



Fresenius Medical Care

June 30, 2010

Mr. Craig R. Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Human Resources
701 Barbour Drive
Raleigh, NC 27603

Received by the
CON Section
30 JUN 2010 03 : 50

Re: Public Written Comment, CON Project ID # G-8521-10, Mebane Dialysis
FID# 100545

Dear Mr. Smith:

On behalf of Bio-Medical Applications of North Carolina, I am forwarding the attached as Public Written Comments regarding the CON Application filed by Renal Treatment Centers Mid-Atlantic, Inc., to develop a 10 station dialysis facility in Mebane, Alamance County, North Carolina. BMA is pleased to have the opportunity to submit comments, and trusts that the CON Project Analyst will consider these comments during the review process.

If you have any questions, or I can be of further assistance, please contact me via email, jim.swann@fmc-na.com.

Sincerely,

Jim Swann

Jim Swann
FMC Director, Market Development and Certificate of Need

2 Attachments:

1. Public Written Comments, CON Project ID# G-8527-10
2. Final Agency Decision, 08 DHR 0818

Received by the
CON Section
30 JUN 2010 03 : 50

3725 National Drive, Suite 130
Raleigh, North Carolina 27612

1. The need methodology employed by the applicant has been faulted by DHSR Director Jeff Horton, in 08 DHR 0818, Final Agency Decision for Contested Case of Total Renal Care of North Carolina, LLC, d/b/a TRC-Leland v. North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section and Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Brunswick County, March 19, 2009 (the "Brunswick Case"). In the case at hand, the applicant has sought to retroactively begin growth of a patient population beginning July 1, 2009, fully 10 months prior to the filing of this application.

The applicant indicates that 26 patients have extended support for this CON application; the applicant has included 25 patient letters of support for the application. Each of these letters was signed in May 2010.

In the Brunswick Case, Director Jeff Horton indicated that it was inappropriate to retroactively grow the patient population projected to transfer to the new facility because the applicant (TRC) "did not provide any evidence" that the patients projected to transfer were in existence on the starting date the applicant used for growth projections (Finding of Fact #108, reprinted below).

From the Final Agency Decision, 08 DHR 0818, Findings of Fact:

"108. Moreover, TRC sought to retroactively grow the population of 29 patients. The TRC application was filed on September 17, 2007 and the application referred to these 29 patients as currently dialyzing with TRC outside of Brunswick County. The TRC application did not provide any evidence that the 29 patients were in existence on January 1, 2007."

Absent any confirmation that the 26 patients (projected to transfer) actually existed on July 1, 2009, the Agency can not accept the 25 letters of support, and the assertion of the applicant for the one patient without a letter of support, as a basis for the growth projections of the patient population to be served at the proposed facility. The applicant has failed to satisfy Criterion 3, Need, and therefore the application can not be approved. See Brunswick Case, Finding of Fact 100, reprinted below.

From the Final Agency Decision, 08 DHR 0818, Findings of Fact:

"100. An application for a CON cannot be conditioned upon the showing of need for a proposed project. Need must be adequately accounted for on the face of an application."

2. In addition to the dubious retroactive need methodology, 12 of the letters of support provided by the applicant are from dialysis patients who are patients of the University of North Carolina Hospital, Division of Nephrology and Hypertension. The UNC nephrology physicians were not contacted regarding the proposed project prior to the application being filed. It is BMA's understanding, belief and knowledge that the nephrology physicians from the UNC Hospital, Division of Nephrology and Hypertension will not be seeking admitting privileges at the proposed facility. Thus, the 12 patients in question will either not transfer to the proposed facility, or will have to change nephrology physicians to a nephrologist who does have admitting privileges at the proposed facility.

BMA understands that the UNC Hospital Division of Nephrology and Hypertension physicians certainly will not be seeking admitting privileges at the proposed new facility. The physicians have indicated that in addition to their hospital privileges at UNC Hospital, they already have admitting privileges at the following dialysis facilities:

- Carolina Dialysis – Carrboro
- Carolina Dialysis – Siler City
- Carolina Dialysis – Pittsboro
- Carolina Dialysis – Sanford
- BMA Burlington
- DaVita Burlington

The Division physicians are satisfied that their current obligations coupled with other pending projects will, in effect, be the limit of their practice abilities based upon current staffing. The Division Director, Dr. Ronald Falk, has indicated to BMA representatives that "there simply isn't enough to go around" to allow these physicians to seek admitting privileges at the proposed facility. [For the record, Dr. Falk has worked closely with Jim Swann, FMC Director, Market Development and Certificate of Need, on other recent CON applications; thus, Jim Swann does have direct knowledge of these discussions.]

