

PARKWAY UROLOGY, P.A. d/b/a CARY UROLOGY, P.A., Petitioner v. NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION, Respondent And RALEIGH HEMATOLOGY ONCOLOGY ASSOCIATES, PC d/b/a CANCER CENTERS OF NORTH CAROLINA, AOR MANAGEMENT COMPANY OF VIRGINIA, LLC, REX HOSPITAL, INC., and WAKE RADIOLOGY ONCOLOGY SERVICES, PLLC, Respondent-Intervenors

WAKE RADIOLOGY ONCOLOGY SERVICES, PLLC, Petitioner v. NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION, Respondent And RALEIGH HEMATOLOGY ONCOLOGY ASSOCIATES, PC d/b/a CANCER CENTERS OF NORTH CAROLINA, AOR MANAGEMENT COMPANY OF VIRGINIA, LLC, REX HOSPITAL, INC. and PARKWAY UROLOGY, P.A., d/b/a CARY UROLOGY, P.A., Respondent-Intervenors

REX HOSPITAL, INC., Petitioner v. NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION, Respondent And RALEIGH HEMATOLOGY ONCOLOGY ASSOCIATES, PC d/b/a CANCER CENTERS OF NORTH CAROLINA, AOR MANAGEMENT COMPANY OF VIRGINIA, LLC, PARKWAY UROLOGY, P.A. d/b/a CARY UROLOGY, P.A., and WAKE RADIOLOGY ONCOLOGY SERVICES, PLLC, Respondent-Intervenors

NO. COA09-1490

(Filed 20 July 2010)

1. Hospitals and Other Medical Facilities - certificate of need - contested case hearing - showing of prejudice required

The North Carolina Department of Health and Human Services did not err by requiring that a hospital show that it was substantially prejudiced by the award of a certificate of need to a competitor in order to file a contested case hearing.

2. Hospitals and other Medical Facilities - certificate of need - complete review of statutory criteria - findings

There was no merit to a hospital's contention that it was substantially prejudiced in the award of a certificate of need to a competitor by the North Carolina Department of Health and Human Services's (NCDHHS) failure to conduct a complete review of the statutory criteria. The findings in the final agency decision indicate that NCDHHS satisfied its obligation to conduct an independent analysis of the challenged criterion.

3. Hospitals and Other Medical Facilities - certificate of need - affected person - substantial prejudice not shown

The North Carolina Department of Health and Human Services (NCDHHS) properly denied a hospital relief from a certificate of need awarded to a competitor due to the hospital's failure to establish substantial prejudice. Obtaining the status of an affected person does not satisfy the prima facie requirement of a showing of substantial prejudice.

4. Hospitals and Other Medical Facilities - certificate of need application - purchase of equipment - funding by nonapplicant

A certificate of need (CON) application by Cancer Centers of North Carolina (CCNC) was not fatally flawed because it did not list the company providing the funding for the desired equipment and holding the title as a co-applicant. The application clearly indicated how the equipment would be purchased and transferred; the CON law allows applicants to rely upon other non-applicant entities for funding the proposed project.

5. Hospitals and Other Medical Facilities - certificate of need - application - Equivalent Simple Treatment level - findings

The North Carolina Department of Health and Human Services did not err by determining that a certificate of need application did not comply with a statutory criterion for a linear accelerator involving the minimum Equivalent Simple Treatment (ESTV) level. The final agency decision included a finding that a weekly radiation therapy management (WRTM) does not involve the use of the linear accelerator and does not fall within the definition of an ESTV; without the WRTM, the application fell below the required threshold.

6. Hospitals and Other Medical Facilities - certificate of need - application - population to be served - substantial evidence

The North Carolina Department of Health and Human Services (NCDHHS) did not err by finding that a certificate of need application satisfied criterion 3 of N.C.G.S. § 131E-183(a)(3) (identification of population to be served). There was substantial evidence under the whole record test; the appellate court will not substitute its judgment for that of the agency in certificate of need cases if substantial evidence exists.

7. Hospitals and Other Medical Facilities - certificate of need - application - financial projections

There was substantial evidence in the whole record to support the North Carolina Department of Health and Human Services' (NCDHHS) finding that a certificate of need complied with the statutory criterion regarding financial projections.

8. Hospitals and Other Medical Facilities - certificate of need - application - linear accelerator

A certificate of need application for a linear accelerator complied with the statutory criterion for showing availability of the resources, including manpower, needed for provision of the proposed services. Although there was testimony that the medical standard of care includes a physician team with a neurosurgeon and a radiologist, the administrative code did not include that requirement.

