROVIDERS LACKED NOTICE OF THE PLANNED CLOSURE OF BON SECOURS

Roper argues that other providers had knowledge of the closure of Bon Secours and, therefore, the ability to submit competing applications based upon the required public notices related to the filing of a CON application. This argument is meritless. The mere filing of a CON application would not give providers any reason to believe that the Department would overlook the requirements of the State Health Plan to approve an application that was clearly non-compliant. In fact, Trident's health care planning expert, Daniel Sullivan, testified that he assumed that East Cooper Medical Center's CON application for the establishment of a new diagnostic catheterization lab would be denied, given its failure to comply with CON Standard 3. *See* Trial Tr., 151:10 – 16. The Court's finding reflects that none of the public notices Roper expects providers to rely upon would put providers on notice that the Department and Roper would devise a plan to skirt compliance with CON laws.

F. TRIDENT'S POSITIONS BEFORE THE DEPARTMENT WITH RESPECT TO ROPER'S CON ARE NOT INCONSISTENT AND ARE IRRELEVANT TO THE COURT'S DECISION

Roper alleges that Trident made inconsistent statements with regard to Roper's Proposed Project and argues that it is "inequitable and unfair" to "ignore and disregard" those positions. *See* Mot., p. 7. Roper then quotes from a letter in opposition to the Proposed Project submitted to the Department by Trident's health care planning consultant, Mr. Sullivan. *Id.* Notably, however, the quote from Mr. Sullivan is taken entirely out of context. Mr. Sullivan addressed all the ways in which Roper's Proposed Project failed to comply with the State Health Plan, including its failure to meet the CON Standards specific to the transfer of health care services between affiliated facilities. *See* Joint Ex. 1, p. 0198. *See also* State Health Plan, p. II-2.

¹ Roper's Motion inadvertently mislabels section "D" as section "E." For ease of reference, Trident will use the lettering contained in Roper's filing in this Response.

Mr. Sullivan's letter states,

Given the Roper-Berkeley application is proposing a new diagnostic cardiac cath service, the relevant standards for review are those for Cardiac Catheterization Services and specifically the criteria relating to Diagnostic Cardiac Catheterization. Roper-Berkeley does not address the Exceptions to Service Area Standards, which are considered when an applicant seeks to transfer beds or services between two related facilities. **Given that these Exceptions are not addressed by the applicant, there is no basis to approve the project under these criteria, however, this letter will address the reasons why the Roper Berkeley project fails to satisfy these Exceptions as well.**

Joint Ex. 1, p. 0191 (emphasis added). Mr. Sullivan then addresses how the CON application fails to comply with the CON Standards for the establishment of a new diagnostic cardiac catheterization laboratory, including its failure to meet the requirements of CON Standard 3. *Id.* at p. 0194 – 0195. Mr. Sullivan's statement that "DHEC should not recognize [Bon Secours'] diagnostic catheterization program as an existing service" was part of an argument made specifically with regard to the requirements for the transfer of health care services. *See* Mot., p. 7. *See also* Joint Ex. 1, p. 199. There is nothing disingenuous or inappropriate about making alternative arguments. In fact, it would be remiss to not make all available arguments in opposition to a project when it so clearly fails to meet the applicable requirements on every level.

Mr. Sullivan testified that he addressed both the CON Standards for new diagnostic cardiac catheterization services and the CON Standards related to the transfer of health care services because of the unusual nature of Roper's proposal to close Bon Secours' cath lab upon approval (and only upon approval) of the CON Application:

Q: And you listed both Standard 3 and the transfer exception in your letter?

A: I did.

Q: And why did you do that again?

A: Again, because it was such an unusual structure to this application in terms of the applicant talking about conditioning the closure of a lab upon the approval of another lab. **That's in effect what transfers usually are, we're going to shut down one program and then open it somewhere else. The applicant never said it was going to be a transfer but I've**

been surprised before when an applicant presents an application one way and then amends it late in the process to make a different argument and so that was just, sort of, if the applicant tries to say, this is a transfer rather than a new program, then I don't believe they meet this transfer standard.

Q: You were hedging?

A: I was.

Trial Tr., 245:21 – 246:16 (emphasis added).

Roper's allegation that "[t]he outcome now challenged by Trident here, despite having actual notice of the plan with regard to the closure of Bon Secours St. Francis Xavier laboratory, was never made to DHEC or asserted as an area of noncompliance with the Health Plan Standards" is patently incorrect. Mot., p. 7. Mr. Sullivan unequivocally addressed the application's noncompliance with CON Standard 3 in his letter of opposition. He did not specifically refer to Bon Secours as an existing lab that failed to perform more than 500 procedures in the previous year because there was no need to expound upon the obvious. In fact, at the hearing, Mr. Sullivan testified,

Q: Turn over to your letter at Joint 1-194. And, Ms. Hollingsworth asked you a few questions about this diagnostic cath lab. **She said that there was no mention about existing labs but could you please read the very first line under Standard 3?**

A: **All existing labs in the service area have not performed a minimum of 500 diagnostic catheterization procedures per laboratory in 2015.**

* * *

Q: **And then, you provided a table on Joint 1, 195 that states – that presents what information?**

A: **Utilization of existing labs and showing that, among other things, that the Bon Secours St. Francis lab was underutilized.**

Q: **As a health planner, did you feel like you needed to give The Department any more information than that?**

A: **It seemed pretty straight forward to me, but, you know, the standard wasn't met which was why later on I went into the transfer standards.**

My assumption was well, they can't possibly be approved under Criteria 3, so they would have to be approved under some other mechanism.

Trial Tr., 250:13 – 251:14 (emphasis added).

There is nothing disingenuous, inequitable, or unfair about making all available arguments against a project that fails to comply with the CON requirements. Trident's arguments with regard to the CON Standards governing the transfer of health care services are wholly irrelevant to the issue of whether Roper's project complied with the requirements of CON Standard 3, which was the sole issue before this Court. Consequently, there was no reason for the Court to address Trident's arguments with respect to the CON application's failure to comply with the health service transfer standards in the Final Order.

G. THE FINAL ORDER REPRESENTS AN ACCURATE INTERPRETATION AND APPLICATION OF THE LAW

(1) The Court Correctly Adhered to the Applicable Statutory Construction Principles.

Roper acknowledges that the State Health Plan is interpreted using the rules of statutory construction. Mot., p. 8, (citing *Trident Med. Ctr. v. S.C. Dept. of Health & Envtl. Control*, 412 S.C. 341, 355, 772 S.E.2d 177, 184 (Ct. App. 2015) (“[W]e may interpret the State Health Plan using the rules of statutory construction applied to regulations with one caveat, each section of the State Health Plan must be read as a whole.”)). Roper argues that because the State Health Plan does not define “existing,” the Court must defer to the interpretation of the Department. Mot., p. 8. To do so, however, would be in direct contradiction to the very rules Roper acknowledges are applicable. A Court cannot defer to an agency's interpretation of law that is contrary to the plain language of the law. *Abraham*, 343 S.C. at 48-49, 538 S.E.2d at 663.

The Legislature cannot define every word or term within a statute, and therefore it is not reasonable to assume that the State Health Planning Committee will define every word or term

within the State Health Plan. The State Health Planning Committee could not possibly foresee the myriad ways in which the ordinary meanings of words might be twisted to justify a desired result.

[A] primary rule of statutory interpretation is that ‘words must be given their plain and ordinary meaning without resort to a subtle or forced construction which limits or expands the statute’s operation.’ Thus, when a statute contains ‘clear and unambiguous’ terms, this Court “must apply those terms according to their literal meaning.’

Id. (internal citations omitted) (emphasis added).

Roper’s reliance on *Murphy v. South Carolina Department of Health and Environmental Control*, 396 S.C. 633, 723 S.E.2d 191 (2012) is misplaced. At issue in *Murphy* was the meaning of the word “vicinity,” which naturally requires some level of interpretation as the Department would have to determine what the boundaries are for determining whether something is in the “vicinity” of a given area. *See id.* at 640, 723 S.E.2d at 195. There are no similar boundary or scope issues with respect to what it means for a thing to exist.

Roper alleges that Trident has engaged in a metaphysical exercise over the meaning of existence, when, in fact, the exact opposite is true. Roper created a situation wherein the parties were obliged to engage in a theoretical debate over the meaning of the word “exist”. Bon Secours’ catheterization lab physically existed at the time that Roper submitted its CON application. It was operational. It was listed in the inventory in the State Health Plan, and Roper acknowledged its existence and refused to close it unless, and until, it received a CON for the establishment of a catheterization lab at its Berkeley County hospital.

The Court’s interpretation of the plain language of CON Standard 3 of the State Health Plan does not ignore or render any word therein meaningless, and the Court appropriately concluded that it could not defer to an agency’s interpretation of the law that was in contradiction to its plain language and to the ordinary meaning of the words contained therein.

(2) *The Court Applied the Laws Governing Deference to Agency Interpretations Appropriately.*

Roper reiterates its same argument that the Department's interpretation of "existing" should be afforded deference. Mot., p. 10. Quoting *Kiawah Development Partners, II*, 411 S.C. at 32 – 33, 766 S.E.2d at 717, Roper correctly notes that if the language of a statute or regulation speaks directly to an issue, then "the court must utilize the clear meaning of the statute or regulation." Only if the statute is silent or ambiguous does the court defer to an agency interpretation, "assuming the interpretation is worthy of deference." *Id.* CON Standard 3 is neither silent nor ambiguous on the issue at hand. It clearly states that before a new diagnostic catheterization program can be approved, all existing labs must have performed 500 procedures during the most recent year. See State Health Plan, p. VIII-5. The language of the State Health Plan is plain. There is no reason to defer to the Department's interpretation. In fact, there are compelling reasons to not defer to the Department, as the Department's interpretation as to what constitutes an "existing" lab is "arbitrary, capricious, and manifestly contrary" to the State Health Plan. *Id.* at 34, 766 S.E.2d at 718.