It has been BMA experience that while some patients may occasionally change nephrologists, it simply does not happen on a wholesale basis. Thus, it is highly unlikely that the 12 patients in question, who do not know that their nephrologists will not be seeking admitting privileges at the proposed facility, and therefore may not know that they will have to change nephrology physicians to be admitted to the proposed new facility, will actually transfer their care to the proposed new facility. Under these circumstances, BMA suggests that it is highly unlikely that these 12 patients will transfer their care to the proposed new facility. As a consequence, the projections of patients to be served at the proposed new facility are dubious.

3. The application is internally inconsistent with regard to patient projections. In addition to the above comments regarding Criterion 3, BMA notes that the need methodology within the application only addresses in-center patients. There is no single point within the application addressing home dialysis patients.

The applicant states in bold font on page 20 of the application that the patient numbers for Operating Years 1 and 2 will be used to determine the number of treatments, operating revenues and operating expenses.

However, consider the following:

- a. In the Table on page 19 of the application, the applicant indicates that it will be providing treatment for 36 dialysis patients in operating year one; this is 33 in-center patients and three home PD patients.
- b. On the very next page of the application, page 20, the applicant very clearly says that operating year one would be the period July 1, 2012 through June 30, 2013. At the same time, the applicant only projects to serve 33.0904 patients, presumably rounded down to 33.
- c. On page 45 of the application, in the tabular response to X.3, Column A, the applicant has projected that the proposed facility would schedule 5,460 annual treatments in the first year. This number is a function of the number of patients multiplied by three weekly treatments multiplied by 52 weeks. Thus, one can calculate the number of proposed patients by dividing the number 5,460 by 156 annual treatments (3 weekly treatments X 52 weeks). The result is 35 patients.

The application does not include any discussion of the home patient population to be served. Inasmuch as the patient projections are internally inconsistent, the associated Need discussion is unreliable. If the need discussion is unreliable, then it is necessarily not reasonable and must be rejected by the CON Section.

4. BMA suggests that the above noted internal inconsistencies render this application as un-approvable. What number of patients will be served by the facility in operating year one? 33? 35? 36? Or, is it some number that does not include the 12 patients who were admitted to the DaVita Burlington facility by the nephrology physicians from UNC?

BMA notes projections within a CON application must be reasonable. Refer again to the Brunswick Case:

From the Final Agency Decision, 08 DHR 0818, Findings of Fact:

68. *Projections attempt to predict something that will occur in the future; therefore, the very nature of a projection cannot be established with absolute certainty. Craven, 176 N.C. App. at 52-53, 625 S.E.2d 837, 841. Projections of a patient census made in a CON application thus conform to Criterion 3 as long as the projections are "reasonable."* (ALJ Finding 65.). [emphasis added].

In the case at hand, BMA notes first and foremost, the parent company to Renal Treatment Centers Mid-Atlantic, Inc. is DaVita, Inc. This is the very same company opposing BMA's development in the Brunswick case. Therefore, DaVita clearly had knowledge of the Findings of Fact from the Brunswick Case, and should therefore have not attempted to use a retroactive growth methodology.

Furthermore, inasmuch as DaVita Inc., is the parent company of the Burlington Dialysis facility, current home of the 10 stations proposed to be transferred by way of this application, DaVita also knew that the 12 patients referred to in 2. above were patients admitted by the UNC nephrology physicians. DaVita knew, or should have known, that it would only have been appropriate to consult with the admitting physicians before asking patients if they would consider transferring to the proposed new facility.

In fact, it was clearly unreasonable for the applicant to solicit patients without first consulting with the admitting physician. It was equally unreasonable for the applicant to utilize a growth methodology which has been rejected by the Division of Health Service Regulation Director. The applicant has for all intents and purposes submitted a CON applicant devoid of any reasonable basis for the "need" discussions. The application should be denied if for nothing else, the absence of reasonable need projections.

