

TOTAL RENAL CARE OF NORTH CAROLINA, LLC d/b/a TRC-LELAND,
Petitioner, v. NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN
SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF
NEED SECTION, Respondent, and BIO-MEDICAL APPLICATIONS OF NORTH
CAROLINA, INC., d/b/a FRESENIUS MEDICAL CARE OF BRUNSWICK COUNTY,
Respondent-Intervenor.

NO. COA09-879

(Filed 7 September 2010)

1. Appeal and Error - preservation of issues - failure to make specific argument

Although petitioner generally contended that the Department of Health and Human Services's (DHHS) final agency decision failed to apply the correct legal standards, the Court of Appeals (COA) did not address this argument. Petitioner did not specify how any of the alleged general failures to apply the correct legal standards changed the outcome of the case. Further, the COA addressed DHHS's application of standards of review in regard to each substantive issue argued by petitioner.

2. Hospitals and Other Medical Facilities - approval of certificate of need application - dialysis facility

The Department of Health and Human Services (DHHS) did not err by approving respondent intervenor's certificate of need (CON) application for a new dialysis facility. Petitioner failed to cite any law suggesting that patient letters should be given greater weight during the CON process. DHHS complied with the public hearing requirement under N.C.G.S. § 131E-185(a1)(2). Further, DHHS properly concluded that respondent intervenor reasonably determined travel distances and dialysis patient growth, that the Anson County case was markedly different from the present one, and that respondent intervenor's application was in compliance with Criterion 3 and the Performance Standards Rule.

3. Hospitals and Other Medical Facilities - rejection of certificate of need application - dialysis facility

The Department of Health and Human Services did not err by finding that petitioner's certificate of need application did not conform with Criterion 3 or 14 of N.C.G.S. § 131E-183(a) or with 10A N.C. Admin. Code 14C.2202(b)(2). Furthermore, findings of fact 116 and 141 were not inconsistent.

4. Hospitals and Other Medical Facilities - certificate of need application - dialysis facility - comparative review argument rejected

Although petitioner contends the Department of Health and Human Services erred by engaging in a comparative review of the pertinent certificate of need applications, this argument was deemed meritless based on the prior conclusions that respondent intervenor conformed to Criterion 3, and petitioner failed to comply with Criterion 3 and 14 and the Transplantation Standard Rule.

Appeal by petitioner from Final Agency Decision entered on or about 19 March 2009 by the North Carolina Department of Health and Human Services. Heard in the Court of Appeals 13 January 2010.

Poyner Spruill LLP, by William R. Shenton, for petitioner-appellant.

Attorney General Roy A. Cooper, III, by Scott Stroud, for respondent-appellee.

Wyrick Robbins Yates & Ponton LLP, by K. Edward Greene, Lee M. Whitman, and Tobias S. Hampson, for respondent-intervenor-appellee.

STROUD, Judge.

Total Renal Care of North Carolina, LLC d/b/a TRC-Leland appealed the final agency decision affirming the decision of the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section to approve the application of Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Brunswick County for a new dialysis facility. For the following reasons, we affirm.

I. Background

On 28 March 2008, Total Renal Care of North Carolina, LLC d/b/a TRC-Leland ("TRC") filed a petition for a contested case hearing regarding the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of

Need Section's ("the CON Section") decisions denying "TRC's application to develop and operate a new ten-station dialysis facility in the town of Leland in Brunswick County" and approving Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Brunswick County's ("BMA") application "to develop and operate a new dialysis facility in the town of Supply, also in Brunswick County[.]" Both applications were submitted after a need was recognized "for 13 additional dialysis stations in Brunswick County, North Carolina." TRC requested that both decisions be reversed and that it be awarded a certificate of need ("CON") for a new dialysis facility in Leland. On or about 17 April 2008, BMA filed a motion to intervene in the case. On 1 May 2008, BMA's motion was granted.

On or about 23 December 2008, Joe L. Webster, administrative law judge, recommended that BMA and TRC be granted "a new review of the applications utilizing reviewers not involved in the initial review, and in the alternative, reverse the CON Section's decision to grant BMA's application for a certificate of need and to affirm the CON Section's decision to deny TRC's applications for a certificate of need." On or about 5 March 2009, TRC submitted its exceptions to the recommended decision and a proposed final agency decision. Also on or about 5 March 2009, the CON Section and BMA submitted their exceptions to the recommended decision and their proposed final agency decision. On or about 19 March 2009, the North Carolina Department of Health and Human Services Division of

Health Service Regulation ("DHHS") affirmed the CON Section's decision to award BMA a CON. TRC appealed.