9. Hospitals and Other Medical Facilities - certificate of need - application - effects on competition - independent analysis

Findings in the final agency decision in a certificate of need case indicate that the North Carolina Department of Health and Human Services (NCDHHS) satisfied its obligation to conduct an independent analysis of the statutory criterion concerning the effects of the proposed services on competition in the proposed service area.

10. Hospitals and Other Medical Facilities - certificate of need - application - duplication of services

A medical provider was not entitled to a certificate of need where its application did not conform to the statutory criteria concerning unnecessary duplication of health service capabilities.

11. Hospitals and Other Medical Facilities - certificate of need - comparative analysis - not addressed

An argument in a certificate of need case concerning the comparative analysis of competing applications was not addressed where neither of the applications competing with the winner conformed to all of the applicable statutory review criteria.

Appeal by petitioners/respondent-intervenors and cross-appeal by respondent-intervenor from Final Agency Decision entered 3 August 2009 by the North Carolina Department of Health and Human Services. Heard in the Court of Appeals 11 May 2010.

Brooks, Pierce, McLendon, Humphrey & Leonard, L.L.P., by Forrest W. Campbell, Jr. and James C. Adams, II for petitioner/respondent-intervenor-appellant Parkway Urology, P.A., d/b/a Cary Urology, P.A.

Kirschbaum, Nanney, Keenan & Griffin, P.A., by Frank S. Kirschbaum and Chad Lorenz Halliday for petitioner/respondent-intervenor-appellant Wake Radiology Oncology Services, PLLC.

K & L Gates LLP, by Gary S. Qualls and William W. Stewart, Jr., for petitioner/respondent-intervenor-appellant Rex Hospital, Inc.

Attorney General Roy Cooper, by Assistant Attorney General June S. Ferrell, for respondent-appellee North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section.

Poyner Spruill LLP, by William R. Shenton and Pamela A. Scott for respondent-intervenor-appellees Cancer Centers of North Carolina, P.C. and AOR Management Company of Virginia, LLC.

CALABRIA, Judge.

Parkway Urology, P.A. d/b/a Cary Urology, P.A. ("Cary"), Wake Radiology Oncology Services ("WROS") and Rex Hospital, Inc. ("Rex") (collectively "petitioners") appeal the Final Agency Decision of the North Carolina Department of Health and Human Services, Division of Health Service Regulation ("NCDHHS"), awarding a certificate of need ("CON") to Cancer Centers of North

Carolina, P.C.¹ ("CCNC") and AOR Management Company of Virginia, LLC ("AOR") to purchase a new linear accelerator ("LINAC"). We affirm.

I. Background

Governor Michael F. Easley inserted into the 2007 North Carolina State Medical Facilities Plan ("SMFP") a need for one additional LINAC in Service Area 20 ("Area 20"), which includes Wake, Harnett and Franklin Counties, to be awarded to "an existing provider of radiation oncology services in Service Area 20[.]" CCNC, WROS, Cary and Duke University Health System d/b/a Duke Raleigh Hospital ("Duke") each applied for the CON to operate a LINAC in Wake County. At the time the applications were filed, CCNC and WROS were each currently operating one LINAC, while Cary had none. In addition, Rex, which was located three-tenths of a mile away from CCNC, was operating four LINACs.

CCNC submitted two applications for the CON, including an application for a LINAC that could provide stereotactic radiosurgery ("SRS") services. At the time of CCNC's application, there were no existing LINACs that could provide SRS services in Area 20. Cary submitted an application for a LINAC that would exclusively treat prostate cancer patients. WROS submitted an application for a second LINAC to provide the same services as their existing LINAC. WROS did not apply for a LINAC that could provide SRS services.

¹ Cancer Centers of North Carolina, P.C. was formerly known as Raleigh Hematology Oncology Associates, P.C.

The CON section of NCDHHS conducted a competitive review of each of the applications. On 1 February 2008, the CON section issued findings as a result of this review. The CON section approved the application of CCNC for the LINAC with SRS services, but the applications of WROS and Cary were disapproved.² The CON section determined that both the WROS application and the Cary application failed to comply with various statutory and regulatory criteria. In addition, the CON section determined that the CCNC application would be the most effective under its comparative analysis methodology.

WROS, Cary and Rex each filed a Petition for Contested Case Hearing in the Office of Administrative Hearings. CCNC intervened in all three of these cases, and each petitioner intervened in the cases of the other two petitioners. The cases were all consolidated for hearing. A contested case hearing was conducted 10-21 November 2008 and 10-19 February 2009 before Administrative Law Judge Selina M. Brooks ("the ALJ"). On 27 April 2009, the ALJ issued a Recommended Decision that NCDHHS should uphold the CON section's determinations.