Roper Hospital tries to analogize the Department's interpretation of the word "area" in *Kiawah Development Partners, II* to the Department's interpretation of "existing" in this case. Mot., p. 11. Once again, the analogy fails. Similar to the problem with Roper's attempts to analogize the Department's interpretation of the word "vicinity" in *Murphy*, the word "area" naturally includes a boundary and the extent of that boundary would necessarily require some interpretation. There are no similar boundaries or limits inherent in the word "exist." With the possible exception of certain particles in the realm of quantum mechanics, a thing either exists or it does not.

Roper Hospital has once again taken Mr. Sullivan's testimony out of context in an attempt to create an inconsistency where none exists. *See id.* At the hearing, Mr. Sullivan testified that approved, but not operational (i.e., not yet existing), labs would have to be considered by the Department in its review of a CON application for additional cardiac catheterization services. *See generally* Trial Tr., 143:1 – 150:2.

Q: Okay. So if – I believe some of the other definitions you offered me at your deposition for existing meant, open for business.

A: Right.

Q: Is that right. And then, you also said that it would mean approved, correct?

A: Yeah. We had quite a discussion about that, I mean, **existing doesn't mean approved. I mean, approved is a different category.** You know, my feeling is that somehow once a project is approved, it has to be given some weight in the evaluation of the need for another lab.

Q: Uh-huh. Because what I think you actually said was, in your word, that there was a gap in the standard there in looking at when a lab is open for business and how you would deal with an approved lab. Isn't that right?

A: Right. It's not specifically spelled out in the standard.

Id. at 143:14 – 144:11 (emphasis added).

Mr. Sullivan's testimony speaks only to the issue that the Department must consider approved, but not yet existing labs, when evaluating a CON application for additional services. He neither creates nor acknowledges an ambiguity with respect to what it means to exist for purposes of CON Standard 3, because there is no ambiguity in CON Standard 3. An approved lab (one that does not exist) would never be able to demonstrate 500 procedures in the previous year. The language of CON Standard 3 clearly requires retrospective application. Mr. Sullivan's testimony merely speaks to another consideration that the Department would, and naturally should, consider in reviewing a CON application. It would defy logic, good sense, and good health planning principles to approve a new cardiac catheterization lab for one provider if

another provider had already been approved to open a lab but had not yet completed the project. The failure to include approved but not yet existing labs as a consideration may be a gap in the CON Standards as a whole, but it is not a gap with respect to CON Standard 3.

In fact, Mr. Sullivan goes on to state,

Q: Okay. Now, you would agree with me that the Health Plan though is to read where an entire chapter is read together, right?

A: Sure.

Q: And so, when evaluating how to apply all of the standards that are applicable to a diagnostic cath laboratory, that you would be looking at Standard 2 and Standard 3 at the same time, correct?

A: Sure.

Q: And so, doesn't that suggest that The Department can interpret that an existing lab is not necessarily all the facilities in a service area for purposes of evaluating Standard 3?

A: I don't believe so, I mean, **it says all existing labs. It doesn't say some existing labs and all existing labs means any labs that are open and serving patients.**

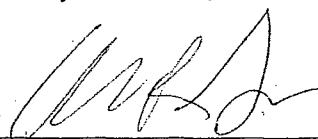
Id. at 147:6 – 148:1 (emphasis added). Yet, the Department arbitrarily determined which labs should be considered “existing” for purposes of evaluating compliance with CON Standard 3. Only by twisting the plain meaning of the word “existing” could the Department cherry pick which labs should be considered when evaluating Roper’s compliance with CON Standard 3, and only by cherry picking those labs could the Department contrive a means of approving Roper’s CON application. The Department’s arbitrary interpretation and application of CON Standard 3, in a manner that is manifestly contrary to the plain language of the statute, simply is not entitled to deference. *See Kiawah Development Partners, II*, 411 S.C. at 34, 766 S.E.2d at 718.

Ironically, Roper alleges that “[o]ther than Trident’s displeasure with the outcome, the Court was not presented with any **compelling reason** to differ with DHEC’s interpretation. . . .” Mot., p. 12 (emphasis in original). As demonstrated herein, the record is replete with compelling

reasons to differ with DHEC's decision, including the CON Program Director's own admission in writing that St. Francis' low volume catheterization lab "prohibits the entry of *any* additional cath labs in the service area as outlined in SC Health Plan standards . . ." (Exh. P.05, p. 1 - 2)(emphasis added). However, Roper has failed to provide any compelling reason to uphold the Department's decision. Nevertheless, to the extent that Roper moves this Court to explicitly state what is patently evident, Trident has no objection to amending the Final Order to clarify that the Department's decision was arbitrary, capricious, and in error of both law and fact.

WHEREFORE, for the reasons set forth herein, and within the record as a whole, Trident respectfully requests that the Court deny Roper's Motion to Alter or Amend.

Respectfully Submitted,



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Columbia, South Carolina
 January 5, 2019

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

Trident Medical Center, LLC, d/b/a Trident
Medical Center,

Petitioner,

vs.

South Carolina Department of Health and
Environmental Control and Roper St. Francis
Hospital - Berkeley, Inc., d/b/a Roper St.
Francis Hospital - Berkeley,

Respondents.

Docket No.: 2016-ALJ-07-0386-CC

**RESPONDENT ROPER ST. FRANCIS
HOSPITAL – BERKELEY’S
REPLY IN FURTHER SUPPORT OF
MOTION TO ALTER OR AMEND**

Incorporating all issues and arguments raised in the Motion to Alter or Amend and in the course of this contested case proceeding, Roper St. Francis Hospital – Berkeley, Inc. d/b/a Roper St. Francis Hospital – Berkeley (“Roper Berkeley”) hereby files this Reply to the Response of Trident Medical Center, LLC, d/b/a Trident Medical Center (“Trident”) in opposition to Roper Berkeley’s Motion.

Interpretation of the South Carolina Health Plan

As explained by the United States Supreme Court in the seminal opinion of *Chevron U.S.A., Inc. v. Natural Resources Defense Counsel, Inc.*, 467 U.S. 837 (1984), it has long been the judicial policy of this country that courts must defer to reasonable agency constructions of statutory provisions that agency is charged with administering. *See Chevron* at 844 (“We have long recognized that considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations.”) South Carolina’s agency deference doctrine is traced back to *Read Phosphate Company v. South Carolina Tax Commission*:

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The construction given to a statute by those charged with the duty of executing it is always entitled to the most respectful consideration, and ought not to be overruled without cogent reasons. The officers concerned are usually able men, and masters of the subject. Not unfrequently they are the draftsmen of the laws they are called upon to interpret.

169 S.C. 314, 168 S.E. 722, 728 (1933) (quoting *U.S. v. Moore*, 95 U.S. 760, 763 (1877)). Trident's suggestion that Roper Berkeley's position affords DHEC "unfettered interpretation and application" of the South Carolina Health Plan's ("Health Plan") language is absurd, when in fact Roper Berkeley seeks only to have the Court follow the long-established framework for review of agency decisions involving interpretations of regulations for which the agency is statutorily charged with implementing. *See e.g., Chevron* at 865 (holding agency's interpretation of the word "source" was a permissible construction of the statute and decision involved reconciling conflicting policies); *see also Kiawah Dev. Partners, II v. S.C. Dep't of Health and Envtl. Control*, 411 S.C. 16, 36, 766 S.E.2d 707, 719 (2014) (herein "*Kiawah II*"). (rejecting ALC's theory that DHEC's interpretation of regulation would improperly permit DHEC to "trump" other zoning or development agreements unrelated to land development regulations).

As to Trident's support for the Final Order's finding that the Health Plan is intended to be used by a provider "to determine need for additional services in the service area," the very language quoted by Trident shows that Trident similarly misapprehends the document's purpose. (Trident Resp., p. 2). Quoting from Page I-2 of the 2015 Health Plan (with bolding by Trident), the Health Plan is designed to give applicants notice of the requirements for application submissions. *See id.*; *see also* J04-006. This language does not support Trident's argument or the Final Order's conclusion that the document is a static measuring stick *for the public to decide* whether services are needed at any point in time (such decision-making authority, notably and contrary to the Final Order, is in fact statutorily vested in the Department). *See* S.C. Code Ann. § 44-7-140. Such a conclusion is thus necessarily directly in conflict with the law and statutory scheme for the State

Certification of Need and Health Facility Licensure Act (“CON Act”).

Trident’s response in support of the challenged finding in the Final Order that Standard 3 requires “retrospective application” misrepresents the trial testimony of Louis Eubank. (Trident Resp., p. 2). Roper Berkeley agrees with Mr. Eubank’s testimony that the words “have performed” are past tense but disagrees with Trident’s characterization of his testimony as “admitting” that Standard 3 “required retrospective application.” (Trident Resp., p. 3). Mr. Eubank only agrees that “have performed” is past tense, and to the extent utilization is evaluated under Standard 3, utilization data is necessarily historical information because by its very nature the data is reporting information about the past. (Platt Trial Tr. 424:13-23 (“Obviously, to have data it has to have occurred”)). More importantly, and overlooked by Trident in response, Mr. Eubank’s testimony was consistent with the Department’s decision and the expert opinions of Kathy Platt, in that Standard 3 looks at the historical utilization of “existing labs” and “existing labs” for purposes of planning additional services evaluates the impact approving a new service will have on the providers in the service area who will also be providing those services. (Eubank Trial Tr. 268:24-269:6, 369:4-9; Platt Trial Tr. 390:15-21, 394:16-395:9; 398:9-21). In fact, it is contradictory to acknowledge that the Health Plan is a planning tool used by DHEC to guide the establishment of health services (which necessarily involves future events), but argue that the inventory and standards are inflexible and frozen in time. *See Chevron* at 865 (explaining that an agency may interpret a term flexibly – “not in a sterile textual vacuum”).