II. Standard of Review

The standard of review of an administrative agency's final decision is dictated by the substantive nature of each assignment of error.

Where the appellant asserts an error of law in the final agency decision, this Court conducts de novo review. When the issue on appeal is whether a state agency erred in interpreting a statutory term, an appellate court may freely substitute its judgment for that of the agency.

Fact-intensive issues, such as sufficiency of the evidence or allegations that a decision is arbitrary or capricious, are reviewed under the whole record test.

A court applying the whole record test may not substitute its judgment for the agency's as between two conflicting views, even though it could reasonably have reached a different result had it reviewed the matter de novo. Rather, a court must examine all the record evidence--that which detracts from the agency's findings and conclusions as well as that which tends to support them--to determine whether there is substantial evidence to justify the agency's decision. Substantial evidence means relevant evidence a reasonable mind might accept as adequate to support a conclusion. However, the whole record test is not a tool of judicial intrusion; instead, it merely gives a reviewing court the capability to determine whether an administrative decision has a rational basis in the evidence.

In *Britthaven* and *Total Renal Care*, this Court applied a standard of deference first described by the United States Supreme Court in *Skidmore v. Swift & Company*, 323 U.S. 134, 89 L.Ed. 124 (1944), regarding agency interpretations of enabling statutes.

Although the interpretation of a statute by an agency created to administer that statute is traditionally accorded some deference by appellate courts, those interpretations are not binding. The weight of such an interpretation in a particular case

will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.

In *Total Renal Care*, this Court added: If appropriate, some deference to the Agency's interpretation is warranted when we are operating under the traditional standards of review.

Good Hope Health Sys., L.L.C. v. N.C. Dep't. of Health and Human Servs., 189 N.C. App. 534, 543-44, 659 S.E.2d 456, 462-63 (citations, quotation marks, ellipses, brackets, and headings omitted), *aff'd per curium*, 362 N.C. 504, 666 S.E.2d 749 (2008).

III. Legal Standards

[1] TRC first contends that "the final agency decision failed to apply the correct legal standards." (Original in all caps). TRC argues DHHS cited the wrong standard for reviewing a recommended decision, "mischaracterized the standard for finding harmless error[,] " and misstated "principles applicable to reviewing applicants for conformity with review criteria and determining whether an applicant may receive a certificate of need." In its first argument, TRC does not specify how any of the alleged general failures "to apply the correct legal standards" changed the outcome of the case in any way, and therefore we will not address this argument further. See *Responsible Citizens v. City of Asheville*, 308 N.C. 255, 271, 302 S.E.2d 204, 214 (1983) ("The burden is on the appellant not only to show error, but to show *prejudicial* error, *i.e.*, that a different result would have likely ensued had the error not occurred." (emphasis in original) (citations

omitted)). However, we will address DHHS's application of standards of review in regard to each substantive issue argued by TRC.

IV. BMA Application

[2] N.C. Gen. Stat. § 131E-183 sets forth the criteria for issuing a CON. See N.C. Gen. Stat. § 131E-183 (2007). N.C. Gen. Stat. § 131E-183(a) provides that "[t]he Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued." N.C. Gen. Stat. § 131E-183(a). N.C. Gen. Stat. § 131E-183(a)(3) ("Criterion 3") provides that

[t]he 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). Furthermore, "[a]n applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility[,]" 10A N.C. Admin. Code 14C.2203(a) (2008); this rule is under the "Performance Standards[.]" "[T]here is no specific methodology that must be used in determining patient origin, under CON regulations, patient origin must be projected and

all assumptions, including the specific methodology by which patient origin is projected, must be clearly stated." *Retirement Villages, Inc. v. N.C. Dept. of Human Res.*, 124 N.C. App. 495, 500, 477 S.E.2d 697, 700 (1996) (citation, quotation marks, and brackets omitted).

TRC argues that DHHS erroneously determined that BMA complied with Criterion 3 and the Performance Standards Rule because "[t]he record shows that the CON Section simply did not consider whether BMA's fundamental assumption - that all Brunswick County patients who had been going to a facility outside the county would choose to dialyze at its Supply facility - was reasonable." (Emphasis added.) TRC contends that

[t]he crux of this appeal involves the CON Section's failure to consider pertinent information contained in the BMA and TRC Applications, presented in written comments and at the public hearing, and gathered by the CON Section Project Analyst herself. That information was directly pertinent to the fundamental assumption in BMA's Application. The Final Agency Decision upholds the CON Section's erroneous determinations.