5. To the extent that the patient projections are inconsistent, and unreliable, then the resultant financial projections are likewise inconsistent. Financial projections are a direct function of the number of patients proposed to be served by the dialysis facility. To the extent that the projections of patients to be served are not reasonable, the obvious consequence, is that the resultant financial projections are not reliable. Thus, the applicant is nonconforming to Review Criterion 5.
6. The application is internally inconsistent with regard to staffing. The tabular response to VII.1 indicates that the facility will have all new staff. On page 36 of the application, the applicant says that they will, "...transfer some of the teammates from the Burlington Dialysis Center to help staff Mebane Dialysis." Following this statement, on page 42 of the application, the applicant says that they will "...hire all staff for the facility three months prior to the projected certification date."

Given the above noted inconsistencies, the CON Analyst can not know if the applicant will hire all new staff, or transfer staff, or even have enough staff for the facility. The ambiguities are so vague that the information must be deemed unreliable, and therefore the application is non-conforming to review Criterion 7 and must be denied.

7. The application has proposed a questionable amount of square footage for the facility. On page 54 of the application, the applicant suggests that the facility will be 6,500 square feet. The email in Exhibit 25 regarding the primary site indicates that the annual rent is \$9.00 per square foot; this equates to \$58,500. In Table X.4, page 46 of the application, the Applicant reports rent of \$104,000; this equates to 11,556 square feet.

Furthermore, the applicant's secondary site is proposed to be 8,450 square feet; the rent is reported at \$9.00 per square foot plus \$1.70 per square foot for common area maintenance. The calculated rent for this space would be \$90,415. The information is not representative of the costs reflected in the application.

The information is unreliable. The application should therefore be found non-conforming to both Review Criterion 5 and 12.

8. The applicant has failed to provide a commitment to acquire the property after the CON is issued, as required by 10A NCAC 14C .2202 (b) (5). This rule is reprinted here for reference:

*"For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the **applicant must provide a written commitment to pursue acquiring the site** if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition."* [emphasis added]

The information included in response to XI. 2 (j) only indicates that the landlord will pursue a lease for the property; the rule requires the applicant to provide such commitment. Furthermore, there is nothing in Exhibit 25 of the application which indicates that the applicant has any intent to pursue control of the site. The absence of such commitment on behalf of the applicant is non-conforming to the stated rule.

9. The applicant has proposed that it would purchase only two dialysis machines and would be transferring eight dialysis machines from its Burlington facility. In as much as this is an application for a 10 station dialysis facility, what will the applicant do for back-up machines in the event of machine failure? The absence of any back-up machine capability must necessarily call into question the applicant's commitment to quality of care and Policy Gen 1.

CON Project ID # G-8521-10, Mebane Dialysis

Renal Treatment Centers Mid-Atlantic, Inc.

Prepared by Jim Swann, FMC Director, Market Development and Certificate of Need

10. Given the applicant's failure on Criteria 3, 5, 7, and 12, the application is also non-conforming to Review Criteria 4; this clearly is not the best alternative for the patients of Alamance County.

Summary:

The CON Application filed by Renal Treatment Centers Mid-Atlantic, Inc. is internally inconsistent, provides vague and ambiguous answers, and fails to meet Review Criteria 3, 4, 5, 7, and 12; in addition the application is non-conforming to rule 10A NCAC 14C .2202 (b) (5). Furthermore, the application fails to assure an adequate quality of care and is non-conforming to Policy Gen 1.

The application submitted by Renal Treatment Centers Mid-Atlantic, Inc. to develop a new 10 station dialysis facility in Mebane, Alamance County, North Carolina is fatally flawed and should not be approved.



**North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director**

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Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

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March 19, 2009

CERTIFIED MAIL

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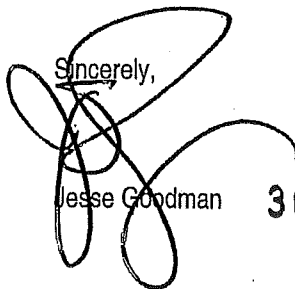
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Raleigh, NC 27607

Re: Final Agency Decision for Contested Case of Total Renal Care of North Carolina, LLC d/b/a TRC-Leland v. North Carolina Department of Health and Human Services; Division of Health Service Regulation, Certificate of Need Section and Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Brunswick County: 08 DHR 0818

Dear Counsel:

Enclosed is the Department of Health and Human Services' final agency decision in the above-referenced matter. You may obtain judicial review of this decision, pursuant to N.C. General Statute §131E-188(b). The appeal shall be to the N.C. Court of Appeals as provided in N.C. General Statute §7A-29(a).