Distinction Between Existence Versus “existing lab” Analysis

Roper Berkeley wholeheartedly agrees with Trident that this Court should “presume[] that the State Health Planning Committee had a reason for including the word ‘existing’ in CON Standard 3 when it approved the [South Carolina] Health Plan; therefore the Court must give effect to that word and cannot ignore it.” (Trident Resp., p. 4). Confoundingly, Trident still fails to

appreciate that it is the interpretation advanced by Trident and seemingly adopted in the Final Order that ignores the word “existing” in Standard 3. Trident does not explain or defend the Final Order’s failure to consider the strong evidence that “existing” must have meaning in Standard 3. A critical fact overlooked in the Final Order is that the definition of service area in Standard 2 of the Health Plan does not include the word “existing” and uses “all facilities,” yet the evaluation of historical utilization in Standard 3 is limited to that of “existing labs.” This distinction necessarily provides DHEC with the flexibility to determine what is existing for purposes of planning additional diagnostic catheterization services.¹ The **plain language** of the Health Plan Standards clearly anticipate that there may be laboratories in a service area (which is defined as “all facilities”) that are not “existing labs” for purposes of evaluating the addition of services. See *Hodges v. Rainey*, 341 S.C. 79, 86, 533 S.E.2d 578, 582 (2000) (The canon of construction “*expressio unius est exclusio alterius*” or “*inclusio unius est exclusio alterius*” holds that “to express or include one thing implies the exclusion of another, or of the alternative.”) (quoting Black’s Law Dictionary 602 (7th ed. 1999)).

At the heart of this issue is that DHEC interpreted Standard 3’s use of “existing labs” to allow for consideration of the laboratories providing diagnostic cardiac catheterization services at the point in time when the applicant would be providing the services, and to not include a laboratory that would not be providing those services. In contrast, the Court adopted Trident’s interpretation that “existing labs” is evaluated “at the time that Roper filed its CON application.” (Trident Resp., p. 4; see also Final Order, pp. 17-18 (inserting “at the time a CON Application is filed” into the Standard)). Roper Berkeley submits that this disagreement as to the point in time when “existing” is evaluated for purposes of planning new diagnostic cardiac catheterization

¹ Standard 2 provides: “The service area for a diagnostic cardiac catheterization laboratory is defined as all facilities within 45 minutes’ one way automobile travel time . . .” (J04-046 (emphasis added)).

services under Standard 3 is precisely the circumstance where our jurisprudence requires the Court give deference to DHEC's interpretation, addressed in more detail *infra*. Roper Berkeley further submits that the Final Order's addition of the timing element to Standard 3 where one does not exist is an error of law that requires reconsideration. "[The Court's] role is to apply and interpret, not rewrite, regulations." *Kiawah II* at 39, 766 S.E.2d at 720-21 (reversing the ALC's reading of a substantiality requirement into disputed regulation).

Bon Secours never operated "in violation of Standard 3"

Trident raises then entirely sidesteps Roper Berkeley's challenge to the Final Order's finding that Standard 3 has a 'volume requirement' that the Bon Secours catheterization laboratory somehow violated. (Trident Resp., p. 5; Final Order, p. 18). The Health Plan is used for the administration of the CON Program and serves as a basis for the review of applications for specified health services. S.C. Code Ann. §§ 44-7-180(B), -210(B). Standard 3 of the Health Plan is not a continuing volume requirement for any previously approved laboratories licensed to offer diagnostic catheterization services.² Trident avoids acknowledging this error in the Final Order and instead references the enforcement powers of the Department as set forth in the CON Act, a point not disputed by Roper Berkeley nor relevant to the Motion.

Trident's assertion that Roper Berkeley's "interpretation of the [South Carolina] Health Plan" is one "that would render the inclusion of the word existence in CON Standard 3 superfluous" is nothing short of baffling. (Trident Resp., p. 6). Trident's expert clearly testified that he believed "all labs" and "all existing labs" mean the same thing under Standard 2 and Standard 3; quite clearly, it is his definition advanced by Trident that ignores and renders

² Notably, if the Court's interpretation of Standard 3 as an ongoing volume requirement were correct, at least 22 other hospitals, including *Trident Medical Center*, operated in "violation" of Standard 3 according to the 2013 volumes reported in the 2015 South Carolina Health Plan. (J04-120).

superfluous an otherwise meaningful distinction within the Standards. (Sullivan Trial Tr. 143:14-21).³ It is nonsensical that Trident levies this argument against Roper Berkeley when it is the testimony of its expert that quite literally deletes the word from the Standard. "A statute should be so construed that no word, clause, sentence, or provision or part shall be rendered surplusage, or superfluous." *Matter of Decker*, 322 S.C. 215, 218, 471 S.C.2d 462, 463 (citing C.J.S. *Statutes* § 346) (finding reporter's shield law inapplicable to proceedings where disclosure sought by trial court and statute's plain language reflected limitation of use to parties). The Final Order's adoption of Trident's interpretation represents an error of law.

Actual Notice of Proposal to Close Bon Secours St. Francis's Laboratory

Contrary to Trident's argument, there is no evidence that DHEC "overlook[ed] the requirements of the [South Carolina] Health Plan to approve an application that was clearly non-compliant." (Trident Resp., p. 7). The evidence, even viewed favorably to Trident, establishes that reasonable, educated minds differ as to the application of Standard 3 and meaning of "existing labs" therein. The statutory and regulatory framework of the CON program provide the means by which persons interested in an application should participate in the review process. *See e.g.* S.C. Code Ann. §§ 44-7-130(1), -210. There is no evidence that Roper Berkeley did not comply with all required public notices, nor any evidence that DHEC did not comply with all required public notices and notifications to affected persons. The proposal to close the Bon Secours St. Francis catheterization laboratory is identified and discussed throughout the CON Application and specifically discussed and addressed in Trident's opposition during staff review. (J01-190; Sullivan Trial Tr. 182:1-183:4, 184:12-185:7). Trident's support notwithstanding, the Final

³ Mr. Sullivan testified:

Q. Okay. So all existing labs in your mind is the same thing as saying all labs. Is that right?

A. Yes.

(Sullivan Trial Tr. 143:14-17).

Order's finding with regard to knowledge about the impact on the inventory an approval of the Roper Berkeley CON Application would have is unsupported by and contrary to the substantial evidence in the record.

Trident's Inconsistent Positions

Trident seeks to minimize the significance of its inconsistent positions through deflection and distraction. (Trident Resp., p.7). What Trident does not address, not surprisingly, is that these "alternative arguments" as Trident calls them are in fact conflicting interpretations of the same word. It cannot be sustained that Trident can espouse one meaning of "existing" for purposes of the transfer standards during DHEC staff review of the CON Application, and an opposite meaning of "existing" for purposes of Standard 3 and the challenge in this Court. Trident responds to the Motion complaining that the quoted opinion of Mr. Sullivan is "taken out of context," but such argument is unavailing when Mr. Sullivan *specifically addresses* Standard 3 and *specifically opines* that "[t]he Department should not recognize BSSFH's diagnostic catheterization program as an existing service merely because (3) diagnostic caths are performed on average each year, which is not indicative of an actual program." (J01-199; *see also* J04-009).⁴ This opinion that the laboratory was not an "existing lab" under Standard 3 presented to DHEC staff is not an "alternative argument," but represents a materially inconsistent position that, following DHEC's agreement that the Bon Secours St. Francis laboratory was not considered an existing lab for purposes of Standard 3, Trident now challenges as arbitrary and capricious. "The issues considered

⁴ The record reflects that Trident's expert advised DHEC staff during review that Roper Berkeley could not be approved for a laboratory under the transfer standards because the first criterion required that a "transfer . . . of services may be approved only if there is no overall increase in the number . . . of such services." (J04-009). To oppose such consideration, Mr. Sullivan opined that transferring the Bon Secours St. Francis laboratory to Roper Berkeley would be "an overall increase in the number of diagnostic cath services in the service area," and quoted the requirement of Standard 3 to then explain that DHEC staff "should not recognize BSSFH's diagnostic catheterization program as an existing service . . ." (J01-198-99). The result of this analysis is that the laboratory cannot be transferred because nothing "exists" to transfer and it would be an increase in the number of such services. The arguments advanced by Trident in this Court are materially inconsistent with the positions taken during staff review.

at the contested case hearing considering a Certificate of Need are limited to those presented or considered during the staff review.” S.C. Code Ann. § 44-7-210(E).

The Errors of Law Require Reconsideration

Trident misses the forest for the trees in claiming that *Murphy* is distinguishable and that the point at issue here is “what it means for a thing to exist.” (Trident Resp., p. 11). The question, and resulting difference in interpretation, is at what point in time existence is evaluated for purposes of guiding the establishment of additional diagnostic catheterization services under Standard 3 in the Health Plan. The Court adopted Trident’s argument that the determination of what are the “existing labs” under Standard 3 is made at the time the CON application is filed. DHEC interpreted “existing labs” at a different point in time and considered those laboratories that would “continue to be” offering the services the applicant proposed to serve, an interpretation consistent with a generally accepted definition of “existing” in the Merriam-Webster Dictionary⁵ and entirely consistent with the purpose of the Health Plan to “guide the establishment of health facilities and services.” S.C. Code Ann. § 44-7-120; *see Murphy* at 640-41, 723 S.E.2d at 195. “[The Court’s] task is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency’s interpretation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation.” *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (internal quotations omitted) (finding broad deference all the more warranted where complex and highly technical regulatory program was involved). In *Thomas Jefferson University*, the United State Supreme Court held that where the agency’s construction of a regulation was “at the very least, a reasonable one, [] we are required to afford it controlling weight.” *Id.* at 515 (internal quotation omitted).