Thus, TRC asserts that letters in support of its application, information presented at the public hearing, and information regarding travel distances reveal the flaw in "BMA's fundamental assumption - that all Brunswick County patients who had been going to a facility outside the county would choose to dialyze at its Supply facility[.]" TRC further contends that the CON Section departed from its normal standards in reviewing TRC and BMA's competing applications, thus leading to DHHS's erroneous conclusion.

A. Letters

TRC claims that "there were 35 letters of support in the TRC Application but only six letters of support in the BMA Application." In the final agency decision DHHS found as fact that

TRC's application was accompanied by a significant number of letters of support. Patient letters of support are not as relevant in a county need review because the patients typically know only one of the providers. . . . It would thus not be appropriate for the CON Section to have given great weight to these letters in determining whether BMA's need methodology was reasonable. . . . If patient support was the only deciding factor, there would be no need for publication of county need in an SDR or review of CON applications.

TRC fails to cite any law suggesting that patient letters should be "given great weight" during the CON process. Furthermore, TRC concedes that there were also letters in support of BMA's application.

As long as both applications are reasonable and supported by substantial evidence, this Court will not overturn the decision of DHHS through the use of contrary evidence. *See Craven Reg'l Med. Auth. v. N.C. Dep't. of Health and Human Servs.*, 176 N.C. App. 46, 59, 625 S.E.2d 837, 845 (2006) ("There were reasons to support both applications and deference must be given to the agency's decision where it chooses between two reasonable alternatives. It would be improper for this Court to substitute its judgment for the Agency's decision where there is substantial evidence in the record to support its findings. This argument is without merit." (citation omitted); *see also Good Hope Health Sys., L.L.C.*, 189 N.C. App. at 544, 659 S.E.2d at 462 ("Substantial evidence means relevant

evidence a reasonable mind might accept as adequate to support a conclusion." (citations and quotation marks omitted)). Thus, we cannot substitute our judgment for that of DHHS in its consideration of the letters submitted on behalf of TRC or BMA.

B. Public Hearing

TRC also argues that

[w]hile the CON Section held a public hearing as required, neither the Project Analyst nor the supervisor assigned to this review attended the hearing, listened to, or reviewed a transcript of, the oral comments presented at the hearing by patients and family members before the decision on the applications.

However, Ms. Tanya Rupp, the project analyst who reviewed the TRC and BMA applications, testified that after she reviewed the applications she "read through the public hearing materials." These materials included a sign-in sheet which indicated in whose favor each individual spoke and "written summaries of the comments made at the public hearing[.]" Thus, there was substantial evidence that Ms. Rupp was aware of the comments at the public hearing and that she considered the public hearing in her decision. *See Good Hope Health Sys., L.L.C.* at 544, 659 S.E.2d at 462. As long as the public hearing is in compliance with the applicable statutes and regulations, we cannot impose a requirement that the project analyst be personally present for the entire public hearing.

Furthermore, though the CON Section was required to conduct a public hearing, *see* N.C. Gen. Stat. § 131E-185(a1)(2) (2007), TRC has failed to direct our attention to any law regarding what

specifically must be done with the information gathered at the public hearing. While a failure to consider information from the public hearing at all would render N.C. Gen. Stat. § 131E-185(a1)(2) meaningless, we also do not read the statute to require the stringent application that TRC advocates. The CON Section conducted the hearing in accordance with N.C. Gen. Stat. § 131E-185(a1)(2); the CON Section employees who attended noted individuals who attended the meeting and their comments; and the public comments were summarized and reviewed by the project analyst. We conclude the CON Section did enough to comply with N.C. Gen. Stat. § 131E-185(a1)(2).

C. Travel Distances and Dialysis Patient Population Growth

TRC also argues that Ms. Rupp "gathered information on travel distances between the available and proposed dialysis facilities[,] but failed to use this information properly, along with other information that "demonstrated an increase in the Leland dialysis patient population and a decrease in the Supply dialysis patient population." TRC contends that Ms. Rupp knew that

[t]he distance between the proposed site of the TRC-Leland Facility and the TRC-Wilmington Facility was 8.81 miles or 14 minutes of travel time. . . .

The distance between Supply, where BMA proposed its facility and the Leland area was 23.65 miles or 33 minutes of travel time. . . .

The distance between the existing TRC-Shallotte Facility and Supply was 7.86 miles or 11 minutes of travel time. . . .

Defendant contends "[t]his data established that the TRC-Wilmington facility was much closer to northern Brunswick County than the site of the BMA Supply facility[,] thus "for patients leaving northern Brunswick County to get treatment at TRC's Wilmington facility, that facility still would be closer[.]"

