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STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

SC Court of Appeals

Grand Strand Regional Medical)
Center, LLC,)
)
Petitioner,)
)
vs.)
)
South Carolina Department of Health and)
Environmental Control,)
)
Respondent.)
_____)

Docket No.: 12-ALJ-07-0090-CC

AMENDED FINAL ORDER
AND DECISION

Grand Strand Regional Medical)
Center, LLC,)
)
Petitioner,)
)
vs.)
)
South Carolina Department of Health and)
Environmental Control and Carolinas)
Regional Cancer Center,)
)
Respondents.)
_____)

Docket No.: 12-ALJ-07-0091-CC

(Consolidated)

Appearances:

For Petitioner Grand Strand: William R. Thomas, Esq. and Walter H. Cartin, Esq.

For Respondent CRCC: James G. Long III, Esq.; E. Wade Mullins, III, Esq.;
and Jennifer J. Hollingsworth, Esq.

For Respondent SC DHEC: Ashley C. Biggers, Esq.

STATEMENT OF THE CASE

The above-captioned matters come before the South Carolina Administrative Law Court (ALC or Court) upon the requests of Petitioner Grand Strand Regional Medical Center, LLC (Grand Strand) for a contested case hearing to review the decisions of Respondent South

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ADMINISTRATIVE LAW COURT

Carolina Department of Health and Environmental Control (DHEC or the Department) (1) to deny Grand Strand's Certificate of Need (CON) application for the addition of a linear accelerator and CT Simulator for a radiation therapy center at its hospital location in Myrtle Beach, South Carolina; and (2) to approve the CON application of Respondent Carolina Regional Cancer Center (CRCC) for an additional linear accelerator to expand its existing linear accelerator services to Conway, South Carolina.¹ CRCC moved to intervene in the matter pending between Grand Strand and the Department, which was granted in an Order dated May 4, 2012. Also, the cases were consolidated by a Consent Order also dated May 4, 2012. After timely notice to the parties, the Court conducted a hearing on the merits September 12, 2013 through September 24, 2013. On March 20, 2014, CRCC filed a Motion to Alter or Amend the Court's Final Order and Decision dated March 10, 2014. On March 28, 2014, Grand Strand filed a Memorandum in Opposition to CRCC Motion to Alter or Amend.² After careful consideration of the arguments made by both parties, the Court has amended its March 10, 2014 Order accordingly below.

The Department found the CON applications to be competing applications as defined by the CON Regulations. CRCC supports DHEC's finding that Grand Strand's and its CON applications are competing and that Grand Strand's application should be denied. Grand Strand, on the other hand, challenges the Department's finding that the CON applications are competing applications and argues in the alternative that even if the applications were competing, DHEC should have approved Grand Strand's application and denied CRCC's application because Grand Strand's application more fully complies with the South Carolina CON Act, its regulations, and the applicable South Carolina Health Plan (State Health Plan or Health Plan).

I find that Grand Strand's and CRCC's CON applications are not competing applications as defined by the applicable law and both applications satisfy the State Health Plan, the Project Review Criteria (PRC),³ and the purposes of the Certificate of Need Act. Furthermore, there is a

¹ Initially, an additional applicant and petitioner, North Strand Radiation Oncology Center (North Strand) filed a contested case challenging DHEC's denial of its CON application and the approval of CRCC's CON application, but North Strand withdrew from the contested case and was formally dismissed with prejudice on March 5, 2013.

² Grand Strand filed a hard copy and electronic copy of its Memorandum on March 28, but due to an error in the Court's emailing system, the electronic version that Grand Strand submitted was not discovered by the Court until March 31

³ The PRC, consisting of 33 general criteria, including subcriteria, are set forth in 3 S.C. Code Ann. Reg. 61-15 § 802 (Supp. 2013). Each criterion will henceforth be referred to using PRC in place of the regulatory citation followed by the subsections. For example, 3 S.C. Code Ann. Reg. 61-15 § 802(2)(b) will be cited as PRC 2(b).

need for two additional linear accelerators in the Service Area⁴ under the 2012-2013 State Health Plan. In reaching this decision, this Court compared the CON applications to determine which application more fully complied with the requirements, goals, and purposes of the CON program, State Health Plan, PRC, and the regulations developed by the Department. Therefore, I conclude that both CRCC and Grand Strand should be granted CONs.

FINDINGS OF FACT

Having observed the witnesses and exhibits present at the hearing and closely passed upon their credibility, taking into consideration the burden of proof upon the parties, I make the following Findings of Fact by a preponderance of the evidence:

The Parties

Grand Strand, a for-profit subsidiary of Hospital Corporation of America (HCA),⁵ is a 269-bed tertiary-care hospital located in Myrtle Beach, South Carolina, that opened in 1978. Grand Strand is an accredited community cancer center by the Commission on Cancer of the American College of Surgeons.

CRCC is a freestanding radiation therapy provider currently operating three linear accelerators at one location in Myrtle Beach, South Carolina. CRCC's Myrtle Beach facility is located three miles from Grand Strand's campus. CRCC is a 100% subsidiary of Atlantic Urology Clinics, LLC (AUC), which is a 100% subsidiary of 21st Century Oncology of South Carolina, LLC, which is, in turn, a 100% subsidiary of Radiation Therapy Service, Inc. (21st Century).⁶ CRCC has been approved for, but has not been issued, a CON to relocate one of its three linear accelerators from its facility in Myrtle Beach, South Carolina, to a facility in Murrells Inlet, South Carolina, which is located in northern Georgetown County.

Applications at Issue

The applications at issue in this case are for the three-county Service Area. CRCC filed an application on March 10, 2011, to install a Varian TrueBeam linear accelerator (TrueBeam)

⁴ The Service Area consists of three counties comprised of: Horry, Georgetown, and Williamsburg Counties (Service Area).

⁵ HCA is the nation's largest provider of hospital services, based out of Nashville, TN, with approximately 174 hospitals. HCA operates about 40 linear accelerators across the country.

⁶ 21st Century is the largest provider of radiation therapy services in the United States. It operates approximately 100 radiation therapy centers in 16 U.S. States and approximately 30 additional centers in South America, employing over 125 radiation oncologists and more than 250 oncology-related physicians.

and a CT simulator⁷ at a new location in Conway, South Carolina to provide conventional, Intensity Modulated Radiation Therapy (IMRT), and Image-Guided Radiation Therapy (IGRT) radiotherapy services to treat cancer patients in the Service Area. Grand Strand subsequently filed an application on July 19, 2011, to install a Varian Clinac iX linear accelerator (Clinac iX) and a CT simulator on the campus of its hospital in Myrtle Beach, South Carolina to provide conventional, IMRT, and IGRT radiotherapy services to treat cancer patients in the Service Area.

Radiotherapy, or “radiation therapy,” is a service covered by the State Health Plan. Radiation therapy is one of three major modalities to treat cancer, along with surgery and chemotherapy. Between 50% and 60% of all cancer patients receive radiation therapy as part of their cancer treatment. External beam radiation therapy is the most common form of radiation therapy, which focuses the beam of radiation to a precise treatment field with fewer side effects. IMRT and IGRT are types of external beam radiation therapy.