⁵ Available at <https://www.merriam-webster.com/dictionary/exist> (last visited Jan. 10, 2019)

This Court is required to “interpret the State Health Plan using the rules of statutory construction applied to regulations, with one caveat: each section of the state health plan must be read as a whole.” *Trident Med. Ctr. v. S.C. Dep’t of Health and Envtl. Control, et al.*, 412 S.C. 341, 355, 772 S.E.2d 177, 184 (Ct. App. 2015) (internal quotation omitted). To determine the plain language of Standard 3 and the meaning of “existing labs,” the Court must consider all of the Standards in the Cardiovascular Care section of the Health Plan and that necessarily includes Standard 2 in addition to Standard 3. *See* Final Order, p. 2 (adopting written stipulations of fact and affirming that Standards 1, 2, 3 and 4 apply to the CON Application). It is undisputed that Standard 2 defines the applicable services area to include “all facilities,” yet Standard 3 addresses historical utilization for planning additional laboratories only of “existing labs” in the service area. (J04-046-047). Other than this intentional distinction to limit Standard 3 to “existing” laboratories, Standard 3 does not address and is *silent as to the point in time* at which “existing labs” is evaluated. The Final Order concludes that “‘existing’ as used in Standard 3 [means] that a lab is open and is offering and has the capacity to provide catheterization services . . . at the time a CON Application is filed,” whereas DHEC interpreted the Standard to evaluate the impact the additional provider will have on the utilization of laboratories existing at a future time. (Final Order, pp. 17-18 (emphasis added); Eubank Trial Tr. 267:17-269:6; J01-207). Even though the Final Order necessarily concludes that “existing” is not defined in the Health Plan, the Court impermissibly adopts an alternative meaning of the word rather than evaluating the deference due to DHEC’s interpretation. (Final Order, p. 17). This is an error of law. *See Chevron* at 842 (“The basic legal error of the Court of Appeals was to adopt a static judicial definition of the term ‘stationary source’ when it had decided that Congress itself had not commanded that definition.”)

In the cited case of *Trident Medical Center v. South Carolina Department of Health and*

Environmental Control, Trident challenged DHEC's interpretation of the Bed Transfer Provision in the 2008-2009 South Carolina Health Plan and asserted that the "plain language" of the provision required that the facility receiving transferred beds must be in existence at the time the application is submitted and that the transferred beds could not be used to establish a new facility in the future: *See Trident Med. Ctr.* at 349, 772 S.E.2d at 181. The reasoning of the Court of Appeals in rejecting Trident's challenge and affirming the ALC's deference to DHEC's interpretation is directly on point:

The language [in the transfer criteria] certainly *accommodates* those CON applications for the transfer of beds to a receiving facility already in existence at the time the application is submitted. Yet, there is no language in this list that either expressly or impliedly *requires* the receiving facility to be in existence when the CON application is submitted. Therefore, the plain language of the Bed Transfer Provision can be reasonably interpreted to include a receiving facility that will be constructed after DHEC issues the CON.

Id. at 354-55, 772 S.E.2d at 185 (emphasis in original). Roper Berkeley submits that the very same analysis is applicable here. Nothing in Standard 3 or the Cardiovascular Care section of the Health Plan *requires* that DHEC evaluate "existing labs" and service area utilization at the time the application is filed. As in *Trident Medical Center*, "there is no language [in the Standards] that either expressly or impliedly *requires*" that the determination of what are the "existing labs" must be as of the moment "when the CON application is submitted." *Id.* Moreover, DHEC's recognition that the Bon Secours St. Francis catheterization laboratory would be closed and that it would not be an "existing lab" when Roper Berkeley would be offering diagnostic catheterization services is reasonable; consistent with the plain language of the Standards, and consonant with the General Assembly's stated purpose of the CON Act to *guide the establishment* of health services. *See Trident Med. Ctr.* at 360, 772 S.E.2d at 187; S.C. Code Ann. § 44-7-120; *see also Murphy* at 640-41, 723 S.E.2d at 195 (holding where DHEC's interpretation is reasonable and consistent with the plain language, there is "no reason to deviate from DHEC's construction and application.")

Notably, this interpretation is also consistent with the position taken by Trident during staff review of the CON Application. (*See supra* at pp. 7-8, and J01-0198-0199).

The Court is well familiar with the wealth of jurisprudence surrounding agency deference, and the recent, relevant opinions of the South Carolina Supreme Court in *Murphy* and *Kiawah II* that were raised prior to trial and reviewed in the Motion to Alter or Amend. Roper Berkeley respectfully reiterates that the framework established by case law requires deference to DHEC's interpretation of Standard 3 and that no compelling reason exists to differ.⁶ The courts "must be mindful of the General Assembly's entrustment of South Carolina's health care marketplace to DHEC for cost containment, prevention of unnecessary duplication of services, serving public needs, and ensuring high quality of healthcare services." *Trident Med. Ctr.* at 355, 772 S.E.2d at 184 (citing S.C. Code Ann. § 44-7-120). Roper Berkeley submits that reconsideration is required because the Court cannot conclude that the interpretation adopted in the Final Order is the clear meaning of Standard 3 when the interpretation is based upon the Court's own conflicting definition of "existing." *See Chevron* at 844 ("[A] court may not substitute its own construction of a statutory provision for a reasonable interpretation by the . . . agency.") Moreover, there is nothing that expressly or impliedly requires that the Standard be evaluated only "at the time the CON application is filed." The Court's imposition of this requirement is contrary to the holding of *Trident Medical Center* and the authority of *Kiawah II*. *See Trident Med. Ctr.* at 360, 412 S.E.2d at 187 ("All of these criteria undoubtedly afford DHEC broad discretion in bringing its expertise in health care planning to the evaluation of CON applications for general hospitals."); *see also Kiawah II* at 35, 766 S.E.2d at 719 (holding that an interpretation by DHEC that was reasonable

⁶ The oft-repeated two-step analysis is that if the meaning of a disputed provision is clear, that meaning must be followed; but if the precise question at issue is not addressed, and the provision is silent or ambiguous with respect to the issue, the court must give deference to the agency's interpretation absent compelling reason. *See Kiawah II* at 32-33, 766 S.E.2d at 717, 18.

and consistent with its statutory authority was therefore neither arbitrary, capricious, nor manifestly contrary to the statute.)

As established by the substantial evidence in the record, Trident's challenge amounts to no more than a disagreement with DHEC's interpretation and application of Standard 3 to the CON Application of Roper Berkeley, such disagreement based on Trident's inserting language into the Standard (*i.e.* labs existing at the time of filing the CON application) and ignoring a key material term (*i.e.* existing labs means all labs). "When a challenge to an agency construction of a statutory provision, fairly conceptualized, really centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by [the Health Planning Committee], the challenge must fail." *Chevron* at 866. Roper Berkeley submits that "under the circumstances of this case, where the agency's interpretation of its regulation is at least as plausible as competing ones, there is little, if any, reasons not to defer to its construction." *Thomas Jefferson Univ.* at 517 (internal quotation omitted).

CONCLUSION

For the reasons set forth herein, and as stated in the Motion to Alter or Amend and supported by the record, Roper Berkeley respectfully requests this Court reconsider its Final Order and affirm the decision of the Department to approve Roper Berkeley's CON Application.

RESPECTFULLY SUBMITTED,



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January 14, 2019
Columbia, South Carolina

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

Trident Medical Center, LLC, d/b/a
Trident Medical Center,

Petitioner,

vs.

South Carolina Department of Health and
Environmental Control and Roper St.
Francis Hospital – Berkeley, Inc., d/b/a
Roper St. Francis Hospital – Berkeley,

Respondents.

Docket No.: 2016-ALJ-07-0386-CC

**PETITIONER'S SUR-REPLY IN
OPPOSITION TO RESPONDENT ROPER
ST. FRANCIS HOSPITAL – BERKELEY'S
MOTION TO ALTER OR AMEND**

Petitioner Trident Medical Center, LLC, d/b/a Trident Medical Center ("Trident"), by and through its undersigned counsel, submits its Sur-Reply in Opposition to Respondent Roper St. Francis Hospital – Berkeley's ("Roper") Motion to Alter or Amend. In further support of its position, Trident submits the following:

AGENCY DEFERENCE

Roper continues to roll out the same unconvincing arguments that the Department's interpretation of the South Carolina Health Plan, enacted August 13, 2015 ("State Health Plan"), is entitled to deference. There may be a "long-established frame-work for review of agency decisions," but that framework does not compel deference to an agency interpretation that is in contradiction of the plain language of the statute or regulation, particularly one which defies common sense. *See Kiawah Dev. Partners, II v. S.C. Dept. of Health & Envtl. Control*, 411 S.C. 16, 32, 766 S.E.2d 707, 717 (2014). Moreover, the Department's interpretation of Certificate of Need ("CON") Standard 3 is certainly not long-established. The email correspondence between the Department and Roper, dated April 14, 2016, indicates that the Department's interpretation of the CON Standard 3 was a "solution" devised by the Department and Roper to circumvent the

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plain language requirements of the State Health Plan. In the Department's email to Roper's Counsel, the Department stated,

[T]he continued operation of St. Francis Xavier cath lab at such low volume prohibits the entry of any additional cath labs in the service area as outlined in the SC Health Plan standards for such services. The low volume would also likely prohibit the transfer of that cath lab from one operator's facilities to another under the service transfer criterion which requires adequate historic utilization figures. In order to provide for the public benefit in the Roper/St. Francis service area with regard to appropriate access to high-quality cardiac catheterization, we believe enforcement action against St. Francis-Xavier may be necessary. Enforcement actions pursuant to St. Francis-Xavier's failure to obtain a new CON in 2010 for its cath lab are provided for in Section 44-7-320 through 44-7-340 of the Code of Laws of South Carolina, as amended.

As you know, the Department takes any possible enforcement action very seriously and holds out this action as a 'last resort' when interacting with the Regulated Community. **I would ask that you provide to the Department, on behalf of your client, a proposed solution to this continuing issue in the hopes of avoiding any such action.**

Pet.'s Tr. Ex. P05-002 (emphasis added). The Department's correspondence clearly demonstrates that the Department concurred with Trident's and this Court's interpretation of the requirements of the State Health Plan, an interpretation that gives effect to its plain language and its intent, prior to being presented with an alternate, self-serving interpretation by Roper, which defies logic and the principles of good health planning.