If you choose to seek judicial review, you must file notice of appeal with the Division of Health Service Regulation, Department of Health and Human Services. Your notice of appeal must be filed within 30 days after you receive your copy of the final agency decision. You must also file copies of the notice of appeal with all other affected persons who were parties of the contested case hearing. The procedure for the appeal shall be as provided by the N.C. Rules of Appellate Procedure.

Sincerely,

Jesse Goodman

**Received by the
CON Section**

30 JUN 2010 0 3 10

JG:peb
Enclosure

cc: Emery Edwards Milliken, General Counsel, Legal Affairs
Jeff Horton, Acting Director, DHSR
Lee Hoffman, Chief, Certificate of Need Section
Azzie Conley, Chief, Licensure and Certification Section
Kim Hausen, Chief Hearings Clerk
Bill Hyland, Director of Healthcare Planning, Davita, Inc.
Jim Swann, Regional Director of Health Planning, Fresenius Medical Care, Brunswick County



**IN THE NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION**

**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.)

FINAL AGENCY DECISION

**From the Office of Administrative Hearings
File No. 08 DHR 0818 (Brunswick County)**

I, the undersigned designee of the Secretary of the North Carolina Department of Health and Human Services, having received authorization from the Secretary to render Final Agency Decisions in contested cases brought under N.C. Gen. Stat. § 150B-23, after reviewing the official record in this contested case, and having considered the exceptions, written arguments, and oral arguments submitted by the parties, hereby issue the Final Agency Decision in this contested case, pursuant to N.C. Gen. Stat. §§ 150B-34(c) and 150B-36(a).

STATEMENT OF THE CASE

At issue in this contested case is the decision of the Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section ("CON Section") to approve Respondent-Intervenor Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of North Carolina's ("BMA") application for a certificate of need ("CON") to develop and operate a new ten (10) station dialysis facility in Brunswick County (the "BMA application" or "BMA's application") as well as the CON Section's decision to deny Petitioner Total Renal Care of North Carolina, LLC d/b/a TRC-Leland's ("TRC") application for a certificate of need to develop and operate a new ten (10) station dialysis facility in Brunswick County (the "TRC application" or "TRC's application").

This contested case came on for hearing on October 14-16 and 20, 2008, in Raleigh, North Carolina. Administrative Law Judge Joe L. Webster (the "ALJ") recommended that the decision to approve the BMA application be reversed and the decision to deny the TRC application affirmed.

For the reasons stated herein and in Appendix A hereto, which is incorporated by reference as if fully set forth herein, I do not adopt the ALJ's Recommended Decision and I enter the following Final Agency Decision upholding the CON Section's decision approving BMA's application and denying TRC's application.

APPEARANCES

William R. Shenton
Jessica M. Lewis
Poyner Spruill LLP
Raleigh, North Carolina

For Petitioner TRC

Scott T. Stroud
Assistant Attorney General
North Carolina Department of Justice
Raleigh, North Carolina

For Respondent CON Section

Lee M. Whitman
Sarah M. Johnson
Wyrick Robbins Yates & Ponton LLP
Raleigh, North Carolina

For Respondent-Intervenor BMA

ISSUES

The parties set forth the following issues for resolution in this contested case in the Pre-Hearing Order:

Petitioner TRC'S List of Issues

TRC contends that the issues for resolution in this contested case are as follows:

1. Whether the CON Section deprived TRC of property or otherwise substantially prejudiced TRC's rights when the CON Section conditionally approved the BMA Application and denied the TRC Application.

2. Whether the CON Section exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule, in determining that the BMA Application conformed, or could be found conforming with conditions, with the review criteria codified at N.C. Gen. Stat. § § 131E-183(a)(3), (4), (5), (6) and (18a), and 10A NCAC 14C.2203(a) and (c).

3. Whether the CON Section exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule, in determining that the TRC Application did not conform, or should not be found conforming with conditions, with the review criteria codified at N.C. Gen. Stat. § § 131E-183(3), (a), (4), (5), (6) and (18a), and 10A NCAC 14C.2203(a) and (c).