A linear accelerator delivers an external beam of radiation to the patient. It puts out high-energy radiation to reach the tumor, with the ability to rotate 360° around the patient to treat from any angle. Before radiation therapy begins, the treatment is planned using a CT scan with a CT Simulator, which identifies the tumor, and nearby vital structures to avoid. The doctor then uses the results of the CT scan to enter coordinates for the radiation to enter the patient’s body.

Though radiation therapy is used to treat many different types of cancer, it is most commonly used for breast cancer, prostate cancer, lung cancer, and metastatic cancer (where the cancer has spread from its primary site). Radiation therapy can be a palliative treatment (to provide pain relief) and/or a curative treatment (to cure the disease). The overwhelming majority of radiation therapy is delivered on an outpatient basis. The patient is typically treated once a day, five days per week, for a number of weeks. The number of radiation therapy treatments a patient will have depends on several factors, including the type of cancer, the stage of the cancer, and the size of the tumor. The average number of treatments for commonly seen cancers is typically thirty or more treatments for each patient, though some patients receive fewer treatments due to the location of the tumor or the advance stage of the disease.

⁷ A CT simulator stands for Computerized Tomography scanner and is used to identify tumors and surrounding tissue in order to plan the precise radiation therapy treatment.

Both Applicants (CRCC and Grand Strand) applied under the 2010-2011 State Health Plan, each projecting that its proposed linear accelerator will achieve more than 50% capacity (3,500 treatments) by the third year. The 2010-2011 State Health Plan sets forth the Plan standards for Radiotherapy. The 2010-2011 State Health Plan states that the “following project review criteria are considered to be the most important in evaluating [CON] applications for [radiation therapy] services: (a) Compliance with the Need Outlined in this Section of the Plan; (b) Community Need Documentation; (c) Distribution (Accessibility); (d) Projected Revenues; (e) Projected Expenses; (f) Financial Feasibility; and (g) Cost Containment.” Additionally, the State Health Plan states that the “benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.”

The following standards from IX-5, -6 of the 2010-2011 State Health Plan are directly applicable to the CON applications in this case and are relevant to the ultimate decision:

- 1.⁸ The capacity of a conventional linear accelerator . . . is 7,000 treatments per year.
2. Linear accelerators providing IMRT or IGRT have a capacity of 5,000 treatments per year. A Facility must document that it is providing or will provide these specialized treatments in sufficient volume to justify why it should be held to this planning capacity.
* * *
6. New Radiotherapy services shall only be approved if the following conditions are met:
 - A. All existing units in the service area have performed at a combined use rate of 80 percent of capacity for the year immediately preceding the filing of the applicant’s CON application; and
 - B. An applicant must project that the proposed service will perform a minimum number of treatments equal to 50 percent of capacity annually within three years of initiation of services, without reducing the utilization of the existing machines in the service area below the 80 percent threshold
7. Expansion of an existing service, whether the expansion occurs at the existing site or at an alternate location in the service area, shall only be approved if the service has operated at a minimum use rate of 80 percent of capacity for each of the past two years and can project a minimum use rate of 50 percent of capacity per year on the additional equipment within three years of its implementation.

⁸ Each of these numbers is a subsection under Chapter IX, Section 4 of the 2010-2011 State Health Plan.

8. The applicant shall project the utilization of the service and document referral sources for patients within its service area, including letters of support from physicians and health care facilities indicating a willingness to refer patients to the proposed service, with expected annual referral volumes.

* * *

Standards 6(A) and 6(B) apply to Grand Strand as a new provider, but not to CRCC, while Standard 7 applies to CRCC because its proposal is an expansion project.

Need for a Linear Accelerator in the Service Area

Grand Strand presented Dan Sullivan as a healthcare planning and finance consultant. Mr. Sullivan explained the need for the CON application and presented a review of the competing CON applications. Mr. Sullivan has worked on CON applications for three decades, concentrating on radiation therapy services for the past seven to eight years. He is very familiar with the Service Area in terms of the market for acute care and radiation therapy. He is also familiar with the applicable Health Plans and has been qualified as an expert in healthcare planning and finance in South Carolina and nearly a dozen other states. I find that Mr. Sullivan is a well-qualified and accomplished expert in healthcare planning and finance and will be basing these findings of fact on the analysis used by Mr. Sullivan unless otherwise indicated.

According to the 2010 U.S. Census data, Horry County has 269,291 people, the majority of the population in the Service Area, and four times the population of Georgetown County. Horry County has the fastest population growth in the Service Area, and there is a strong indication that the future demand for radiation therapy services would be greatest in Horry County since the fastest growing segment of society is the aged-65-and-older category, which has the highest incidence of cancer.

In the year immediately preceding the filing of its CON application, all existing units in the Service Area were performing well above the 80% threshold, as required by Standard 6(A) in the Health Plan.⁹ Generally, between 50% and 60% of all cancer patients will require radiation therapy. Grand Strand applied 55% to new cancer cases. Taking the cancer incidence rate and applying it to the age-specific component of population in each of the Service Area's three

⁹ The total percentage of utilization for the Service Area in 2010 was 110.3%.

counties, there would be 2,622 cancer cases by 2015, with 1,442 patients, or 55%, requiring radiation therapy.¹⁰ This represents a growth of 194 new cancer cases over the 2010 estimate.

At the time of the filing of the applications, the 2010-2011 State Health Plan was in effect. The 2010-2011 State Health Plan indicates that the four existing linear accelerators in the Service Area, three at CRCC and one affiliated with Georgetown Memorial Hospital (GMH), were operating at 80.5% of capacity, based on a total 2009 Service Area utilization of 20,918 "Total Area Treatments" with a "Planning Area Capacity" of 26,000 treatments. Since the DHEC Staff (Staff) made the decisions with respect to the two instant applications, the 2012-2013 State Health Plan took effect. The 2012-2013 Health Plan's linear accelerator standards and relative importance of Project Review Criteria are nearly identical to those in the 2010-2011 State Health Plan.¹¹ The 2012-2013 State Health Plan sets forth that there are five linear accelerators in the Service Area that were operating at 96.7% capacity in 2011, based on 31,902 "Total Area Treatments," with a "Planning Area Capacity" of 33,000 treatments. Moreover, the 2012-2013 State Health Plan indicates a "Need" in a column entitled "UNMET NEED?" Although the 2012-2013 State Health Plan identifies five linear accelerators in the Service Area, a footnote indicates that the Department included CRCC's approved, but not yet operational, Conway facility in the linear accelerator count, which is under review in this Contested Case. Thus, even with four operational linear accelerators, and one that has been approved, the 2012-2013 State Health Plan denotes that there is potentially an unmet need for another unit in the Service Area.

Grand Strand's Project

In its application, Grand Strand seeks to establish a new 9,519 square foot radiation therapy facility located within its main hospital in Myrtle Beach, South Carolina. Grand Strand applied to install a Varian Clinac iX linear accelerator at a cost of \$2.8 million.¹² The Clinac iX is very reliable; can perform all conventional cancer treatments including IMRT treatments and

¹⁰ Because of the twenty-one month time span between the decision date and the contested case hearing, the year 2015 is no longer a viable third year of operations. Presently, the third year of Grand Strand's operation would be 2017.