CON Standard 3 plainly provides that

[n]ew diagnostic catheterization services, including mobile services, shall be approved only if **all existing labs** in the service area **have performed** a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year. . . .

State Health Plan, p. VIII-5 (emphasis added). An interpretation of the State Health Plan which is in contradiction to its plain language is not entitled to agency deference, particularly one that requires the Court to engage in a hypothetical, theoretical exercise as to what it means to exist and at what point existence should be measured. *Hodges v. Rainey*, 341 S.C. 79, 85, 533 S.E.2d

578, 581 (2000) (“Under the plain meaning rule, it is not the court’s place to change the meaning of a clear and unambiguous statute.”).

Trident does not disagree that the State Health Plan is a planning tool utilized by the Department to guide the establishment of health services and, therefore, cannot be considered inflexible and frozen in time. *See* Roper’s Reply, p. 3. For example, the Department logically would consider approved but not yet operational projects in reviewing a CON application. However, by statute, the State Health Plan is required to be updated at least once every two years. S.C. Code Ann. § 44-7-180(C). The Department was aware of the low volume (at times, no volume) of procedures performed at Bon Secours St. Francis-Xavier’s (“Bon Secours”) catheterization lab for years. The Department could have taken steps to close the facility and remove it from the State Health Plan. In fact, the Department stated that it was considering enforcement action against Bon Secours in its email correspondence to Roper’s counsel. *See* Pet. Tr. Ex. 05-002. Instead of pursuing enforcement action and removing Bon Secours’ lab from the State Health Plan inventory, however, the Department adopted a “solution” proposed by Roper, one which was in direct contradiction to the requirements of the State Health Plan and one which was detrimental to other area providers. Thus, what Roper categorizes as the Department’s “interpretation” of the State Health Plan is not an interpretation entitled to agency deference under *Chevron* or any other law.

ROPER’S EXISTENTIAL CRISIS

Roper continues to argue that the Court should evaluate whether Bon Secours’ cath lab existed for purposes of CON Standard 3 at some arbitrary point in time established by Roper and the Department. This argument continues to fail. The State Health Plan is a planning tool for both the Department and providers. The CON Standards were devised to “guide medical providers throughout the State” by giving “applicants notice of the requirements” that must be

met to have a given project approved. *See* State Health Plan, p. I-2. Thus, the time at which an applicant's compliance with the State Health Plan requirements should be measured is the time at which the application is filed and under review. The Court has not inserted a time requirement into the State Health Plan, as Roper alleges. *See* Roper's Reply, p. 4. Rather, the Court has engaged in an appropriate, reasonable, statutory construction analysis, which gives effect to the plain language of the State Health Plan and allows for all the cardiac catheterization requirements set forth therein to be read in harmony.

Roper continues to beleaguer the fact that CON Standard 2 does not include the word "existing," yet CON Standard 3 does. *Id.* Roper's continual haranguing on this difference is of no consequence. CON Standard 2 provides that "[t]he service area for a diagnostic catheterization laboratory is defined as **all facilities** within 45 minutes one way automobile travel time. . . ." State Health Plan, p. VIII-4 (emphasis added). The inclusion of "all facilities" within CON Standard 2 has no bearing on CON Standard 3's requirement that "**all existing labs**" must have met certain historical utilization requirements. *Id.* at p. VIII-5 (emphasis added). CON Standard 2 sets the service area for proposed cardiac catheterization services and, therefore, must include *all facilities* (i.e., those existing and those which have been approved but are not yet operational). By contrast, CON Standard 3 is necessarily limited to only *existing facilities* because only existing facilities would have historic utilization to report.

Trident's health care planning expert, Daniel J. Sullivan, essentially acknowledges this fact in his testimony at the hearing. As Roper alleges, Mr. Sullivan testified that he "sees no distinction between all facilities and all existing facilities." Trial Tr., p. 148:4 – 5. However, Roper fails to mention that Mr. Sullivan also testified that "[a]pproved isn't existing, it's another category of lab that I think has to be factored into the analysis. But, I would agree with you that approved is not part of existing." *Id.* at p. 145: 9 – 14. *See also* Trial Tr., p. 148:9 – 11

(“Because, I mean, what I can’t figure out is what other labs would not be an existing lab other than an approved lab.”). Thus, Mr. Sullivan clearly understood and advocated for a reading of the State Health Plan that distinguished approved labs and existing labs.

Consequently, there is nothing about Trident’s arguments that renders the word “existing” in CON Standard 3 superfluous. The word “existing” in CON Standard 3 certainly has meaning, and its meaning is plain. Consequently, the Department’s “interpretation” of that meaning in contradiction to the plain language is arbitrary and capricious; cannot withstand application of the rules of statutory construction, and is not entitled to deference. Roper alleges that “[t]he evidence, even viewed favorably to Trident, establishes that reasonable, educated minds differ as to the application of Standard 3 and meaning of ‘existing labs’ therein.” Roper’s Reply, p. 6. In fact, with the possible exception of erstwhile philosophers, reasonable, educated minds easily comprehend what it means to exist and the meaning of “existing labs” within CON Standard 3.

TRIDENT’S ALLEGED INCONSISTENT POSITIONS

Roper continues its meritless allegations that Trident has taken inconsistent positions and attributed different meanings to the word “existing” with respect to Trident’s analysis of the health care service transfer provisions in the State Health Plan and CON Standard 3. Roper’s Reply, p. 7. Roper references Mr. Sullivan’s statement, in his July 21, 2016 submission to the Department, in which Mr. Sullivan argued that “[t]he Department should not recognize [Bon Secours’s] diagnostic catheterization program as an existing service merely because only (3) diagnostic caths are performed on average each year. . . .” *See* J. Tr. Ex. 1, p. 199. As Mr. Sullivan testified at trial, however, he was merely making the argument that should the Department consider Roper’s CON application a request to transfer the service, the volume at Bon Secours’ was insufficient to meet the requirements for transfer under the State Health Plan.

See Trial Tr., pp. 204:3 - 209:4. Mr. Sullivan further testified that his use of the word “existing” was “probably inartfully used. What I was saying is, this is not a full-time operational program that would warrant transfer to another provider. . . .” *Id.* at p. 206:13 – 18. Whether Mr. Sullivan’s use of the word was inartful or not, his arguments were certainly not inconsistent. At the time that Mr. Sullivan drafted his correspondence to the Department, setting forth the myriad ways in which Roper’s application failed to comply with the State Health Plan, he no doubt never imagined that he would be forced into a theoretical debate over what it means to exist.

THE HOLDING IN *TRIDENT MEDICAL CENTER V. SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL*, 412 S.C. 341, 772 S.E.2D 177 (CT. APP. 2015) IS INAPPOSITE

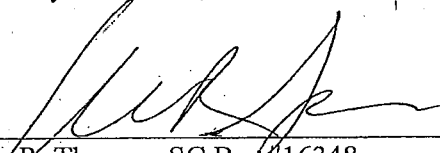
Finally, Roper attempts to analogize the holding in *Trident Medical Center v. South Carolina Department of Health and Environmental Control*, 412 S.C. 341, 772 S.E.2d 177 (Ct. App. 2015) to this case. See Roper’s Rep., p. 10. There is no analogy to be made between these two cases. The holding in *Trident Medical Center* was specific to the hospital bed transfer provisions, which is not at issue in this case. Roper never sought to transfer Bon Secours’ cath lab to its new Berkeley Medical Center location.

Roper’s CON application failed to comply with the State Health Plan requirements as of the date that the application was submitted and as of the date that the Department approved the application. The Department issued its decision letter on July 25, 2016. Roper submitted its letter to the Department confirming the closure of Bon Secours’ cath lab on August 17, 2018, with a retroactive effective date of August 1, 2018. Roper advocates for an application of the State Health Plan Standards not at the time of filing, not during review, not even at the time the decision is rendered, but rather at some arbitrary point in the future decided upon by the Department and the applicant and asks this Court to find this to be a reasonable “interpretation” of the State Health Plan entitled to agency deference.

By Roper's own admission, an "agency's interpretation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." See Roper's Rep., p. 8 (citing *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (emphasis added)). The evidence demonstrates that the Department's interpretation is in direct contradiction to the plain language of the State Health Plan; therefore, it is entitled to no deference by this Court.

WHEREFORE, for the reasons set forth herein, Trident's previously filed Response, and the record as a whole, Trident respectfully renews its request that the Court deny Roper's Motion to Alter or Amend.

Respectfully Submitted,



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January 18, 2019

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

Trident Medical Center, LLC, d/b/a)
Trident Medical Center,)

Docket No.: 16-ALJ-07-0386-CC

Petitioner,)

**PETITIONER'S PREHEARING
STATEMENT**

vs.)

South Carolina Department of Health and)
Environmental Control and Roper St.)

Francis Hospital-Berkeley, Inc., d/b/a)

Roper St. Francis Hospital-Berkeley,)

Respondents.)

Pursuant to the November 28, 2016 Order for Prehearing Statements, Petitioner Trident Medical Center, LLC, d/b/a Trident Medical Center ("Trident") states as follows:

1. The nature of this proceeding.

This matter arises from Petitioner Trident's October 21, 2016 Petition for Administrative Review and Request for Contested Case Hearing regarding (i) the South Carolina Department of Health and Environmental Control's ("Department") July 25, 2016 decision to grant a Certificate of Need ("CON") to Respondent Roper St. Francis Hospital-Berkeley, Inc., d/b/a Roper St. Francis Hospital-Berkeley ("Roper-Berkeley") for the addition of cardiac catheterization services at a total project cost of \$2,873,366 ("Proposed Project"); and (ii) the Department Board's September 21, 2016 decision to deny Trident's request for a final review conference on the matter, rendering the Department's decision the final agency decision (collectively, "Department's Decision").