Respondent CON Section's List of Issues

1. The issue to be resolved is whether Respondent substantially prejudiced Petitioner's rights and exceeded its authority or jurisdiction; acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule when Respondent conditionally approved the CON application filed by BMA, Project I.D. No. O-7965-07 and denied the CON application of TRC, Project I.D. No. O-7973-07.

Respondent-Intervenor BMA's List of Issues

1. Whether the CON Section properly found BMA's application to develop a new ten (10) station dialysis facility in Supply, Brunswick County conditionally conforming to all statutory and regulatory criteria.

2. Whether the CON Section properly found TRC's application to develop a new ten (10) station dialysis facility in Leland, Brunswick County nonconforming to all statutory and regulatory criteria.

FINDINGS OF FACT

After examining the official record of this contested case, including the Recommended Decision, and after considering the exceptions to the Recommended Decision and the arguments of the parties, I adopt certain of the Findings of Fact made by the ALJ. The Findings of Fact that I have adopted from the ALJ's Recommended Decision are indicated below as "(ALJ Finding ____)." I also adopt certain new Findings of Fact as set forth below. Finally, I have also altered certain of the headings to more accurately reflect my Findings of Fact.

Parties, Procedural Points and Other Undisputed Information

1. All the parties are properly before the Office of Administrative Hearings ("OAH"), and OAH has jurisdiction of the parties and of the subject matter. (ALJ Finding 1.)

2. All parties have been correctly designated and there is no question as to misjoinder or nonjoinder of parties. (ALJ Finding 2.)

3. Petitioner TRC is a Delaware limited liability company and is authorized to do business in the state of North Carolina. (Joint Ex. 2 at 71.) TRC is in the business of providing dialysis services. (*Id.* at 9.) (ALJ Finding 3.)

4. Respondent CON Section is the agency within the Department of Health and Human Services that carries out the Department's responsibility to review and monitor new institutional health services under the Certificate of Need Law, codified at N.C. Gen. Stat. § 131E-175 *et seq.* (ALJ Finding 4.)

5. Respondent-Intervenor BMA is a Delaware corporation and is authorized to do business in the state of North Carolina (Joint Ex. 1 at 72.) BMA is in the business of providing dialysis services. (Id. at 6.) (ALJ Finding 5.)

Certificate of Need Regulation of Dialysis Facilities

6. Under North Carolina's certificate of need law, a kidney disease treatment center, also known as a dialysis clinic, is a "health service facility." N.C. Gen. Stat. § 131E-176(9b). (ALJ Finding 6.)

7. The construction, development, or other establishment of a new health service facility is a "new institutional health service." N.C. Gen. Stat. § 131E-176(16)(a). (ALJ Finding 7.)

8. A new institutional health service may not be offered or developed without first obtaining a certificate of need. N.C. Gen. Stat. § 131E-178(a). (ALJ Finding 8.)

9. Therefore, a dialysis clinic cannot be offered or developed without first obtaining a certificate of need. (ALJ Finding 9.)

10. When an applicant applies for a certificate of need, the CON Section must review each application using the criteria outlined in N.C. Gen. Stat. § 131E-183. N.C. Gen. Stat. § 131E-183. (ALJ Finding 10.)

11. A certificate of need cannot be issued to an applicant unless the application is conforming to all statutory and regulatory criteria. 10A N.C. Admin. Code 14C.0207. (ALJ Finding 11.)

12. In a competitive review, the CON Section must first evaluate each application on its own merits and then perform a comparative review to determine which applicant is the superior applicant and should receive the certificate of need. Britthaven, Inc. v. N.C. Dep't of Human Res., 118 N.C. App. 379, 385, 455 S.E.2d 455, 464 (1995). (ALJ Finding 12.)

Standard of Review

13. When challenging the CON Section's decision to issue a certificate of need, a petitioner must establish, by a preponderance of the evidence, a two prong test. N.C. Gen. Stat. § 150B-23(a). The first prong requires that the petitioner establish that the CON Section has substantially prejudiced the petitioner's rights. Id. The second prong requires that the petitioner also establish that the CON Section:

- (1) exceeded its authority or jurisdiction
- (2) acted erroneously;
- (3) failed to use proper procedure;
- (4) acted arbitrarily or capriciously; or
- (5) failed to act as required by law or rule.

Id. The two prongs of this test are independent of one another and the petitioner has the burden of establishing *both* prongs by a preponderance of the evidence. See, e.g., Presbyterian Hosp. v. N.C. Dep't of Health and Human Servs., 177 N.C. App. 780, 784-85, 630 S.E.2d 213, 216 (2006).