¹¹ The notable exception is that in the 2012-2013 Plan, Standard 8 does not require the applicant to provide expected annual referral volumes from physicians and health care facilities. However, that criterion was not an issue in this case.

¹² Since submitting this application, the cost of a True Beam linear accelerator has declined and, as a result, Grand Strand intends to seek a change in its application to install that linear accelerator if DHEC approves the change.

IGRT treatments; and is capable of delivering highly specialized treatments such as stereotactic radiation therapy, although stereotactic treatments comprise a small percentage of the overall number of treatments. CRCC operates a linear accelerator unit, the Varian 2300iX, that is very similar to the unit Grand Strand is proposing in its application. The project is estimated to cost approximately \$9.8 million.

Grand Strand is also accredited by the Commission on Cancer of the American College of Surgeons as a community cancer center and is the only hospital in the region that is accredited as such. Though Grand Strand has no direct experience providing radiation therapy, its parent company, HCA, operates 80 linear accelerators in 40 locations. Furthermore, if approved, Grand Strand intends to partner with Sarah Cannon Center, which is a comprehensive cancer center affiliated with HCA, located in Nashville, Tennessee. The Sarah Cannon Center will provide information, research, and analysis for clinical protocols surrounding the care of cancer patients.

Need for Grand Strand

Grand Strand is the Service Area's largest and most comprehensive tertiary care hospital. A "tertiary care hospital" provides higher-level services than those found in community hospitals, services such as open heart surgery, neurosurgery, and trauma services. Most tertiary care hospitals have at least one linear accelerator. In fact, Grand Strand is one of the only two hospitals in South Carolina operating above 50,000 patient days per year that does not offer radiation therapy services. In addition, Horry County is the only county in the state with more than 250,000 residents that lacks a hospital-based radiation therapy center.

Grand Strand seeks to develop a comprehensive cancer center where patients and their families can go to one facility to receive interdisciplinary cancer care, including radiation therapy. A comprehensive cancer treatment program promotes interdisciplinary care. Interdisciplinary cancer care involves multiple cancer specialists participating in the development of a treatment plan and care of a patient. The patient benefits from the interaction with the doctors caring for them. This personal interaction can assist the physician in planning the patient's treatment, thereby leading to more effective treatment. The best form of communication is face-to-face, though it is not always necessary and might be difficult for physicians, given time restraints. In addition, PET/CT services¹³ are a very important part of a

¹³ PET stands for Positron Emission Tomography and CT stands for Computerized Tomograph; both used to reveal the presence or track the spread of cancer..

comprehensive cancer center. Grand Strand currently offers PET/CT services in a mobile setting at its South Strand location, and it anticipates that it would shift the PET/CT service to the main campus if approved for a radiation therapy center.

Adding a radiation therapy center to its campus in the context of a comprehensive cancer center will also allow Grand Strand to attract surgical and medical sub-specialists who provide cancer care, such as GYN oncologists, oncology surgeons, colorectal surgeons, and fellowship-trained breast surgeons. A hospital cannot establish a comprehensive cancer center without a radiation therapy program. Currently, patients residing in the Service Area must travel to the Medical University of South Carolina in Charleston, South Carolina to receive comprehensive cancer treatment.

Grand Strand proposes to locate its linear accelerator in the hospital because having a radiation therapy facility at the hospital would result in higher and better services available to the patients. Grand Strand proposes to treat both inpatients and outpatients at its facility, but acknowledges the vast majority will be outpatient treatments. Currently, there are no radiation therapy centers in the Service Area that are located within a hospital. Grand Strand's project will alleviate the inconvenient transfer of its inpatients who need radiation therapy out of the hospital via ambulance to an off-site radiation therapy center and then back to the hospital on multiple occasions during the hospital stay. The radiation therapy center will also be positioned proximate to Coastal Cancer Center, (Coastal), an active medical oncology group that consists of five medical oncologists practicing at several locations in the Service Area, including offices in Conway, Myrtle Beach, Loris, and near Waccamaw Hospital.

Grand Strand's Utilization

For 2017, Grand Strand can reasonably assume a 20% market share for Horry County as explained below. Grand Strand can reasonably assume a 1% market share for Georgetown because GMH, the radiation therapy provider located in Georgetown, has a distinct medical staff with local referral patterns. Because Williamsburg is even further from Grand Strand and nearer to the Medical University of South Carolina, Grand Strand can reasonably expect no more than a 1% market share from that area.

Grand Strand can reasonably assume a 20% market share for radiation therapy in Horry County by 2017 because Grand Strand's unit would be the fourth unit in the county, which theoretically lends itself to a 25% market share. Coastal's president, Dr. Lawrence Holt,

expressed that Coastal would be supportive of Grand Strand's project and represented that he thought some patients would choose Grand Strand for radiation therapy.¹⁴ However, CRCC has been operating in Horry County for three decades, so obtaining referrals will be a challenge for a new radiation therapy center. A substantial base of physician support is important to obtain sufficient utilization of the radiation services as required in the Health Plan. Therefore, in this instance, a 25% market share would not likely occur in Horry County because: (a) CRCC is an established provider with solid referral relationships in place; (b) CRCC has an affiliation with an existing urology practice, which means Grand Strand would not receive any urology referrals from that practice; and (c) Grand Strand would have to prove itself to the medical community by demonstrating good service and good outcomes.

In analyzing Grand Strand's potential utilization, it was important to quantify an average number of treatments per patient. Mr. Sullivan projected an average number of treatments of 21 per patient. I find that average to be reasonable under the facts of this case. Importantly, CRCC's actual experience prior to its acquisition by 21st Century on May 3, 2010, was 21 treatments per patient. AUC employs all the urologists who practice in Horry and parts of Georgetown County, and it is the only provider of urological services in the three-county Service Area.

Referrals for prostate issues made up the largest percentage by diagnosis mix and treatment diagnosis at CRCC for the years 2010, 2011, and 2012. While the standard number of IMRT treatments for prostate cancer patients is 40 to 45, some patients may receive up to 48 treatments. The vast majority of referrals from the AUC urologists will be to CRCC for prostate cancer patients. The number increases the average number of treatments per patient for CRCC and decreases the average number of treatments per patient for Grand Strand.

Using the 2015 data as a projection of Grand Strand's utilization in 2017, Grand Strand will likely treat 231 cancer patients at its center by 2015.¹⁵ Assuming an average of 21

¹⁴ Notably, Dr. Holt's support for Grand Strand did inversely suggest an over-utilization of Grand Strand's services. Despite CRCC's assertions to the contrary, Dr. Holt never committed that Coastal would send all, or even a substantial portion, of its patients to Grand Strand for radiation therapy services.