Petitioners appealed the ALJ's decision to NCDHHS. On 3 August 2009, NCDHHS issued its Final Agency Decision ("the FAD"), approving CCNC's application, disapproving the WROS application and the Cary application and directing issuance of a CON to CCNC. In addition, the FAD determined that Rex was not substantially

² Duke's application was also disapproved, but Duke did not appeal the denial of its application and was never a party in any contested case in the Office of Administrative Hearings.

prejudiced by the entry of CCNC's new LINAC into Area 20. Petitioners separately appeal.³

II. Standard of Review

N.C. Gen. Stat. § 131E-183(a) charges the Agency with reviewing all CON applications utilizing a series of criteria set forth in the statute. The application must either be consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued. A certificate of need may not be granted which would allow more medical facilities or equipment than are needed to serve the public. Each CON application must conform to all applicable review criteria or the CON will not be granted. The burden rests with the applicant to demonstrate that the CON review criteria are met.

Good Hope Health Sys., L.L.C. v. N.C. Dep't of Health & Human Servs., 189 N.C. App. 534, 549, 659 S.E.2d 456, 466 (2008) (internal quotations and citations omitted).

In reviewing a CON determination,

[m]odification or reversal of the Agency decision is controlled by the grounds enumerated in section 150B-51(b); the decision, findings, or conclusions must be:

- (1) In violation of constitutional provisions;
- (2) In excess of the statutory authority or jurisdiction of the agency;
- (3) Made upon unlawful procedure;
- (4) Affected by other error of law;
- (5) Unsupported by substantial evidence admissible under G.S. 150B-29(a), 150B-30, or 150B-31 in view of the entire record as submitted; or

³ WROS also appeals and CCNC cross-appeals the FAD's determination that Cary was an existing provider of radiation oncology services.

(6) Arbitrary or capricious.

Total Renal Care of N.C., LLC v. N.C. Dep't of Health & Human Servs., 171 N.C. App. 734, 739, 615 S.E.2d 81, 84 (2005) (quoting N.C. Gen. Stat. § 150B-51(b) (1999)).

The first four grounds for reversing or modifying an agency's decision . . . are law-based inquiries. On the other hand, [t]he final two grounds . . . involve fact-based inquiries. In cases appealed from administrative agencies, [q]uestions of law receive *de novo* review, whereas fact-intensive issues such as sufficiency of the evidence to support [an agency's] decision are reviewed under the whole-record test.

N.C. Dep't of Revenue v. Bill Davis Racing, ___ N.C. App. ___, ___, 684 S.E.2d 914, 920 (2009) (internal quotations and citations omitted).

In applying the whole record test, the reviewing court is required to examine all competent evidence (the 'whole record') in order to determine whether the agency decision is supported by 'substantial evidence.' Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. We should not replace the agency's judgment as between two reasonably conflicting views, even if we might have reached a different result if the matter were before us *de novo*. While the record may contain evidence contrary to the findings of the agency, this Court may not substitute its judgment for that of the agency.

Dialysis Care of N.C., LLC v. N.C. Dep't of Health & Human Servs., 137 N.C. App. 638, 646, 529 S.E.2d 257, 261 (2000) (internal quotations and citations omitted).

III. Rex Hospital

Rex argues that NCDHHS committed an error of law by requiring Rex to show that it was substantially prejudiced by the awarding of the CON to CCNC. In the alternative, Rex argues that NCDHHS erred by determining that Rex failed to demonstrate that it was substantially prejudiced by the awarding of the CON. We disagree with both contentions.

[1] A. Requirement of Substantial Prejudice

After a decision of the Department to issue, deny or withdraw a certificate of need or exemption or to issue a certificate of need pursuant to a settlement agreement with an applicant to the extent permitted by law, any affected person, as defined in subsection (c) of this section, shall be entitled to a contested case hearing under Article 3 of Chapter 150B of the General Statutes.

N.C. Gen. Stat. § 131E-188(a) (2009) (emphasis added). Under N.C. Gen. Stat. § 131-188(c), an "affected person" includes, *inter alios*, "any person who provides services, similar to the services under review, to individuals residing within the service area or the geographic area proposed to be served by the applicant[.]" N.C. Gen. Stat. § 131-188 (c) (2009). The FAD correctly concluded that Rex qualified as an affected person under this definition and was thus entitled to file a petition for a contested case hearing. Consequently, Rex reasons, it was also entitled to relief at such a hearing without any showing of substantial prejudice.