2. Statutory provision(s) conferring subject matter jurisdiction on the Court and other applicable statutes and regulations.

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SC ADMIN LAW COURT

The Court has jurisdiction over this matter under S.C. Const. Art. I, § 22; S.C. Code Ann. §§ 1-23-320; 1-23-600(B); 44-1-60(F) and 44-7-210(D); 24A S.C. Code Ann. Regs. 61-15; and Rule 11 RPALC. In addition to the general laws and regulations of the State of South Carolina, this case is governed by the State Certification of Need and Health Facility Licensure Act (S.C. Code Ann. §§ 44-7-110 *et seq.*) (“CON Act”), the regulations promulgated thereunder (24A S.C. Code Ann. Regs. 61-15) (“CON Regulations”), and the South Carolina Health Plan, enacted August 13, 2015 (“State Health Plan”).

3. The issues to be presented for determination, including any claims or defenses expected to be raised.

Reserving the right to present any issue raised or considered below, and to address any issue that may arise during discovery, Trident alleges that the Department’s Decision to grant Roper-Berkeley a CON for the Proposed Project must be overturned, because Roper-Berkeley’s CON application failed to meet the standards set forth in the State Health Plan, the applicable project review criteria set forth in the CON Regulations, and the purposes of the CON Act.

4. The action requested of the Court and a detailed statement of the law, including statutory and/or case citations, that support the action requested.

Reserving its right to amend this Prehearing Statement to address additional issues and defenses raised during discovery, Trident requests that the Court reverse the Department’s Decision to grant Roper-Berkeley a CON for the Proposed Project because Roper-Berkeley’s CON application failed to meet the standards of the State Health Plan, the applicable project review criteria set forth in the CON Regulations, and the purposes of the CON Act. *See* S.C. Code Ann. § 44-7-210(B); S.C. Code Ann. Regs. 61-15, § 307.1; State Health Plan, Ch. VIII, p. VIII-4 through VIII-5.

Specifically, *Roper-Berkeley's CON application*:

- *Failed to comply with the requirements for the establishment of a new diagnostic cardiac cath lab set forth in the State Health Plan in that Roper-Berkeley failed to demonstrate that "all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year."* State Health Plan, p. VIII-5, ¶ 3. Roper-Berkeley and the Department remarkably discounted Roper-Berkeley's sister facility, Bon Secours St. Francis Xavier Hospital's ("Bon Secours") virtually non-existent utilization on Roper-Berkeley's assertion that Bon Secours' would cease operation after approval of the CON. Bon Secours' subsequent closure is irrelevant and does not cure the fact that Roper-Berkeley did not meet this State Health Plan criteria at the time the Department was reviewing its CON application. Notwithstanding, even discounting Bon Secours' utilization rates, Roper-Berkeley still failed to meet this State Health Plan criteria because the only provider in the service area that met the 500 diagnostic cath *procedures* (not equivalents) threshold was Trident. The Department ostensibly created a new set of standards for Roper-Berkeley when it could not meet the State Health Plan standards.

- *Failed to comply with the 45 minute drive time, service area standard set forth in the State Health Plan.* State Health Plan, p. VIII-4, ¶ 2. Roper-Berkeley relies on an unrealistic service area encompassing four counties in an effort to create sufficient utilization to justify its Proposed Project. The Department argued that an applicant is not required to comply with the 45 minute drive time standard; however, this assertion contravenes the purpose of both the CON standards and projections of need and is more evidence of the Department's willingness to create new requirements for Roper-Berkeley because it cannot meet the applicable requirements of the State Health Plan. *See* State Health Plan, p. I-2. The State Health Plan requirements are based

on reasonable projections of need, but there is nothing reasonable about Roper-Berkeley's service area or the utilization projections upon which they are based.

- *Failed to comply with the State Health Plan requirement that an applicant for a new diagnostic service "must project that the proposed service will perform a minimum of 500 diagnostic equivalents annually within three years of initiation of services, without reducing the utilization of existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory."* State Health Plan, p. VIII-5. Roper-Berkeley's projections are unsupportable and based upon unrealistic assumptions. In addition to Roper-Berkeley's use of an unrealistically broad service area, Roper-Berkeley assumes that it will absorb diagnostic catheterization cases from its sister facility, Roper Hospital. The facts do not support this assumption. There is no reason to believe that either patients or physicians would choose a diagnostic-only catheterization lab over a comprehensive catheterization lab, thereby running the risk that the patient may need to be transferred to another facility or need to schedule a second invasive procedure. The fact that Bon Secours' diagnostic catheterization program has essentially existed in name only is a testament to the fact that Roper-Berkeley cannot rely upon the absorption of diagnostic catheterization cases from Roper Hospital.

Roper-Berkeley also assumes that Roper Hospital's diagnostic catheterization volume will grow in conjunction with the projected rate of population growth; however, this assumption is inconsistent with both Roper Hospital's historical experience and the historical experience of all other area providers. Diagnostic cardiac catheterization procedures actually declined in the service area by twenty (20%) percent between 2011 and 2015, while the population grew, and there is no reason to believe the trend will not continue.

Had Roper-Berkeley used reasonable assumptions in generating its projected utilization, the projections would have been far lower. The facts do not support Roper-Berkeley's projections.

- *Failed to demonstrate community need.* S.C. Code Ann. Regs. 61-15, § 802.2. The CON regulations require that the Proposed Project meet an identified need based upon reasonable assumptions and methods. *Id.* at § 802.2.c. The CON regulations also require that the applicant project utilization sufficient to justify the expansion or implementation of the Proposed Project. *Id.* at § 802.2.e. As demonstrated herein, there is nothing reasonable about either Roper-Berkeley's assumptions identifying community need or its projected utilization. The facts demonstrate that Roper-Berkeley's utilization will actually be much lower than projected and insufficient to justify the Proposed Project.

Further, *Roper-Berkeley's Proposed Project is:*

- *An unnecessary duplication of services.* Roper-Berkeley and the Department incorrectly conclude that as a result of the closure of Bon Secours' diagnostic catheterization program there will be no unnecessary duplication of services. Bon Secours' program was virtually non-existent, as there were never more than ten (10) diagnostic cardiac catheterization cases performed in the Bon Secours lab in the last five years. The absorption of approximately five cardiac catheterization procedures annually will not support the operation of Roper-Berkeley's Proposed Project, and it is unlikely that Roper-Berkeley will absorb any substantial number of diagnostic cardiac catheterization cases from Roper Hospital. The more realistic scenario is that Roper-Berkeley's Proposed Project will redirect patients from Trident, adversely impacting Trident's utilization volumes. There is no need for Roper-Berkeley's Proposed Project. The Proposed Project is an unnecessary duplication of services and does nothing to increase accessibility to services.

- *Not financially feasible.* The CON project review criteria require that the applicant project immediate and long-term financial feasibility of the Proposed Project based upon reasonable projections. S.C. Code Ann. Regs. 61-15, § 802.15. As demonstrated herein, the assumptions underlying Roper-Berkeley's financial projections are not reasonable and cannot be realized. More reasonable assumptions would have resulted in dramatically lower utilization projections and, consequently, dramatically lower financial projections. In reality, the Proposed Project is unlikely to generate an excess of revenue over expenses.

- *Does not promote cost containment.* The Proposed Project has a total project cost of almost \$2.9 million for a service that is not needed, that will be underutilized, and that will adversely impact Trident and other area providers. Roper-Berkeley's Proposed Project will increase health care costs in the service area and, therefore, will do nothing to promote cost containment.

For the foregoing reasons, the Department's Decision must be reversed.

5. A brief summary of the facts to be presented at the hearing.

Reserving its right to present detailed factual and expert evidence to the Court at the hearing, Trident offers the following summary of facts for purposes of this Prehearing Statement:

On May 9, 2016, Roper-Berkeley submitted its CON application for the Proposed Project. By letter, dated May 26, 2016, the Department deemed the CON application complete. Trident timely notified the Department of its status as an affected person and its opposition to the Proposed Project and requested that the Department hold a Project Review Meeting. Subsequently, Trident submitted a letter from its consultant, Sullivan Consulting Group, Inc., detailing its reasons for opposing the Proposed Project. On July 25, 2016, the Department issued its decision letter, approving Roper-Berkeley's CON application, without conducting a Project Review Meeting. Trident then requested that the Department Board conduct a final review

conference on the matter. The Department Board declined to hold a final review conference, rendering the Department's Staff Decision the final agency decision. Trident then filed its Petition for Administrative Review and Contested Case Hearing with this Court on October 21, 2016.

The State Health Plan prohibits the approval of new diagnostic cardiac catheterization labs unless "all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year." State Health Plan, p. VIII-5, ¶ 3. Bon Secours has not met this threshold in several years, and, in fact, has averaged less than 10 cardiac catheterization cases per year for the last four years. *Id.* at p. XIII-33.

Roper-Berkeley stated in its CON application that, upon approval, Bon Secours would close its diagnostic catheterization lab, and by letter dated August 17, 2016, Bon Secours confirmed the closure. However, the subsequent closure of Bon Secours' catheterization lab does not change the fact that at the time the Department approved Roper-Berkeley's CON application, the application did not comply with the provisions of the State Health Plan. More importantly, it does not cure the issues that the addition of a new cardiac catheterization service in the area presents.

Roper-Berkeley could have submitted its CON application as a proposed transfer of services from Bon Secours, but it knew it could not meet the State Health Plan requirements for a transfer. *See generally* State Health Plan, p. II-2. For example, Roper-Berkeley could not demonstrate need for additional capacity based on historical and projected utilization patterns. *Id.* Instead, Roper-Berkeley and the Department chose to treat the CON application as a request for a new diagnostic catheterization service, disregarding the fact that the CON application failed to meet those State Health Plan requirements as well. The Department's decision to grant Roper-Berkeley's CON application as a "new service" allows Roper-Berkeley to skirt compliance with

the State Health Plan by creating its own procedural process. It is fundamentally unjust to create a separate set of standards merely because a provider cannot meet the applicable standards of the State Health Plan.