¹⁵ I find Mr. Sullivan's analysis to be sound, yet find slight discrepancies in his math. The Court projected the total number of cancer patient to be 231 in year 2015. That figure was derived utilizing the "Total Projected Grand Strand Radiotherapy Patients – Service Area" and adding 5% for "patient in-migration." See Joint Exhibit 2, p. 38. On the other hand, I did not find CRCC's draw-rate analysis as reliable as Grand Strand's for a number of reasons. First, it is not reasonable to assume that Grand Strand's penetration rate in the identified zip codes would be the same for radiation therapy as it would be for inpatient services given that Grand Strand, unlike CRCC, enjoys no

treatments per patient, based on CRCC's actual experience prior to its acquisition by 21st Century, Grand Strand will likely perform 4,851 treatments in 2015. With a capacity of 5,000 treatments, given its projection that 60% of treatments will be IMRT, Grand Strand's unit will be 97.02% utilized in year three, satisfying the first part of Standard 6-B in the State Health Plan, which requires a new unit to be operating at 50% capacity by the third year of operations.

At the Department's request, Mr. Sullivan also estimated the number of Grand Strand radiotherapy patients that it would serve by zip code. To accomplish this task, Mr. Sullivan developed a "draw rate" analysis in which he analyzed the origin of Grand Strand's inpatients with cancer by zip code and the population of those zip codes. By analyzing the origin of its inpatients with cancer by zip code and the population of those zip codes, the draw rate can be used to determine the reliance of a particular population on the particular service offered at the hospital. It can also be used to rank the zip codes served by Grand Strand, specifically for cancer patients, so as to determine primary and secondary service areas.¹⁶ Assuming reasonable market-share capture rates for both the primary and secondary service-area zip codes, the draw-rate analysis estimates that Grand Strand would treat 223 radiotherapy patients by year three of operations. Treatment of 223 patients would result in utilization 93.66% in year three.

In its B-11 analysis, Grand Strand addressed each of the nine Standards set forth in the 2010-2011 State Health Plan. Grand Strand addressed how it would staff the facility, which I find reasonable.¹⁷ Grand Strand will also deliver an estimated 3.3% of its radiation therapy center's gross revenue in the form of indigent care.

competitive advantage in radiation therapy. Also, CRCC's draw-rate analysis for Grand Strand does not take into account the fact that Grand Strand will not receive any urology referrals, which is a material percentage of the referral market.

¹⁶ I find a "draw rate" analysis to also be a reasonable and reliable method by which to estimate the number of radiotherapy patients Grand Strand would serve. On the other hand, I did not find CRCC's draw-rate analysis as reliable as Grand Strand's for a number of reasons. First, it is not reasonable to assume that Grand Strand's penetration rate in the identified zip codes would be the same for radiation therapy as it would be for inpatient services given that Grand Strand, unlike CRCC, enjoys no competitive advantage in radiation therapy. Also, CRCC's draw-rate analysis for Grand Strand does not take into account the fact that Grand Strand will not receive any urology referrals, which is a material percentage of the referral market.

¹⁷ Grand Strand, like CRCC, did not quantify expected referral volumes by physician because there is no practical way to project the referrals three years from opening. CRCC did provide current volumes from all referral sources. However, if a facility has not had a service in the past, and therefore has no historical basis for projecting referrals by physician, this standard becomes nearly impossible to satisfy. While Standard 8 in the 2010-2011 State Health Plan appears to require an annual referral volume projection by referral source, DHEC appears to have recognized the difficulty of making such a projection by referral source and removed the requirement from Standard 8 in the 2012-2013 State Health Plan that applicants document "expected annual referral volumes."

CRCC's Project

CRCC applied for a CON to establish a freestanding radiation therapy facility located in Conway, South Carolina on March 9, 2011, and it thus falls under the guidelines of the 2010-2011 State Health Plan. CRCC proposes to install a state-of-the-art TruBeam linear accelerator, which is considered to be superior to the Clinac iX. CRCC plans to use an existing site so its total project costs, including the cost of equipment, are \$5.1 million.

CRCC chose to locate its services in Conway using a facility that was previously constructed to house a linear accelerator. Nevertheless, I find the proposed facility to be underwhelming. Grand Strand's proposed facilities are far superior. The CRCC-Conway radiation therapy center would be in an older building that would require considerable renovation. Moreover, though the typical size of a 21st Century radiation therapy center is between 5,000 and 12,000 square feet, CRCC-Conway will only be 3,616 square feet.

Patients from the Conway and Loris areas drive an average of 45 minutes to the closer of the two Service Area cancer centers with linear accelerators. Though CRCC's Conway facility would reduce the average round-trip drive for a patient from the Conway and Loris areas, that drive time would be reduced by only an average of 20 minutes.

CRCC'S Utilization

CRCC operates three linear accelerators at its location in Myrtle Beach: a TomoTherapy linear accelerator, a 2300iX unit, and a 6EX unit. In 2012, CRCC performed 9,437 treatments on its Varian Clinac iX unit, which was more than any other unit. CRCC has been providing radiation therapy services in the Service Area for over 31 years and has earned the support of the provider community based on its long track record of providing quality cancer treatment services to the Service Area.

On May 3, 2010, CRCC was sold to AUC and 21st Century.¹⁸ AUC employs all the urologists who practice in Horry and parts of Georgetown County, and it is the only provider of urological services in the three-county Service Area. From 2009 to 2011, CRCC's treatment volumes increased by approximately 65%. When CRCC's treatment volumes are removed from statewide totals, treatment volumes statewide increased just 2.2% over that same time period.

¹⁸ 21st Century establishes group practices like AUC and pays employed physicians in the practice profits using an ancillary profit formula from revenues generated by their referrals to the affiliated radiation therapy center. The AUC-employed urologists have a financial relationship with CRCC by virtue of participating in an ancillary bonus pool. However, the AUC urologists are not contractually obligated to refer all of their cancer patients to CRCC.

Statewide, linear accelerator treatments actually decreased from 2010 to 2011, while CRCC's treatments increased from 20,946 treatments in 2010 to 25,709 treatments in 2011, an increase of 23%. In 2011, CRCC was the highest volume treatment provider in South Carolina.

Prior to CRCC's acquisition by AUC and 21st Century, the AUC urologists referral of prostate cancer patients to CRCC was limited because of a business dispute with CRCC's previous owner arising out of a CON challenge in which AUC was an applicant. CRCC had a significant increase in treatment volume after AUC was sold to 21st Century. The number of urologist referrals from AUC to CRCC increased from 39 in 2009 to 292 in 2010. The number of referrals in 2011 from AUC to CRCC increased to 406. In 2012, there were 886 patients who underwent treatment at CRCC. Of these 886 patients, AUC referred 263.

Referrals for prostate cancer made up the largest percentage by diagnosis mix and treatment at CRCC for the years 2010, 2011, and 2012. In 2012, 43.7% of all treatment diagnoses at CRCC were related to prostate cancer. IMRT is one of the procedures used for treatment of prostate cancer and is reimbursed at a higher rate. About 75% of CRCC's treatment volume comes from the higher reimbursed IMRT procedure. 28.4% of all revenues generated from CRCC radiation therapy treatments came from prostate cancer diagnoses.