However, TRC itself is making a fundamental assumption, which is that patients will automatically choose the closest facility, no matter the county. TRC ignores other relevant information presented before the CON Section and DHHS regarding the heavy traffic in Wilmington, the lack of public transportation options across county lines, and the Wave county van system that provides transportation for qualified dialysis patients within Brunswick County. As DHHS had substantial evidence before it as to why a patient might choose dialysis in his or her own county rather than to travel to Wilmington in New Hanover County, we again will not find error based upon conflicting evidence. *See Good Hope Health Sys., L.L.C.* at 544, 659 S.E.2d at 462.

TRC also contends that "[t]he data showed that BMA had proposed a facility in a zip code with a shrinking population of dialysis patients who would need hemodialysis treatments, and that the Leland zip code, where TRC had proposed to locate its facility, was experiencing significant patient growth." However, TRC failed to challenge the findings of fact which state that BMA based its projected patient population on "the Five Year Annual Change Rate published within the July 2007" Semiannual Dialysis Report by DHHS. "The Five Year Annual Change Rate represents the average annual

growth rate over a five (5) year period so as to capture the dynamics of the population and account for all upswings and downturns in the population." TRC, on the other hand, based its projected patient population "on the Brunswick County growth rate over a six (6) month period, the Shallotte facility growth rate over an eight (8) month period and over a five (5) year period, and the North Carolina growth rate for all patients in the state over a five (5) year period." Based on this information, we conclude DHHS did not err in determining that it was reasonable for BMA to base its projected population growth on five years' worth of data, rather than relying upon six month's worth of data which allegedly indicated a decrease. *See id.*

D. Prior Practice

TRC also argues that

[t]he CON Section's approach in this review directly conflicts with its analysis of a similar situation [regarding Anson County. In the Anson County application,] the . . . Project Analyst concluded that one applicant had overstated the number of patients who would transfer to its Anson County facility by relying on the unreasonable assumption that a number of patients who lived in Anson County but were choosing to dialyze at a facility in Union County would transfer to the proposed Anson County facility. On that basis, the Project Analyst concluded that the applicant failed to conform to Review Criterion 3 or to meet the Performance Standard Rule. . . . In the instant case, BMA likewise overstated its projected patient population, but the Project Analyst failed to analyze and reject this overstatement, and this oversight was not addressed in the Final Agency Decision.

DHHS found that the Anson County case was "substantively and materially different" from this case. DHHS ultimately concluded

that the Anson County case was "not determinative of the ultimate decision reached in this case." We agree from our review that the facts of the Anson County case are markedly different from the present one.

With regard to Anson County, BMA included in its patient population 14 patients who lived in Anson County but stated "they wanted to go to the [proposed] Marshville facility [in Union County]." The Marshville facility was eventually approved and BMA's Anson County facility was not, in part because BMA's patient origin methodology did not take into account the 14 patients who wanted to dialyze in the Marshville facility. The Anson County situation is entirely different from the situation here; TRC has not identified specific patients who want to use its facility which were also included in BMA's calculation of its projected patient population. DHHS's finding of fact that the two cases are distinguishable on this point is supported by the record.

E. Criterion 3 and Performance Standards Rule

As to Criterion 3 and the Performance Standards Rule, TRC only contests BMA's assumption that Brunswick County patients would want to receive dialysis in Brunswick County. TRC does not challenge any other portion of compliance with Criterion 3 or the Performance Standard Rule. Therefore, as we have concluded that DHHS could properly decide, based upon the substantial evidence before it, that it was reasonable for BMA to assume that Brunswick County patients would want to receive dialysis in Brunswick County, we also conclude that DHHS properly concluded that BMA's application

was in compliance with Criterion 3 and the Performance Standards Rule, as the "fundamental assumption" was the only challenge TRC brought as to these two requirements. These arguments are overruled.

V. TRC Application

[3] TRC argues that DHHS erred in finding its application non-conforming to Criterion 3, N.C. Gen. Stat. § 131E-183(a)(14), in findings of fact 116 and 141, and 10A N.C. Admin. Code 14C.2202(b)(2). We disagree.

A. Criterion 3

TRC directs our attention to DHHS's determination that TRC did not did not comply with Criterion 3.

Again, Criterion 3 provides,

[t]he 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).

As to Criterion 3, DHHS concluded that TRC's application did not conform due to TRC's methodology in projecting patient population. In its application, TRC projected that 29 of its existing patients would transfer to the new facility due to proximity to their homes and because they could continue seeing their current doctors. However, TRC projected it would open its facility with 31 patients. TRC did not explain where the two other

patients came from, as it had specifically identified only 29. Furthermore, in predicting its annual growth rate, TRC began its calculations from January 1, 2007. However, TRC did not submit its application until September of 2007 and did not project opening the facility until 2009. Therefore, we agree with DHHS's determination that TRC's methodology did not conform with Criterion 3 as TRC's population projections were "unreasonable and unsupported by the evidence."

