

**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**

**RECEIVED**  
MAR 05 2019  
SC Court of Appeals

**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 lab<sup>1</sup> (Project) at its medical facility which is under construction in Berkeley County and is scheduled to open in the fall of 2019.

<sup>1</sup> 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.<sup>2</sup>

### **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.

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<sup>2</sup> 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)."<sup>3</sup>

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.

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<sup>3</sup> "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.<sup>4</sup>

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,

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<sup>4</sup> 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.<sup>5</sup>

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.<sup>6</sup>

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.<sup>7</sup>

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.

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<sup>5</sup> 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."

<sup>6</sup> 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.

<sup>7</sup> 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.<sup>8</sup> 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

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<sup>8</sup> 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.<sup>9</sup>

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."

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<sup>9</sup>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 14<sup>th</sup> 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.<sup>10</sup>

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

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<sup>10</sup> 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.”<sup>11</sup> 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

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<sup>11</sup> 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.

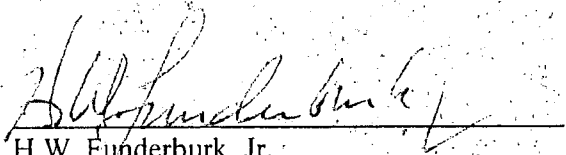
I find that Bon Secours was an existing lab offering and providing cardiac catheterization procedures in the service area in which Roper-Berkeley seeks to establish a new diagnostic catheterization lab, and that Bon Secours was not performing a minimum of 500 diagnostic catheterization procedures as 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

SC ADMIN. LAW COURT

**CERTIFICATE OF SERVICE**

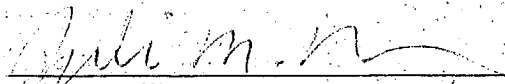
I, Julia M. Miller, hereby certify that I have this date served this Order upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, in the Interagency Mail Service, or by electronic mail to the address provided by the party(ies) and/or their attorney(s).

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December 3, 2018  
Columbia, South Carolina

  
Julia M. Miller  
Judicial Law Clerk

**FILED**

DEC 03 2018

SC ADMIN. LAW COURT

**AMENDED FINAL ORDER**  
**(February 21, 2019)**