CRCC addressed the applicable radiotherapy standards in the 2010-2011 State Health Plan. As mentioned above, Standards 6(A) and 6(B) do not apply to CRCC. Furthermore, CRCC identified the capacity of the existing units and found that the units collectively were operating at 102% of capacity as of 2010, with CRCC at 20,946 treatments on its 3 units, and GMH at 5,515 treatments on its unit. CRCC identified the target population and made reasonable projections for the Service Area, concluding that the Service Area would have 392,450 people in 2015. Twenty-two (22) percent of CRCC's patients originate from the Conway area, which has a population of 80,355 people. Finally, CRCC addressed Standards 8 and 9, although, like Grand Strand, CRCC did not project expected annual referral volumes by physicians. CRCC also set forth its staffing plan and financial *pro formas* and associated assumptions in the CON application, which I find reasonable.¹⁹

¹⁹ Although CRCC takes the position in this case that Grand Strand's project will adversely impact its operation due to the loss of Coastal referrals, CRCC never took the position with the DHEC staff at the project review meeting (PRM) or in follow-up written submission that Grand Strand's project would result in a substantial loss of Coastal referrals. See Brandt Tr. 1052:1-1053:5; Lewis Tr. 1340:25-1342:1; Tolbert Tr. 1834:13-1835:1-21-.

Approval of Both Projects

As addressed above, there is a need for two linear accelerators in this service area.²⁰ Nevertheless, even if there is a “need,” an applicant cannot receive a CON if approval of two linear accelerators in the service area would bring the use of the existing linear accelerator providers below the 80% threshold. CRCC and the Department assert that the approval of both applications will exceed the need for the services in the Service Area. I find that the evidence established otherwise. Both Grand Strand’s and CRCC’s CON applications can be approved without reducing the existing providers’ utilization below the 80% threshold.²¹

As required by Radiotherapy Standard 6-B, Grand Strand should not bring existing providers below the 80% threshold by the third year of operations based on growth in the market and Grand Strand’s projected utilization. Based on CRCC’s own growth projections, AUC is projected to refer 284 patients for treatment to CRCC in 2017, and the number of non-AUC patient referrals to CRCC is projected to increase to 669 in 2017. An estimated 11,360 treatments in the market in 2017 will not be available for capture by Grand Strand. Stated differently, nearly half of CRCC’s treatment volume is not at risk in 2017 because of CRCC’s relationship with AUC. Thus, Grand Strand would be competing for the remaining treatments against an existing provider with more capacity and potentially more locations.

CRCC projects that its new facility in Conway will have 5,499 treatments in 2017. If Grand Strand’s volume exceeds 5,525 treatments in 2017, also referred to as a “tipping point,” Grand Strand’s project would cause the existing providers to fall below the 80% threshold. However, as found above, Grand Strand would likely perform 4,851 based upon a 2015 projection, or the 5,168 treatments in 2017.²²

CRCC’s Projections

CRCC’s projects 7,500-8,000 treatments for Grand Strand in 2017 by creating five different adverse impact scenarios, four of which were premised on applying assumed market

²⁰ Also as addressed above, the parties chose the year 2017 as the third year of operations for the respective projects due to the time interval between the date of the Staff’s decision in this case and the date of the Contested Case.

²¹ CRCC never performed any financial-adverse-impact analysis with respect to the impact Grand Strand’s approval would have on CRCC if only one is approved or if both are approved.

²² CRCC’s expert projected that Grand Strand would perform 4,934 treatments in 2017 based upon Grand Strand’s 2015 projections. Since the Court found that the treatments performed by Grand Strand in 2015 would be 4,851, the Court added 4.76% to CRCC’s projection which is the percentage difference between 4,620 and 4,851.

shares for Grand Strand that differed from the market share assumed by Grand Strand in its CON application.²³ CRCC's analysis makes flawed assumptions about the market. In CRCC Scenarios 1-4, CRCC applied an inpatient acute market share, which was not proper. The inpatient market is much different from the outpatient radiation therapy market share in this instance because of the presence of entrenched competitors who have solid historical reputations. In Scenarios 1, 2, and 4, CRCC assumed that all 31,824 treatments were available for capture by Grand Strand, even though nearly half of CRCC's treatments are likely not available to Grand Strand because of CRCC's affiliation with AUC. Although inpatient market share and inpatient oncology market share are appropriate metrics to use in projecting market share for a new radiation therapy center, these would not be appropriate metrics in this instance for the primary reason that the Service Area urology referrals will likely not be captured by Grand Strand.²⁴

Furthermore, if Grand Strand were to achieve CRCC's projection of nearly 8,000 treatments by 2017, when compared to treatment volumes in 2011, Grand Strand would be operating at 153% of the average for the top five highest treatment volume providers and 165% of the average for single unit operators. This would be occurring in a market with a high-volume, entrenched provider. I do not find CRCC's projections to be realistic for a new provider in the Service Area.

Moreover, to show that the CON applications should be considered "competing," CRCC introduced its 2013 treatment data through July to show that the Service Area capacity at the end of 2013 would be below the 80% threshold, assuming five units are operating. CRCC took its treatment volume through July 2017 and compared it to the first seven months of 2012. Based on a 10.3% decline in the first seven months of 2013 over the same period for 2012, CRCC projected that its 2013 year-end utilization would be 20,450 treatments, or 10.3% lower than 2012. However, I do not find CRCC's analysis reliable.

²³ Mr. Tolbert created two separate Threshold Analyses based on the application of Grand Strand's market share to a projected Service Area volume of radiation therapy treatments for 2017. Both are similar in terms of the purported volume Grand Strand will capture from CRCC, but a later version includes a referral-shift analysis, an adjusted-market-share analysis, and an analysis based on Grand Strand's three-county inpatient oncology admission, which are discussed herein.

²⁴ While this Court has specifically found that inpatient market share can be used as a proxy to determine radiation therapy market share, the specific facts of that case, *Beaufort-Hilton Head Radiation Oncology Center v. S.C. Dep't of Health & Envtl. Control*, 01-ALJ-07-0507-CC (Mar. 19, 2003 S.C.A.L.C), are quite distinct from the instant case where there are two providers in the Service Area, one of which has been operating for over 30 years and is currently owned by a major referral source whose employed physicians receive a financial benefit from referring to CRCC.

There is no evidence that the utilization during the first seven months of 2012 was representative of CRCC's typical treatment volume experience for the first seven months in any other year. CRCC assumed that GMH's volumes would be the same as in 2012, despite having no hard data to support that conclusion. CRCC's 2013 decrease is more likely due to less referrals from the urologists and, in particular, one urologist, who accounted for more than half of the decline, which could be a mere aberration. As such, concluding that the first seven months of 2013 is indicative of the rest of the year or future years is not reliable.²⁵

CRCC also claims that the CRCC-Myrtle Beach radiation therapy center volumes declined significantly from 2011 to 2012 due to a change in the Prostate-Specific Antigen (PSA) guidelines, which resulted in a decline in the number of prostate cancer patients referred to CRCC from AUC. However, a change in a guideline or protocol to screen for cancer does not validate that the actual rate of cancer will be impacted; rather, it suggest that the date the cancer is detected will be impacted. I find that the change in the PSA guidelines will not likely result in a significant decrease in treatment volumes in the Service Area or a decrease in referrals to CRCC.²⁶

CRCC's further assumed that Grand Strand's presence in 2017 would cause a significant shift in physician referrals from CRCC to Grand Strand and that Grand Strand would capture approximately 60% of the Coastal referrals in 2017. I do not find Mr. Tolbert's referral-shift analysis reliable. For instance, Mr. Tolbert never spoke to any physicians who referred patients for cancer treatment to CRCC, and he conceded that he did not have any idea of what the referral sources thought about CRCC. Also, Mr. Tolbert's analysis is based in part on one or two thirty-minute phone calls with Ms. Price and Dr. Francke, both of whom are CRCC employees strongly opposed to Grand Strand's project.²⁷ The low-volume physician referrers, which accounted for 127 patients to CRCC in 2012, were never discussed with Ms. Price or Dr. Francke. Furthermore, although Coastal indicated strong support for Grand Strand's project, the three

²⁵ Mr. Tolbert, in fact, testified that it is preferable to use a full year's data when projecting utilization because of the uncertainty of what can occur in the remaining part of the year.