B. Criterion 14

TRC next contends that DHHS erred in determining it did not comply with N.C. Gen. Stat. § 131E-183(a)(14) ("Criterion 14") which provides that "[t]he applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable." N.C. Gen. Stat. § 131E-183(a)(14). TRC argues that the CON Section and DHHS should have taken note of a letter it submitted regarding "the President of Brunswick Community College indicating the College's appreciation of its long-standing relationship with TRC and the use of the Shallotte facility as training site for its nursing students." Assuming *arguendo*, as TRC argues, that the CON Section should have even considered this letter which was part of an entirely separate application not at issue, the letter still in no way establishes TRC conformed with Criterion 14. While TRC may have allowed Brunswick Community College use of its Shallotte facility, it cites to no evidence which showed it would allow the Brunswick Community College to use its Leland facility. As this is

the only evidence TRC directs us to that it conformed with Criterion 14, DHHS properly concluded that TRC did not conform.

C. Findings of Fact 116 and 141

TRC next directs our attention to findings of fact 116 and 141 which provide:

116. The TRC application was nonconforming to Criterion 3.

141. . . . If TRC's application had been found comparatively superior to BMA's application, the CON Section would have conditionally approved TRC's application and disapproved BMA's application.

TRC argues that these two findings are inconsistent. However, we find this argument meritless as finding of fact 141 is clearly conditioned by the word "[i]f." Certainly, *if* TRC's application were found to be comparatively superior to BMA's application, it would have been appropriate for it to have been conditionally approved. However, TRC's application was not found to be comparatively superior; BMA's was. This argument is meritless.

D. Transplantation Standard Rule

TRC also argues that the CON Section erred in determining TRC had not complied with 10A N.C. Admin. Code 14C.2202(b)(2) ("Transplantation Standard Rule"), while concluding BMA had conformed. The Transplantation Standard Rule requires that

a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility.

10A N.C. Admin. Code 14C.2202(b)(2) (2008). While TRC alleges DHHS erred in concluding BMA had conformed with the Transplantation Standard Rule, the final agency decision provides a list of TRC's issues, which does not include this contention. Furthermore, TRC did not challenge this list by claiming it had further issues. Therefore, we will not review this issue regarding BMA. However, TRC has assigned error to the finding that it did not comply with the Transplantation Standard Rule, and we will review this contention.

TRC directs our attention to "a letter from Duke University Medical Center and an unsigned agreement between TRC-Leland and Carolinas Medical Center pertaining to provisions of transplant services." The letter from Duke University Medical Center was from Stephen R. Smith, M.D., an Associate Professor of Medicine in the Division of Nephrology at Duke University Medical Center. The letter stated that "Dr. McCabe and [sic] will continue to provide transplant services to the new unit DaVita Leland." Furthermore, although the record contains a document noted as a "Transplant Agreement[,]" the only signature on this agreement is on behalf of Davita Dialysis of Leland and the signature space on behalf of Carolinas Medical Center is blank. These two documents are neither "a letter of intent to sign a written agreement or a written agreement with a transplantation center[.]" While Dr. Smith indicated he and a colleague will provide services at TRC's new facility, he in no way indicated that Duke University's transplantation center will be doing the same. Furthermore, while

TRC does have a written document purporting to be an agreement with Carolinas Medical Center, this document is not an agreement until actually signed by an authorized representative of Carolinas Medical Center. We therefore conclude that DHHS did not err in concluding TRC did not conform with the Transplantation Standard Rule.

VI. Comparative Review

[4] Lastly, TRC contends DHHS should not have engaged in a comparative review of the applications, and even if it did, it should have found TRC's to be the superior application. TRC's contention that there should not have been a comparative review is based upon the argument that BMA did not conform to Criterion 3. However, we have already concluded that DHHS did not err in concluding BMA conformed to Criterion 3, and therefore this argument is meritless. TRC also points to various other errors in DHHS's consideration, but we have already concluded that DHHS did not err as to its determinations regarding TRC's previous contentions of BMA's application and that TRC failed to comply with Criterion 3 and 14 and the Transplantation Standard Rule; these findings alone establish that TRC's application could not have been superior to BMA's application. This argument is also meritless.

VII. Conclusion

We conclude that DHHS properly allowed BMA's application and disapproved TRC's application. We affirm.

AFFIRMED.

Judges BRYANT and ELMORE concur.