However, N.C. Gen. Stat. § 131E-188 provides only the statutory grounds for and prerequisites to filing a petition for a contested case hearing regarding CONs. It does not alter the

statutory requirements that must be met in order for a petitioner to be entitled to relief. The actual framework for *deciding* the contested case is governed by Article 3 of Chapter 150B of the General Statutes. N.C. Gen. Stat. § 131E-188(a) (2009). N.C. Gen. Stat. § 150B-23(a) states, in relevant part:

A petition shall be signed by a party or a representative of the party and, if filed by a party other than an agency, shall state facts tending to establish that the agency named as the respondent has deprived the petitioner of property, has ordered the petitioner to pay a fine or civil penalty, or *has otherwise substantially prejudiced the petitioner's rights*[.]

N.C. Gen. Stat. § 150B-23(a) (2009) (emphasis added). This Court has previously addressed the burden of a petitioner in a CON contested case hearing pursuant to this statute.

Under N.C. Gen. Stat. § 150B-23(a), the ALJ is to determine *whether the petitioner has met its burden in showing that the agency substantially prejudiced petitioner's rights*, and that the agency also acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule.

Britthaven, Inc. v. N.C. Dep't of Human Res., 118 N.C. App. 379, 382, 455 S.E.2d 455, 459 (1995) (emphasis added). In addition, in *Presbyterian Hosp. v. N.C. Dep't of Health & Human Servs.*, this Court affirmed a grant of summary judgment against a non-applicant CON challenger specifically because it had failed to demonstrate any genuine issue of material fact as to whether it had been substantially prejudiced by the award of a CON to a nearby competitor. 177 N.C. App. 780, 785, 630 S.E.2d 213, 216 (2006).

Rex's contention that it was unnecessary for it to show substantial prejudice to be entitled to relief is contrary to our case law and is without merit.

[2] B. Evidence of Substantial Prejudice

____ Rex still contends that the evidence presented at the contested case hearing was sufficient to show that it was substantially prejudiced by the award of the CON to CCNC. Rex argues first that it was entitled to a finding of substantial prejudice as a matter of law because NCDHHS failed to conduct a complete review of all of the statutory criteria in N.C. Gen. Stat. § 131E-183(a). Specifically, Rex argues that the FAD indicates that NCDHHS failed to independently review N.C. Gen. Stat. § 131E-183(a)(6) (2009) ("Criterion 6").⁴

Rex cites *Hospice at Greensboro, Inc. v. N.C. Dep't of Health & Human Servs.*, 185 N.C. App. 1, 647 S.E.2d 651 (2007) in support of this argument. The *Hospice* Court held that "the issuance of a 'No Review' letter, which results in the establishment of 'a new institutional health service' without a prior determination of need, substantially prejudices a licensed, pre-existing competing health service provider as a matter of law." *Id.* at 18, 647 S.E.2d at 662. Rex argues that the failure of NCDHHS to adequately review Criterion 6 is equally prejudicial to a competitor as a matter of law.

⁴ Each of the criteria listed in N.C. Gen. Stat. § 131-183(a) will henceforth be referred to as "Criterion [number]."

Criterion 6 states that "[t]he applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities." N.C. Gen. Stat. § 131E-183(a)(6) (2009). Rex argues that NCDHHS failed to independently analyze Criterion 6 and instead determined that compliance with Criteria 1 and 3 required a determination that Criterion 6 was met. The basis of this argument is finding of fact 174 of the FAD, which stated:

The Agency has determined that Criteria 1, 3 and 6 address need-related issues which overlap and which should be analyzed together and consistently. Consequently, the Agency analyzes Criteria 1, 3 and 6 together and if the Agency determines that a need is identified in the SMFP for the service of equipment proposed in the application, and that an application is consistent with the need determination in the SMFP and demonstrates that the population it proposes to serve needs the services it proposes to provide, then to be consistent, *the Agency also will determine that the application does not unnecessarily duplicate existing or approved services.*

(Emphasis added). Standing alone, this finding by NCDHHS is problematic. Each criterion contained in N.C. Gen. Stat. § 131-183(a) must be separately analyzed by NCDHHS. See *HCA Crossroads Residential Ctrs. v. N.C. Dep't of Human Res.*, 327 N.C. 573, 578, 398 S.E.2d 466, 470 (1990) ("[A] statute must be construed, if possible, to give meaning and effect to all of its provisions.").

However, while finding of fact 174 seems to indicate that NCDHHS felt that review of Criterion 6 may have been unnecessary after it had determined CCNC's compliance with Criteria 1 and 3, there are additional findings contained in the FAD that indicate

that NCDHHS did, in actuality, separately consider whether CCNC's new LINAC would result in unnecessary duplication under Criterion

6. For instance, finding of fact 202 stated:

The need for any such duplication is supported by the following factors: (1) Service Area 20 population to linear accelerator ratio of at least 132,664 residents per machine; (2) the large and rapidly growing population and urban nature of Wake County and surrounding communities; (3) strong historical utilization of [CCNC's] existing linear accelerator; (4) continued growth in utilization of [CCNC's] existing linear accelerator; (5) continued substantial decline in utilization of Rex's linear accelerators from 2001 through 2006; and (6) the declining utilization of WROS' linear accelerator from 2004 through 2006.