The State Health Plan provides that “[t]he service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes one way automobile travel time. . . .” *Id.* at p. VIII-4, ¶ 2. Roper-Berkeley’s CON application fails to comply with this State Health Plan requirement as well. Roper-Berkeley’s service area is much broader than the 45 minute one way automobile travel time standard and is defined as encompassing four counties: Berkeley, Dorchester, Charleston, and Colleton. Many portions of Charleston and Colleton Counties lie well outside of the 45 minute drive time service area established by the State Health Plan.

In its response to Trident’s request for a final review conference before the Department Board, the Department staff stated that “[n]either the Plan nor applicable law require an applicant to limit its projected utilization to only those individuals residing in the Plan-defined service area.” The 45 minute drive time service area is a CON standard for diagnostic cardiac cath services. CON standards were formulated by the Department “to guide medical providers throughout the State. Inclusion of these standards in the application process is designed to give applicants *notice of its requirements and to elicit from them a commitment to incorporate these standards into both their applications and finished projects.*” *Id.* at p. I-2 (emphasis added).

The State Health Plan prescribes service areas based on “an assessment of existing resources and need in the relevant service area, along with other factors set forth in [the] Plan, applicable statutes, and regulations.” State Health Plan, p. II-2. Thus, the services area is defined through a reasonable analysis of the needs of an area. There is nothing reasonable about Roper-Berkley’s service area. To allow an applicant to create a service area as broad as necessary to allow the applicant to ramp up sufficient utilization to justify a proposed project

would defeat the need for the inclusion of a service area within the State Health Plan CON standards and render the Department's review with respect to projected utilization meaningless. Yet, this is exactly what the Department did when it accepted Roper's unrealistic service area.

Roper-Berkeley's service area is unrealistic, *inter alia*, because it illogically assumes that patients would travel greater distances past other providers with existing cardiac cath programs, including providers operating comprehensive programs, to have the procedure performed at Roper-Berkeley, which will be a small 50-bed community hospital.

Roper-Berkley's sister facility, Roper Hospital, is located in downtown Charleston. Roper Hospital aligned physicians historically referred all patients to the comprehensive cardiac catheterization program at Roper Hospital, not the diagnostic-only catheterization program at Bon Secours. Consequently, Bon Secours' diagnostic program was essentially non-existent. Physicians who believe there is a likelihood that a patient will require percutaneous coronary intervention ("PCI") will naturally refer that patient to a comprehensive cardiac cath program where both procedures can be performed during the same visit. It is highly unlikely that the physician instead would send that patient to a facility with only a diagnostic program available and risk having to transfer the patient to another facility or require the patient to be scheduled for another procedure at a different time, thereby unnecessarily subjecting the patient to two separate, invasive procedures. Bon Secours' virtually non-existent utilization rates over the last several years are a testament to the fact that Roper aligned physicians recognize that referral to a comprehensive cardiac cath program is in the patient's best interest. There is no reason to believe that the physicians' referral patterns would change upon the opening of a diagnostic only cardiac cath program at a small, 50-bed community hospital, such as Roper-Berkeley.

Roper-Berkeley claims that Roper Hospital will transfer some of its existing diagnostic caseload to Roper-Berkeley. However, again, there is no evidence that patients or physicians

will choose Roper-Berkeley rather than continue to utilize the comprehensive cardiac cath services provided at Roper Hospital. Roper-Berkeley attempts to bolster its projected utilization under the premise that it will absorb some of the volume from Roper Hospital; however, the fact that Bon Secours' diagnostic cardiac cath program was virtually non-existent demonstrates that this premise is meritless and unsupportable.

Roper-Berkeley's CON application fails to meet the State Health Plan requirement that a new diagnostic cath service can only be approved "if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year." *Id.* at p. VIII-5, ¶ 3. Roper-Berkeley and the Department apparently misinterpreted this provision as requiring existing facilities to have provided 500 diagnostic equivalents per lab in the most recent year, despite the plain language of the State Health Plan. Only one facility, Trident, met the threshold of 500 diagnostic procedures for each of its two labs. Roper Hospital, MUSC, and Bon Secours fell well below this threshold.

The State Health Plan states that

An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic *equivalent* procedures annually within three years of initiation of services, without reducing the utilization of existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization *procedures* per laboratory.

State Health Plan, p. VIII-5, ¶ 4 (emphasis added). In addition to the fact that Roper-Berkley's service area cannot support its utilization projections, Roper-Berkeley's projections are seriously flawed in that Roper-Berkeley's claims that it will absorb volume from Roper Hospital are unsupportable. Yet, Roper-Berkeley presumes that it will absorb eighty (80%) percent of Roper Hospital's Berkeley County cases, sixty-five (65%) percent of its Dorchester County cases, and fifty (50%) percent of its Charleston County cases. Such dramatic shifts in market share are not supported by the facts.

Rather than absorbing Roper Hospital's cardiac cath patient base, the more likely scenario is that Roper-Berkeley's Proposed Project will redirect patients from Trident. Trident is currently a major provider of diagnostic and therapeutic catheterization services to residents in Berkeley and Dorchester Counties. Yet, the Department gave no consideration to the potential adverse impact the Proposed Project would have on Trident. The Department stated that "[a]s one lab in the service area is being closed as a result of this approval. . . no unnecessary duplication of services is expected." Bon Secours' utilization was *de minimis*, and the closure of its cardiac cath program will have no material impact on utilization at Roper-Berkeley. The absorption of the less than five diagnostic cath cases annually performed at Bon Secours will not keep Roper-Berkeley in operation. Roper-Berkeley will have to redirect significant market share from Trident to achieve its projected volumes. Nevertheless, both Roper-Berkeley and the Department dismissed the issue of adverse impact, despite the fact that Trident is located only seven miles from the Roper-Berkeley campus.

Roper-Berkeley's utilization projections are also based on the assumption that Roper Hospital's historical diagnostic cardiac cath volume will grow in conjunction with the projected rate of population growth. However, this assumption is inconsistent with Roper Hospital's recent historical experience, as well as the experience of all other area service providers. Every provider in the service area has seen a decline in diagnostic cath procedures since 2011, and utilization of diagnostic cardiac cath services through the service area declined by twenty (20%) percent between 2011 through 2015. There is no reason to believe that this trend will not continue.

Essentially all of Roper-Berkeley's patients will likely originate from its primary service area. As such, Roper-Berkeley cannot meet the required 500 diagnostic catheterization equivalents annually, even assuming the redirection of patients from Roper Hospital. In all

likelihood, Roper-Berkeley will operate a low volume program, while redirecting market share from Trident, adversely impacting Trident's utilization. Yet, the Department never questioned the legitimacy of Roper-Berkeley's utilization projections.

There is no community need for Roper-Berkeley's Proposed Project. As noted above, Roper-Berkeley utilized an unrealistic service area to bolster its utilization projections. In its approval letter, the Department stated that all labs within the planning area operate between seventy-nine (79%) percent and nearly ninety-four (94%) percent capacity. The Department then concludes that Roper-Berkeley has sufficiently demonstrated community need. *Id.* However, the CON project review criteria for community need requires that the Proposed Project:

meet an identified (documented) need of the target population. The assumptions and methods used to determine the level of need should be specified in the application and *based on a reasonable approach* as judged by the review body.

S.C. Code Ann. Regs. 61-15, § 802.2.c. (emphasis added). The project review criteria further provides that "[c]urrent and/or projected utilization should be sufficient to justify the expansion or implementation of a proposed service." *Id.* at § 802.2.e. There is nothing reasonable about Roper-Berkeley's assumptions with respect to community need or projected utilization. The actual utilization that Roper-Berkeley will realize will be much lower than projected and is insufficient to justify the implementation of the Proposed Project. The area is already well-served by Trident and other area providers, all of whom have capacity to meet the needs of the community, particularly given the fact that all providers have experienced declining utilization over the past several years.

Roper-Berkeley's Proposed Project will unnecessarily duplicate services without increasing accessibility to services. The Department's conclusion that there will be no duplication of services because Bon Secours would close its cardiac cath program upon approval

of the CON is illogical. Bon Secours' cardiac cath program existed in name only. The absorption of less than five diagnostic procedures annually will not support the operation of Roper-Berkeley's Proposed Project, and it is unlikely that any significant number of patients will be redirected from Roper Hospital. The presumption that utilization volumes will grow with the population contravenes the declining utilization trends in the service area, which has experienced significant population growth in the last decade. The likely scenario is that Roper-Berkeley will rely on the redirection of market share from Trident, adversely impacting Trident's utilization. There is no need for the Proposed Project. It does nothing to increase accessibility to services, and it is an unnecessary duplication of services.

The Proposed Project is not financially feasible. The project review criteria require an applicant to project "both the immediate and long-term financial feasibility of the proposal. Such projections should be reasonable and based upon accepted accounting procedures." S.C. Code Ann. Regs. 61-15, § 802.15. The assumptions underlying Roper-Berkeley's projections are unreasonable and unsupportable and cannot be realized. More reasonable assumptions would have produced dramatically lower projected utilization and, therefore, dramatically lower financial projections. In reality, the Proposed Project is unlikely to demonstrate an excess of revenue over expenses.

The Proposed Project does not promote cost containment. The Proposed Project has a total project cost of almost \$2.9 million for an unneeded service, which will likely be underutilized. The Proposed Project will adversely impact Trident and other area providers and will increase health care costs in the service area.

In sum, the Proposed Project does not comply with the requirements of the State Health Plan or the project review criteria set forth in the CON regulations, and the Department's decision to approve Roper-Berkeley's CON application must be reversed.