²⁶ Even though CRCC experienced a volume decrease in 2012 over 2011, nine months into 2012, CRCC's plan was to apply for the additional linear accelerator that would be shown as needed in the 2012-2013 Health Plan, despite knowledge of the change in the PSA screening protocols.

²⁷ Dr. Francke is the Medical Director and staff radiation oncologist at CRCC, and Ms. Price is the Administrative Director.

Coastal physicians who service the Conway area supported CRCC's project.²⁸ CRCC's Medical Director, Dr. Francke, admitted that he has not had an indication from any of the Coastal physicians that they would cease referring to CRCC if both projects are approved. Grand Strand's location would offer no travel time advantage to a significant number of patients who would originate from the area around Murrells Inlet, where two CON applications for radiation therapy centers have been approved. In sum, patient and physician preference for a particular provider depends on many factors, including where the patient resides. Mr. Tolbert's analysis did not sufficiently account for these preferences. Therefore, I find that CRCC's referral-shift analysis is not predictive of Grand Strand's utilization in 2017.

Finally, CRCC's health planning expert did not give any effect to outmigration in preparing his projections. Based on CRCC's projection of new cancer cases in 2017, an additional 6,300 treatments may be performed on patients who leave the Service Area for treatment. The creation of a comprehensive cancer program could reverse at least a portion of the outmigration, which would further mitigate any potential adverse impact on the existing providers in the Service Area.

Other Project Review Criteria

I find that both applications meet the Project Review Criteria to receive a CON. I address this compliance more specifically below.

Community Need Documentation (PRC 2(a)-(c), (e))

As addressed above, Grand Strand seeks to develop a comprehensive cancer center. A comprehensive cancer center can reduce the fragmented nature of cancer treatment, which can be particularly difficult for elderly patients. A more comprehensive setting has the benefit of reducing travel and facilitates consultation between separate providers such as radiologists and radiation oncologists.

There are also advantages in terms of cost, patient care, and convenience with respect to inpatient based radiation therapy offered in a comprehensive cancer treatment setting. An inpatient who can be treated without transport out of the hospital on an ambulance gurney is

²⁸ According to CRCC's 2013 volumes, through May, Dr. Holt was responsible for 30 treatment plans at CRCC. The three medical oncologists whose support for CRCC-Conway was critical—Drs. Cody, Karpenko and Goldberg—were responsible for a combined 100 treatment plans at CRCC through May 2013, and all three provided letters of support for the CRCC-Conway project.

more comfortable because the patient does not have to be strapped-in, as they would in an ambulance. Further, there is a significant cost associated with ambulance transport.

Although infrequent, there are times when patients cannot be transported out of the hospital for radiation therapy treatment, such as when the patient is in an intensive care unit on a ventilator. Dr. Collins testified that he treats several patients a year who are in life-threatening circumstances and cannot be transferred out of the hospital for necessary and critical radiation therapy. An in-hospital radiation therapy program would be of great benefit to these patients.

Distribution (Accessibility) (PRC 3(a)-(c), (e)-(f))

Both CRCC and Grand Strand have documented the means by which a person will have access to their services. CRCC's project improves travel time for patients who reside in the Loris and Conway areas. Additionally, Grand Strand's project is not an unnecessary duplication of services because patients will now have ready access to in-hospital radiation therapy and comprehensive cancer treatment. Currently, the closest comprehensive cancer treatment is approximately 100 miles away, thus requiring patients who desire comprehensive cancer treatment or in-hospital radiation therapy services to drive significant distances to reach either. Grand Strand's project location also allows for the delivery of necessary support services because within the hospital there is a much wider array of support services immediately available to patients, such as radiology, surgical services, and physical therapy.

Record of the Applicant (PRC 13(a)-(b))

Both applicants also have demonstrated the ability to obtain the necessary capital financing for their respective projects. CRCC has been successfully providing radiation therapy services in the Service Area for over 30 years and is supported by 21st Century. Likewise, Grand Strand is affiliated with its parent organization, HCA, and has demonstrated an ability to develop new services into successful programs.

Acceptability (4(a))

Both applicants have demonstrated a significant level of community and provider support for their respective projects to demonstrate that both will be well-utilized.

Distribution (22)

Both projects improve the distribution of health services in the Service Area based on the findings above.

Financial Feasibility (15)

Both CRCC and Grand Strand projected positive net income for their respective projects in all three years of operations, which indicates both the immediate and long-term financial feasibility of the projects. CRCC contends that Grand Strand's *pro formas* indicate that the project might not be financially viable because Grand Strand's internal rate of return and the returns on investment (ROI) for the project were lower than what CRCC's expert would expect. However, given its healthy bottom line, Grand Strand can afford to sustain potential losses in the first three years of operations, even under CRCC's "breakeven" analysis.²⁹

While Grand Strand's *pro forma* contains some errors, when they are corrected, the revenues are understated and the project would still show a profitable bottom line. Grand Strand expects its annual treatment volumes to increase as the market continues to grow and Grand Strand's reputation as a radiation therapy provider improves. I find that Grand Strand's application *pro forma* is a conservative estimate of the project's financial performance.

Cost Containment (16(a)-(c))

Both CRCC and Grand Strand addressed cost containment, identified methods of funding, and demonstrated the feasibility of the funding option. Moreover, Grand Strand does not expect to raise its patient charges to subsidize the cost of the radiation therapy project. Grand Strand's in-hospital radiation therapy center would also alleviate charges associated with transporting patients to and from a freestanding facility. Because the project is self-sustaining, I find that the project will not affect Grand Strand's costs or charges.

CRCC contends that Grand Strand's project will represent higher costs to the healthcare system.³⁰ While Grand Strand's reimbursement from governmental sources like Medicare and Medicaid will be higher than CRCC's, I find that Grand Strand's project will promote cost

²⁹ I decline to rely on CRCC's analysis in which it determined that for a freestanding radiation therapy center to "break even," it would need to operate at 4,500 treatments annually. Mr. Lewis admitted that he never performed a breakeven analysis for a hospital-based radiation therapy center. Grand Strand's project will be a hospital-based facility that, unlike a freestanding facility, is not going to duplicate all of the overhead expenses that a freestanding center would if they were beginning operations; and hospitals have a different revenue profile with a different breakeven point.