This and other findings contained in the FAD indicate that NCDHHS satisfied its obligation to conduct an independent analysis of Criterion 6. Therefore, Rex's argument that it was substantially prejudiced as a matter of law because NCDHHS failed to review all required statutory criteria is without merit.⁵

[3] Finally, Rex contends that the whole record contained sufficient evidence that it would be substantially prejudiced by the awarding of a CON to CCNC. The FAD found that "[t]here is no credible evidence of any substantial harm Rex would suffer as a direct result of the operation of [CCNC's] linear accelerator." Specifically, the FAD noted, *inter alia*, (1) that Rex presented "[n]o data, analysis or other support . . . to show that an

⁵ We therefore do not decide whether a pre-existing, non-applicant competing health service provider is substantially prejudiced as a matter of law if a Final Agency Decision of NCDHHS fails to analyze all required statutory criteria for the grant of a CON.

increase in the number of patients referred to [CCNC] . . . would necessarily translate into lost patients for Rex[;]" (2) that there was "no evidence . . . that [CCNC's] competitive impact would necessarily translate into any substantial loss of patients, reduced revenues or lost opportunities for Rex[;]" and (3) that Rex failed to present credible evidence that "[CCNC's] second linear accelerator would have an additional negative impact on Rex that would not occur if that linear accelerator were not in operation."

Rex presented evidence that the current utilization of its LINACs had been declining for a number of years. Rex also refers to testimony presented to NCDHHS that Rex and CCNC operate in close physical proximity to each other and that Rex receives most of its LINAC referrals from "community physicians." Thus, Rex reasons, any additional LINAC capacity at CCNC would necessarily lower the number of LINAC treatments performed at Rex and, as a result, have a substantial impact on Rex's revenues. Rex did not, however, quantify this financial harm in any specific way, other than testimony regarding the amount of revenue Rex receives from its LINAC treatments.

Rex's argument, in essence, would have us treat any increase in competition resulting from the award of a CON as inherently and substantially prejudicial to any pre-existing competing health service provider in the same geographic area. This argument would eviscerate the substantial prejudice requirement contained in N.C. Gen. Stat. § 150B-23(a). As previously noted, Rex qualified as an affected person because it provided similar services to individuals

residing within the service area of CCNC's proposed LINAC. Obtaining the status of an affected person does not satisfy the *prima facie* requirement of a showing of substantial prejudice. Rex was required to provide specific evidence of harm resulting from the award of the CON to CCNC that went beyond any harm that necessarily resulted from additional LINAC competition in Area 20, and NCDHHS concluded that it failed to do so. After a review of the whole record, we determine that NCDHHS properly denied Rex relief due to its failure to establish substantial prejudice. This assignment of error is overruled.

Since Rex failed to establish that it was substantially prejudiced by the awarding of the CON to CCNC, it cannot be entitled to relief under N.C. Gen. Stat. § 150B-23(a). As a result, we decline to address Rex's additional challenges to the FAD.

IV. Wake Radiology Oncology Services

WROS argues that NCDHHS erred by awarding the CON to CCNC and by determining that the WROS application failed to conform to all of the required statutory criteria. We disagree.

A. CCNC's Acquisition of the LINAC

[4] WROS first contends that CCNC's application was fatally flawed because U.S. Oncology, Inc. ("USO"), the parent company of AOR, should have been listed as a co-applicant, as it would "acquire" the LINAC under our statutes. "No person shall offer or develop a new institutional health service without first obtaining a

certificate of need from [NCDHHS.]" N.C. Gen. Stat. § 131E-178 (2009).

"New institutional health services" means any of the following:

f1. The acquisition by purchase, donation, lease, transfer, or comparable arrangement of any of the following equipment by or on behalf of any person:

5a. Linear accelerator.

N.C. Gen. Stat. § 131E-176(16)(f1)(5a) (2009). WROS argues that because the evidence presented to NCDHHS indicated that funding for the LINAC will be provided by USO and title to the LINAC will be held by USO, it is USO, and not CCNC, who has "acquired" the LINAC. Thus, WROS reasons, the failure of CCNC to list USO on its CON application constitutes a fatal flaw in its application, rendering it invalid.