6. A summary of any motions expected to be raised at the hearing and the appropriate authority for the motion.

Trident intends to file a Motion to Dismiss the Contested Case and Remand in the very near future based on publicly available documents. Should this motion not be granted, Trident will evaluate the necessity for further motions at the completion of discovery, and it reserves the right to raise any motions necessary prior to or at the hearing in this matter.

7. A list of proposed witnesses and exhibits.

Reserving its right to call any witnesses listed by any party to the proceeding, as well as any witnesses that may become known to the parties during the discovery process or as the case develops, at this time, Trident identifies the following persons as potential witnesses at the hearing in this matter:

1. Louis W. Eubank, MSW, MPH
Director, Certificate of Need Program
South Carolina Department of Health and Environmental Control
2. Daniel J. Sullivan
Sullivan Consulting Group, Inc.
3. Melissa Barnes
Director, Catheterization Lab
Trident Medical Center
4. Todd G. Gallati
Chief Executive Officer
Trident Medical Center
5. Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
6. Julie A. Gaudin, CPA
Roper St. Francis Healthcare
7. Allen Carroll
CEO of RSF Bon Secours Hospital

Reserving its right to utilize and introduce as evidence any documents identified by any party to the proceeding and to introduce documents gathered during the discovery period, Trident identifies the following as potential exhibits at the trial of this matter:

1. The Department's Record for the Proposed Project.
2. The South Carolina Health Plan, enacted August 13, 2015.
3. Any other relevant document, data/information or materials produced during discovery by any party or non-party.

8. Whether discovery is necessary and, if so, a proposed schedule.

Trident believes discovery, consistent with the parameters set forth in S.C. Code Ann § 44-7-210(F), is necessary and sufficient.

9. The estimated length of the hearing.

Trident anticipates that the hearing in this matter will take one week.

10. Any dates in the next 120 days when you will not be available for a hearing.

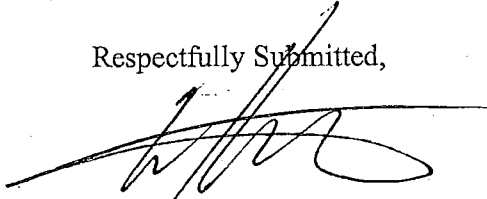
Most of January and March 2017 are not available for the undersigned counsel because of existing contested case matters and hearings. Counsel for Trident would suggest that counsel for all parties confer and develop a consent scheduling order for the Court to review.

11. An email address where you can be reached.

willthomas@parkerpoe.com
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[SIGNATURE PAGE FOLLOWS]

Respectfully Submitted,



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*Attorneys for Petitioner
Trident Medical Center, LLC, d/b/a
Trident Medical Center*

Columbia, South Carolina
December 13, 2016

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

Trident Medical Center, LLC, d/b/a Trident
Medical Center,

Petitioner,

vs.

South Carolina Department of Health and
Environmental Control and Roper St. Francis
Hospital - Berkeley, Inc., d/b/a Roper St.
Francis Hospital - Berkeley,

Respondents.

Docket No.: 2016-ALJ-07-0386-CC

PREHEARING STATEMENT
OF ROPER ST. FRANCIS HOSPITAL -
BERKELEY

Pursuant to the November 28, 2016 Order for Prehearing Statements of the Court, Respondent Roper St. Francis Hospital – Berkeley, Inc. d/b/a Roper St. Francis Hospital – Berkeley (“Roper Berkeley”) respectfully submits the following:

1. The nature of this proceeding.

This action arises from the July 25, 2016 decision of the Respondent South Carolina Department of Health and Environmental Control (“DHEC” or “Department”) to grant the Certificate of Need (“CON”) Application to Roper Berkeley to establish a new diagnostic cardiac catheterization laboratory in conjunction with the planned opening of Roper-Berkeley hospital in 2019 at a total project cost of \$2,873,366. Trident Medical Center, LLC (“Trident”) has challenged this decision.

2. Statutory provision(s) conferring subject matter jurisdiction on the Court and other applicable statutes and regulations.

The Court has jurisdiction over this matter under the South Carolina Administrative Procedures Act, S.C. Code Ann. §§ 1-23-310, *et seq.*; the Certificate of Need and Health Facility

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Licensure Act, S.C. Code Ann. §§ 44-7-110, *et seq.*; the Certificate of Need for Health Facility and Services Regulations, 24A S.C. Code Ann. Regs. 61-15, *et seq.*; and the Rules of Procedure for the Administrative Law Court.

3. The issues to be presented for determination, including any claims or defenses expected to be raised.

The Department granted the CON to Roper Berkeley to establish diagnostic cardiac catheterization services at the campus of the first inpatient acute care hospital to be constructed in the increasingly populated Berkeley County, one of the largest counties in the State by size and population. The CON Application was filed under the *2015 South Carolina Health Plan*, which sets forth the standards necessary for the establishment of diagnostic cardiac catheterization services in South Carolina.

The Department reviewed the CON Application filed by Roper Berkeley and considered, and properly rejected, the arguments of Trident in opposition to the project. Roper Berkeley is informed and believes that the Department's decision to grant the CON should be affirmed by this Court as being consistent with the standards and criteria of the *2015 South Carolina Health Plan*, the CON Act, Regulation 61-15, and other applicable law.

4. The action requested of the Court and a detailed statement of the law, including statutory and/or case citations, that support the action requested.

Roper Berkeley respectfully requests that this Court affirm the decision of the Department in all respects. Where the petitioner cannot show by a preponderance of the evidence that DHEC erred in its decision, this Court must affirm the Department and deny the petitioner's requested relief. *See e.g. Amisub of S.C., Inc. d/b/a Piedmont Med. Ctr. v. S.C. Dept. of Health and Env'tl. Control*, Docket No. 2010-ALJ007-0767-CC, 2011 WL 7119244 (Sept. 13,

2011).

5. A brief summary of the facts expected to be presented at the hearing.

Without waiving and otherwise reserving its right to present detailed factual and expert evidence to the Court, Roper Berkeley submits the following factual summary:

Berkeley County continues to be one of the fastest growing counties in the State of South Carolina. As part of Roper Berkeley's commitment to bring needed health services to the residents of Berkeley County and surrounding communities, Roper Berkeley seeks to add diagnostic catheterization services to those services slated for the acute care hospital opening in 2017 at Carnes Crossroads. It is undisputed that the Roper St. Francis health system serves a substantial portion of the patients originating from Berkeley County. Roper Berkeley's intention to service its existing patient base currently traveling from the Berkeley and Dorchester County areas to downtown Charleston was fully litigated in the Berkeley hospital matter and withstood scrutiny at multiple levels of appeal.

The existing providers of cardiac catheterization services in the applicable service area all reflect high utilization, with the exception of the Bon Secours St. Francis laboratory that is now closed. The Medical University of South Carolina and Trident both perform more than 500 diagnostic cardiac catheterizations per laboratory, as do the laboratories at Roper Hospital in downtown Charleston. *See XIII-33 of the 2015 South Carolina Health Plan.* Trident challenges the Applications use of diagnostic equivalents when addressing volume, but those challenges are meritless given that the underlying data all reflects the necessary volumes and utilizations needed to approve an additional cardiac catheterization laboratory in the service area. Trident's use of partial year 2015 laboratory volumes to assert that Roper Berkeley's application is deficient should be rejected.

The data reflects that Roper Hospital in downtown Charleston provides cardiac catheterization services for more than a quarter of the Berkeley County residents requiring care. Roper-Berkeley's plan to redirect those patients driving long distances into the highly congested Charleston peninsula is a valid and appropriate distribution of services that satisfies the letter and spirit of the South Carolina Health Plan and the CON Act and Regulations. The Department thoroughly considered Roper Berkeley's need analysis, and Trident's objections thereto, and properly determined that the CON should be granted. Roper Berkeley submits that this Court should do the same.

6. A summary of any motions expected to be raised at the hearing and the appropriate authority for the motion.

Roper Berkeley reserves its right to file a dispositive motion in the event it is determined to be appropriate under the facts and law of the case.

7. A list of proposed witnesses and exhibits.

- (a) Allen Carroll

- (b) Michael Grayson, MD

- (c) Shannon Cantwell

- (d) Louis Eubank, Director, CON Program, DHEC

- (e) Kathy Platt, Platt Consulting HMC

- (f) Tori Tibshirany, Platt Consulting HMC

- (g) Roper Berkeley reserves its right to identify an additional expert witness (or witnesses) in those areas determined to be relevant based on the discovery conducted in this case, including additional medical experts, and will supplement this Statement as appropriate.

Reserving its right to utilize and introduce as evidence any documents identified by

any party to the proceeding, and to introduce documents gathered during the discovery period, Roper Hospital identifies the following documents as potential exhibits at the trial of this matter:

- (a) The Department's Record for the Roper Berkeley CON Project;
 - (b) The *2015 South Carolina Health Plan*;
 - (c) Any other relevant evidence produced during discovery by any party.
8. Whether discovery is necessary and, if so, a proposed schedule.

Roper Berkeley believes that discovery pursuant to the CON Act and the Rules of Civil Procedure will be necessary in this case.

9. The estimated length of the hearing.

Roper Berkeley estimates that the hearing on this matter will take five to seven days.

10. Any dates in the next one-hundred twenty (120) days when you will **not** be available for a hearing.

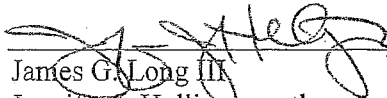
Roper Berkeley anticipates conferring with counsel for all parties to enter an agreeable Consent Scheduling Order and Consent Protective Order to allow for the orderly progression of this case.

11. An email address where you can be reached.

jlong@nexsenpruet.com

jhollingsworth@nexsenpruet.com

RESPECTFULLY SUBMITTED,


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*Attorneys for Respondent Roper Hospital -
Berkeley, Inc., d/b/a Roper St. Francis Hospital -
Berkeley*

December 19, 2016
Columbia, South Carolina

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