³⁰ While CRCC did not discuss the impact of the radiation therapy center project on Grand Strand's patient charges generally, CRCC suggested that Grand Strand expects to receive \$5,000 per radiation treatment from non-governmental payors. There is no credible evidence in the record to suggest that Grand Strand would get \$5,000 per treatment as CRCC suggests. In fact, Grand Strand's charges per procedure are set forth in its CON application, and it estimates it will receive in actual dollars approximately 32% of the charges. The highest listed charge for a radiation therapy treatment plan is \$4,239. On that charge, Grand Strand expects to receive \$1,356.

containment, particularly with private insurance companies, in the Service Area. Both CRCC and Grand Strand are relying on receiving a significant portion of revenues from non-governmental payors, such as PPOs.³¹ However, there is currently no real price competition in Horry County as it relates to radiation therapy services, because there is only one provider.³²

Over the past several years, there has been concern in the radiation therapy industry that urologists who have a financial interest in radiation therapy centers may direct patients to more expensive radiation therapy as opposed to alternative, less expensive, types of cancer treatment. AUC urologists have a financial interest in the operations of CRCC, which appears to promote referrals to CRCC. When CRCC was sold to 21st Century, it had a significant increase in treatment volume, most of which came from the AUC urologists. Grand Strand's project would provide an alternative treatment setting where there are no financial incentives to referring physicians who may over-utilize costly radiation therapy treatments.³³ Therefore, I find that the approval of both projects will further promote cost containment in the Service Area.³⁴

Projected Revenues/Projected Expenses (6(a), 7)

Grand Strand included its chargemaster for radiation therapy services and represented that it estimated the actual dollars reimbursed on those charges to be approximately 32%. CRCC contends Grand Strand's charges will be higher than its own charges for patients insured by governmental programs, which Grand Strand conceded. However, CRCC did not address whether Grand Strand's project costs were inconsistent with those experienced by similar providers offering a similar level and scope of service. For instance, CRCC's Murrells Inlet

³¹ A PPO, or preferred provider organization, is an insurance plan that contracts with providers like hospitals and physicians. In exchange for making them preferred or in-network providers, those providers offer a discount to the insured that is under the PPO plan. It is a different form of insurance where rates are negotiated between the insurance company and the providers. Examples of PPOs would be Blue Cross/ Blue Shield, Aetna, CIGNA, and Humana.

³² CRCC contends that competition is not referenced in the PRC or the purposes of the CON Act. While not directly referenced therein, competition enhances the negotiating power of payors and the choices and quality that may be available for the residents of South Carolina, all of which are related closely to the purposes of CON Act.

³³ Despite the 10,000 treatment increase at CRCC from 2009 to 2011, the Staff did not perform any research or analysis on the issue of the AUC urologists having a financial interest in a radiation therapy center. Even though Grand Strand raised the issue of CRCC's monopoly of radiation therapy services in Horry County and the effect that would have on rates for third-party payors, the Staff did not consider this factor when making its decision on the project generally and with respect to cost containment specifically.

³⁴ While AUC's financial relationship with CRCC is concerning, given the findings above, because CRCC's project costs are significantly lower than those of newly built radiation therapy centers, I find that its project satisfies the PRC for cost containment.

facility, which was also approved by the Staff, is proposed to be nearly 7,000 square feet with a total project cost of approximately \$8 million. Grand Strand's project cost of \$9.7 million is reasonable when compared to other recently approved radiation therapy projects.

I find that both projects can be completed in a reasonable amount of time given their respective scope of construction and services.³⁵

CONCLUSIONS OF LAW

Based on the foregoing 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 South Carolina Administrative Law Court Rules (SCALCR). Grand Strand timely filed its request for a contested case hearing regarding DHEC's decisions. *See* 3 S.C. Code Ann. Regs. 61-15 § 401. Because CRCC is an existing provider of radiation therapy services in the service area, it is an "affected person" for the purposes of participating in a contested case related to DHEC's decisions appealed by Grand Strand. *See* S.C. Code Ann. § 44-7-130(1) (2002); 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 County 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*.

³⁵ Though CRCC's project is estimated to cost \$5.1 million, the evidence reflected that CRCC might have plans to move its radiation therapy facility to another location in Conway where the AUC-employed urologists own property. This could mean additional project costs associated with the same unit. However, the Staff would have to approve any such future relocation, which is not an issue before this Court.

Finally, the CON Act states that the “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 (Supp. 2013).

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 in this State. 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.* (2002 & Supp. 2013); the regulations promulgated thereunder: 3 S.C. Code Ann. Regs. 61-15 (Supp. 2013); 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 (2002).

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) (Supp. 2013). 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 PRC were independent requirements for approval of a CON). The Department can refuse to issue a CON based on PRC and other regulations identified by the Department even if an application complies with the State Health Plan. Section 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). Where the 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.” Section 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.

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 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 either applicant's linear accelerator project is found in Chapter IX, beginning at page IX-1. The Standards applicable to the projects begin at page IX-5.

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. 2013).

Question of Competing Applications

As a threshold matter, the Court must first decide whether the CON applications are competing. The CON Act prohibits the issuance of multiple CONs if two or more CON applications are competing. S.C. Code Ann. § 44-7-210(B). Therefore, if the two CON applications at issue in these contested cases are competing applications, only one CON

application can be approved. CRCC concurs with the Department's finding that the applications are competing applications, while Grand Strand contends that the applications are not competing applications and both can be approved.

Under the CON Act, "competing applicants" are defined as follows:

[T]wo or more . . . health care facilities . . . who apply for Certificates of Need to provide similar services or facilities in the same service area within a time frame as established by departmental regulations and whose applications, if approved, would exceed the need for services or facilities.

S.C. Code Ann. § 44-7-130(5); *see also* 3 S.C. Code Ann. Regs. 61-15 § 103(6). Therefore, to be deemed competing CON applications, two or more CON applications must satisfy four elements:

- (a) The CON applications must be filed within the time period established by the regulations;
- (b) The CON applications must be for same or similar services or facilities;
- (c) The projects must be located in the same service area; and
- (d) The approval of both CON applications must exceed the need for the services or facilities.

S.C. Code Ann. § 44-7-130(5); *see also, e.g., Spartanburg Reg'l Med. Ctr. v. Oncology and Hematology Assocs. of S.C., LLC*, 387 S.C. 79, 90, 690 S.E.2d 783, 789 (2010). It is undisputed that the two CON applications at issue in this case meet the first three elements of the definition of competing applications: *i.e.*, the CON applications were filed within the time period established in the Regulations, the CON applications are for the similar services/facilities, and each proposed project will be located in the same service area. Therefore, the issue for the Court is whether the approval of both CON applications will exceed the need for the services, which is a fact-intensive inquiry dependent upon the evidence submitted by the parties. *Spartanburg Reg'l Med. Ctr.*, 387 S.C. at 91, 690 S.E.2d at 789.