In *Hope-A Women's Cancer Center, P.A. v. N.C. Dep't of Health & Human Servs.*, ___ N.C. App. ___, 691 S.E.2d 421 (2010), this Court held that the determination of an acquisition of medical equipment under N.C. Gen. Stat. § 131E-176(16)(f1) is not controlled by who holds the legal title of medical equipment sought in a CON application. The *Hope-A* Court, after defining the meaning of "acquisition" for the purposes of N.C. Gen. Stat. § 131E-176(16)(f1), then conducted the following analysis of the acquisition at issue in that case:

Although Hope's possession of the Equipment may not be permanent and the Equipment's title may not be in Hope's name, *the fact that the Equipment would be in Hope's possession and control to the extent that it were used to provide services to Hope's patients*

constitutes an "acquisition" in the plain meaning of the term.

Id. at ___, 691 S.E.2d at ___ (emphasis added).

In the instant case, CCNC's application clearly indicated that it was co-applicant AOR, using funds from its parent company USO, that would actually purchase the LINAC. The LINAC would then be transferred to CCNC's possession and control to be used to provide services to CCNC's patients. The fact that the funds used to purchase the LINAC would originate from USO is immaterial to our analysis, as the CON law allows applicants to rely upon other non-applicant entities for funding the proposed project. See *Retirement Villages, Inc. v. N.C. Dep't of Human Res.*, 124 N.C. App. 495, 499, 477 S.E.2d 697, 699 (1996) (holding that the CON statute allows a CON applicant to rely "on the financial resources of another entity for its funding."). Therefore, we hold that AOR and CCNC were correctly determined to be the parties acquiring the LINAC for purposes of the CON application. This assignment of error is overruled.

B. The WROS Application

[5] The WROS application was found nonconforming with Criteria 3, 4, 5, 6 and 18a. Specifically, it was WROS' failure to comply with Criterion 3 that provided the basis for finding its application nonconforming with the remaining statutory criteria.

WROS argues that NCDHHS committed an error of law by analyzing its compliance with Criterion 3 without giving WROS credit for weekly radiation therapy management ("WRTM"), listed as procedure code 77427 in the 2007 SMFP. When WRTM was not included in the

WROS application, the existing WROS LINAC fell below the minimum Equivalent Simple Treatment Visit ("ESTV") level necessary to satisfy Criterion 3 under the rules promulgated by NCDHHS.

N.C. Gen. Stat. § 131E-177 empowers NCDHHS to "adopt rules pursuant to Chapter 150B of the General Statutes, to carry out the purposes and provisions of [section 131E]." N.C. Gen. Stat. § 131E-177(1) (2009). For CON applications, NCDHHS is statutorily empowered "to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed." N.C. Gen. Stat. § 131E-183 (b) (2009).

Pursuant to this statutory authority, NCDHHS requires that

[a]n applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met: (1) an applicant's existing linear accelerators located in the proposed service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted[.]

10A NCAC 14C.1903(a) (2008). Prior to the 2007 SMFP, the definition of ESTV contained in the Administrative Code allowed an applicant to count WRTM as 1 ESTV per visit.

However, in 2006, NCDHHS amended the definition of ESTV. See 11 N.C. Reg. 977 (November 1, 2006). An ESTV is currently defined as "one basic unit of radiation therapy which normally requires up to fifteen (15) minutes for the uncomplicated set-up and treatment

of a patient on a megavoltage teletherapy unit including the time necessary for portal filming." 10A NCAC 14C.1901(3) (2008).

The FAD included a finding of fact that WRTM entails a "patient meet[ing] with his or her radiation oncologist in a weekly office visit." The finding went on to state that "[t]he weekly radiation management consult does not involve the use of a linear accelerator." This finding, which is supported by substantial evidence in the record, supports NCDHHS' conclusion that WRTM does not fall within the definition of an ESTV pursuant to the Administrative Code.

Without WRTM, the WROS application could only demonstrate that its existing LINAC had performed 5,860 ESTVs in the twelve months prior to the application being submitted. Since this number fell well below the threshold of 6,750 ESTVs required by NCDHHS rules, NCDHHS did not err in determining that the WROS application failed to comply with Criterion 3. Therefore, WROS was not entitled to a CON. This assignment of error is overruled.

V. Cary Urology, P.A.

Cary argues that NCDHHS erred by awarding the CON to CCNC and by determining that the Cary application failed to conform to all of the required statutory criteria. We disagree.

A. The CCNC Application

[6] Cary contends that NCDHHS erred in finding that CCNC's application complied with Criteria 3, 5, 7 and 18a.

Criterion 3 states:

The applicant shall identify the population to be served by the proposed project, and shall

demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

N.C. Gen. Stat. § 131E-183(a)(3) (2009). CCNC's application purported to satisfy Criterion 3 by including, *inter alia*, projections derived from two utilization assumptions and one growth assumption. Cary argues that these assumptions used in CCNC's application were unreasonable and do not follow from the evidence presented in the application, such that the numbers in the application vastly overstate any potential need for a LINAC.

CCNC's application identified the patient population in and around Area 20 that would utilize the new LINAC. In addition, the CCNC application indicated that its existing LINAC was operating well above the minimum performance standard, nearing the machine's practical capacity. CCNC presented evidence that it based its increased utilization projections on the previous growth of its practice, as well as the experiences of other oncology practices affiliated with its parent company, USO. CCNC also provided over 100 letters from community physicians, expressing support for the project. Finally, CCNC presented growth projections for cancer incidence from the Solucient database, which bases its projections on Surveillance, Epidemiology and End Results ("SEER") incidence data from the National Cancer Institute.⁶ Dan Sullivan, CCNC's

⁶ CCNC's application erroneously attributed the growth projections to the SEER database itself.

health planning expert, testified at length about the reasonableness of the projections, noting that he had confirmed them by extrapolating from data provided by the Office of State Management and Budget.

We determine that the evidence presented by CCNC in its application and in subsequent hearings constitutes substantial evidence under the whole record test. While Cary may contend that some of the projections relied upon by NCDHHS are flawed, this Court has made clear that "in certificate of need cases, we cannot substitute our own judgment for that of the Agency if substantial evidence exists." *Total Renal Care of N.C., LLC v. N.C. Dep't of Health & Human Servs.*, 171 N.C. App. 734, 739, 615 S.E.2d 81, 84 (2005). This assignment of error is overruled.

[7] Cary next argues that CCNC's application failed to comply with Criterion 5, which states:

Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

N.C. Gen. Stat. § 131E-183(a)(5) (2009). Cary argues that the projections contained in CCNC's application were unreasonable and that the results did not follow from the numbers provided in the application. Cary's arguments are again reviewed under the whole record test.

The FAD indicated that NCDHHS analyzed Criterion 5 by determining whether an application showed the existence of

sufficient initial operating funds and whether the LINAC would be profitable within three years. CCNC provided evidence that all initial operating expenses would be provided to AOR from USO. Additionally, CCNC provided financial statements from previous years that showed that CCNC had operated under a significant budget surplus. CCNC's application also used LINAC utilization projections to create financial projections. These projections, which were supported by underlying evidence in CCNC's application, predicted that CCNC's new LINAC would be profitable within three years as required by NCDHHS.

The FAD acknowledged that CCNC's application contained a number of mathematical errors, but ultimately determined that these errors did not significantly affect the overall projections and were therefore harmless. Ultimately, NCDHHS found, "even taking these errors into account, the proposal set forth in the CCNC application is clearly financially feasible in each of the first three years the [LINAC] would be in operation." Under the applicable standard of review, we find that there was substantial evidence in the whole record to support NCDHHS' finding that CCNC's application complied with Criterion 5. This assignment of error is overruled.

[8] Cary next argues that CCNC's application failed to comply with Criterion 7, which states: "The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided." N.C. Gen. Stat. § 131E-183(a)(7) (2009). Cary

argues that the CCNC application failed to demonstrate that there would be sufficient physicians, specifically neurosurgeons or radiologists, to support a LINAC that provides SRS services.

Cary's argument is based upon the testimony of Dr. Kulbir Sidhu, a CCNC radiation oncologist and an expert in SRS services. Specifically, Dr. Sidhu testified that the medical standard of care for SRS services requires that the physician team include a neurosurgeon, a radiologist and a radiation oncologist. CCNC's application did not demonstrate the availability of either a neurosurgeon or a radiologist.

As previously noted, NCDHHS is statutorily empowered to adopt rules for the review of CON applications. N.C. Gen. Stat. § 131E-183(b) (2009). The staffing requirements for "[a]n applicant proposing to acquire radiation therapy equipment," such as a LINAC, are contained in 10A NCAC 14C.1905(a) (2008). There are no requirements in this portion of the Administrative Code for a LINAC applicant to have either a neurologist or radiologist on staff in order to be awarded a CON. While it may be prudent for NCDHHS to add such requirements for a LINAC providing SRS services, this Court cannot superimpose additional requirements on CON applications above and beyond those that have been promulgated by NCDHHS. Therefore, we determine that, despite Dr. Sidhu's testimony, CCNC was not required to demonstrate the availability of either a neurosurgeon or a radiologist in order to demonstrate compliance with Criterion 7. This assignment of error is overruled.