The Court must first resolve whether the approval of Grand Strand's project would bring the existing linear accelerator providers below the 80% threshold if both projects are approved. Grand Strand, as Petitioner and moving party, bears the burden of establishing by a preponderance of the evidence that approval of both applications for linear accelerator services would not exceed the need for the services in the service area. *See* S.C. Code Ann. § 44-7-210(E) (Supp. 2012); *Anon. v. State Bd. of Med. Exam'rs*, 329 S.C. 371, 375, 496 S.E.2d 17, 19 (1998). CRCC and the Department assert that the approval of both applications will exceed the

need for the services in the Service Area. Grand Strand argues that approval of both applications will not exceed the need for services in the Service Area. Based on the following, I find that the approval of both projects would not exceed the need for the services or facilities in the Service Area and are thus not competing.

In making this determination, I choose to consider the 2012-2013 State Health Plan. It indicates that *in 2011 all of the linear accelerator units in the Service Area, plus one that had been approved but was not operational*, were operating at 96.7% of capacity, well above the 80% threshold, such that there was a “need” identified in the Service Area for another linear accelerator in addition to CRCC’s approved project. The Staff’s decision was made on December 28, 2011, based on CRCC’s *projected* 22,419 treatments for 2011, as stated in its CON application that was filed in March 2011. CRCC’s *actual* 2011 utilization, also set forth in the current State Health Plan, was 25,709 treatments, higher than any other radiation therapy provider in South Carolina. The 2012-2013 State Health Plan thus validates Grand Strand’s position taken during the CON review process that the Service Area could support two new linear accelerators in 2011. Moreover, due to the twenty-one (21) month time span between the Staff’s decision and the Contested Case hearing, the likely third year of operations shifted from 2015 to 2017 with respect to determining the 80% threshold analysis set forth in Radiotherapy Standard 6(B) of the Health Plan. *See Spartanburg Reg’l Med. Ctr.*, 387 S.C. at 86, 690 S.E.2d at 787 (indicating that the competing applicants changed their third year projections at the contested case hearing from what was originally proposed in their applications).

Grand Strand’s radiation therapy treatment volumes and projections in its CON application are reasonable and reliable. Grand Strand’s 2017 threshold analysis is more reliable than CRCC’s because, unlike Grand Strand’s analysis, CRCC fails to properly account for the unavailability of the AUC referrals, it fails to assign any weight to CRCC’s status as an entrenched provider, and it speculates about Grand Strand’s effect on CRCC’s future referral patterns. Even when Grand Strand assumes capturing more than one third of the available market in 2017, GMH is operating at 7,165 treatments and CRCC is operating at 19,934 treatments. Thus, the estimated 2017 utilization in the Service Area indicates that if this Court approves both applications, existing providers operating in the Service Area will not fall below the 80% threshold, the adverse impact on existing providers will be minimal, and all providers will be well-utilized.

While it is appropriate to give due consideration to the Staff's utilization of its specialized knowledge and expertise in the application of the CON Act and CON regulations, I find the testimony of Grand Strand's health planning and finance expert more reliable than the testimonies of the Staff reviewer and CRCC's similarly qualified expert. Consequently, based on the foregoing facts, I conclude by a preponderance of the evidence that the approval of a sixth linear accelerator, to be located at Grand Strand, would not bring existing operators below the 80% threshold. Given the robust estimated 2017 utilization of all existing and proposed radiation therapy providers in the Service Area, the approval of both applications would not exceed the need for services in the Service Area.³⁶

Approval of Both Projects

Since the applications do not exceed the need for facilities and services in the Service Area, and therefore are not competing, I must determine whether each applicant's project can be approved under the CON Act, its regulations, and the State Health Plan. 3 S.C. Code Ann. Regs. 61-15 § 307(1).

A project does not have to satisfy every project review criterion in order to be approved, but no project may be approved unless it is consistent with the State Health Plan. Nevertheless, a project may be denied if the Department determines that the project does not sufficiently meet one or more of the criteria. *Id.* § 801(3). Here, the approval of both projects furthers each of the goals articulated in the CON Act. By approving these projects, the Service Area, and particularly Horry County, will have an additional provider that will foster cost containment by providing private insurance companies leverage in negotiating rates for services. While services are duplicated, the facilities are not because Grand Strand is offering an in-hospital radiation therapy center, which is not currently available in the Service Area. Grand Strand's project will foster the development of a comprehensive cancer center, which is not currently available in the Service Area. The establishment of both Grand Strand's and CRCC's project will best serve the public's need by providing an inpatient option, comprehensive cancer services, and a facility in Conway, which currently lacks local radiation therapy services. The linear accelerator units proposed by Grand Strand and CRCC in their CON applications are both reasonable and

³⁶ CRCC's VP of Finance Operations testified that even if both CON applications are approved, CRCC will still build its facility in Conway.

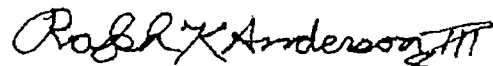
adequate for the proposed radiation therapy services.³⁷ Indeed, both applicants have proven that they will offer high quality radiation therapy services.

I conclude that both applications at issue are consistent with the requirements of the CON Act, its regulations, including the PRC, and the State Health Plan.³⁸

ORDER

IT IS THEREFORE ORDERED that a Certificate of Need for CRCC's proposed project for a radiation therapy center in Conway, South Carolina and a Certificate of Need for Grand Strand's proposed project for a radiation therapy center in Myrtle Beach, South Carolina are **APPROVED**. The Department shall issue a Certificate of Need for each of the proposed projects.

AND IT IS SO ORDERED.



Ralph King Anderson, III
Chief Administrative Law Judge

April 4, 2014
Columbia, South Carolina

³⁷ If Grand Strand chooses to upgrade its linear accelerator unit following the issuance of a CON, it will need to request permission from the Staff pursuant to 3 S.C. Code Ann. Reg. 61-15 § 605 (Supp. 2013). Because I have found that the linear accelerator proposed by Grand Strand in its Application complies with the applicable PRC, I do not find that Grand Strand's intention to upgrade its unit due to a decrease in price constitutes a substantial change at this time requiring remand of its application to the Staff.

³⁸ Grand Strand has taken the position that while both projects can be approved, if only one can be approved, its project is superior. In light of my decision in this case that determination is unnecessary. Nevertheless, based upon the evidence, I agree with Grand Strand that its project more fully complies with the applicable requirements. As set forth in my Findings of Fact above, Grand Strand's project stands apart from CRCC's because it will offer access to comprehensive cancer treatment and in-hospital radiation therapy services in a Service Area where none currently exist. Grand Strand's project will also offer an alternative to radiation therapy services where the referral sources may be financially rewarded. Non-governmental payors like PPOs will have the ability to negotiate rates in Horry County. While Grand Strand's project costs more than CRCC's, the access it affords to the citizens of the Service Area, the vast majority of whom live in Horry County, outweighs any assertion of duplication or adverse impact due to its location in close proximity to CRCC's facility in Myrtle Beach. However, because I have found that both projects can be approved without exceeding the need for facilities and services, and both projects comply with the CON Act, the Health Plan standards, and applicable PRC, I decline to approve only Grand Strand's Application.

CERTIFICATE OF SERVICE

I, E. Harvin Belser Fair, 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).

E. Harvin Belser Fair

E. Harvin Belser Fair
Judicial Law Clerk

April 4, 2014
Columbia, South Carolina