[9] Finally, Cary argues that CCNC's application failed to comply with Criterion 18a, which states:

The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

N.C. Gen. Stat. § 131E-183(a)(18a) (2009). Cary's argument regarding this criterion parallels Rex's earlier argument regarding Criterion 6. Cary contends that NCDHHS failed to independently analyze this statutory factor. This contention is based upon finding of fact 206, which states, in relevant part:

Consequently, if the Agency determines an application demonstrates that the proposed project will satisfy the requirements of Criteria 3, 5, 7, 8, 12 and 13, then the Agency also will determine that the proposed project will enhance competition in terms of cost effectiveness, quality of services, and access to services.

(Emphasis added). Once again, NCDHHS' choice of language in this finding is unfortunate. However, as with NCDHHS' analysis of Criterion 6, the FAD contains additional findings that indicate that NCDHHS did in actuality separately consider whether CCNC's new LINAC would enhance competition under Criterion 18a. The FAD contains findings of fact which note that (1) awarding an additional LINAC to CCNC would "enhance access to [CCNC's]

radiation therapy services and thereby have a positive impact on quality and continuity of patient care[;]" (2) adding an additional LINAC at CCNC's facility would "positively impact cost effectiveness, quality and access to services[;]" and (3) CCNC's application demonstrated "that Medicare and Medicaid patients will have good access to services provided . . . at [CCNC's facility]." These and other findings contained in the FAD indicate that NCDHHS satisfied its obligation to conduct an independent analysis of Criterion 18a. This assignment of error is overruled.

B. Cary's Application

[10] Cary's application was determined to be nonconforming with Criteria 4 and 6. In the FAD, NCDHHS found that "[t]he Cary Application does not conform with Criterion 6 because it proposes a more limited range of services than a linear accelerator that can be used for more general treatment of radiation therapy patients." Cary argues that NCDHHS acted arbitrarily and capriciously in finding that Cary's application failed to comply with Criterion 6. Cary's argument is based upon finding of fact 174, reproduced above. Cary contends that this finding suggests that compliance with Criteria 1 and 3, which Cary's application satisfied, automatically should have resulted in a finding that Criterion 6 was also satisfied. Cary does not provide any additional arguments supporting its purported compliance with Criterion 6.

As previously discussed, there are numerous additional findings in the FAD that showed that NCDHHS actually conducted an independent analysis of Criterion 6 for CCNC's application.

Likewise, the FAD indicates that NCDHHS conducted an independent analysis of Criterion 6 for Cary's application. Because the FAD indicates that NCDHHS did not, in actuality, rely upon compliance with Criteria 1 and 3 as a proxy for compliance with Criterion 6, Cary's argument fails. Since Cary provided no additional arguments regarding Criterion 6, it has failed to demonstrate that its application complied with this criterion. This assignment of error is overruled.

"Each CON application must conform to all applicable review criteria or the CON will not be granted." *Good Hope*, 189 N.C. App. at 549, 659 S.E.2d at 466. Because we have decided that NCDHHS properly determined that Cary's application failed to conform to Criterion 6, Cary is not entitled to a CON. Consequently, we do not address Cary's arguments regarding Criterion 4. In addition, we need not address the argument of WROS and CCNC that Cary failed to comply with Criterion 1.

VI. Comparative Analysis

[11] Cary argues that NCDHHS erred by upholding the CON section's use of two factors in conducting a comparative analysis of all of the competing applications. Specifically, Cary takes issue with the use of "Demand for Applicant's Existing Services" and "Availability of SRS Capability" as applicable factors in the comparative analysis.

In a competitive review, where the Agency finds more than one applicant conforming to the applicable review criteria, it may conduct a comparison of the conforming applications to determine which applicant should be awarded the CON. There is no statute or rule which

requires the Agency to utilize certain comparative factors.

Craven Reg'l Med. Auth. v. N.C. Dep't of Health & Human Servs., 176 N.C. App. 46, 58, 625 S.E.2d 837, 845 (2006) (internal citations omitted).

In the instant case, it has been determined that neither the WROS application nor the Cary application conformed to all of the applicable statutory review criteria, and as a result, neither WROS nor Cary were entitled to a comparative analysis of their respective applications. Therefore, we decline to address Cary's arguments regarding how the comparative analysis was conducted. This assignment of error is overruled.

VII. Conclusion

After reviewing the FAD, we determine that all challenged findings of fact are supported by substantial evidence in the whole record. In addition, NCDHHS committed no errors of law when (1) it determined that Rex was not substantially prejudiced by the award of a CON to CCNC; (2) it determined that the WROS application and the Cary application failed to conform with all required statutory criteria in N.C. Gen. Stat. § 131E-183(a); and (3) it determined that CCNC's application conformed with all applicable statutory criteria. Therefore, we affirm the FAD awarding a CON to CCNC for a LINAC in Area 20.

Affirmed.

Judges WYNN and STEELMAN concur.