14. A petitioner is not entitled to a *de novo* review in the Office of Administrative Hearings. Britthaven, 118 N.C. App. at 381-83, 455 S.E.2d at 458-59. Rather, the CON Section's decision is reviewed for error based on a hearing limited to the evidence presented or available to the CON Section during the review period. Id. at 382-83, 455 S.E.2d at 459. (ALJ Finding 14.)

15. It is improper for a Court to substitute its judgment for the CON Section's decision when substantial evidence in the record supports the CON Section's findings. 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). (ALJ Finding 15.)

16. The CON Section's interpretation of the certificate of need statutes is customarily afforded deference. Christenbury Surgery Ctr. v. N.C. Dep't of Health and Human Servs., 138 N.C. App. 309, 312, 531 S.E. 2d 219, 221 (2000). Deference to agency interpretation is a "long-standing tradition." County of Durham v. N.C. Dep't of Env't & Natural Res., 131 N.C. App. 395, 397, 507 S.E.2d 310, 311 (1998). (ALJ Finding 16.)

17. A Court should also "take into account the specialized expertise of the staff of an administrative agency." High Rock Lake Ass'n Inc. v. N.C. Env't Mgmt. Comm'n, 51 N.C. App. 275, 279, 276 S.E.2d 472, 475 (1981). (ALJ Finding 17.)

18. The CON Section's interpretations and findings must be upheld if they are "reasonable." Good Hope Health Sys., L.L.C. v. N.C. Dep't of Health & Human Servs., ___ N.C. App. ___, ___, 659 S.E.2d 456, 471-472, *aff'd*, 362 N.C. 504, 666 S.E.2d 749 (2008). Further, deference must be given to the CON Section when it has made a choice between two reasonable alternatives. Craven, 176 N.C. App. at 397, 625 S.E.2d at 845. (ALJ Finding 18.)

Background of this Contested Case

19. The North Carolina Department of Health and Human Services (the "Department") publishes a Semiannual Dialysis Report ("SDR"). The SDR is an official document that projects the need for additional dialysis stations as prescribed by North Carolina CON law. (ALJ Finding 19.)

20. The July 2007 SDR identified a need for thirteen (13) new dialysis stations in Brunswick County, North Carolina. (ALJ Finding 20.)

21. In response to the need identified in the July 2007 SDR, TRC submitted two (2) applications: (a) an application to add three (3) dialysis stations to its existing Shallotte, Brunswick County dialysis clinic; and (b) the TRC application, which proposed to develop a new ten (10) station dialysis clinic in Leland, Brunswick County. (Joint Ex. 3 at 633-635.) (ALJ

Finding 21.)

22. Also in response to the need identified in the July 2007 SDR, BMA submitted a single application, the BMA application, which proposed to develop a new ten (10) station dialysis clinic in Supply, Brunswick County. (Id. at 633-34.) (ALJ Finding 22.)

23. Because the TRC application and the BMA application were submitted in the same review period and could not both be approved pursuant to the July 2007 SDR-identified need for dialysis stations in Brunswick County, the review of the two applications was competitive. (Tr. at 152:10-13; 10A N.C. Admin. Code 14C.0202(f).) (ALJ Finding 23.)

24. The CON Section assigned CON project analyst Tanya Rupp ("Ms. Rupp") the task of reviewing the TRC application, the BMA application, and the application for three (3) additional stations in Shallotte. (Tr. at 153:6-9; Joint Ex. 3 at 633.) (ALJ Finding 24.)

25. At the time of the hearing, Ms. Rupp had worked for the CON Section for approximately three (3) years. (Tr. at 490:21-23.) In her three (3) year tenure at the CON Section, Ms. Rupp has performed approximately 100 to 150 reviews of CON applications. (Id. at 491: 13-16.) As a CON project analyst, Ms. Rupp is responsible reviewing the CON applications from an eight (8) county service area, writing the Required State Agency Findings (the "Agency Findings") for those applications, and monitoring her service area. (Id. at 491:1-8.) (ALJ Finding 25.)

26. Ms. Rupp's educational background includes a B.A. degree in political science and a J.D. degree. (Id. at 491:9-12.) (ALJ Finding 26.)

27. Assistant Chief of the CON Section, Craig Smith ("Mr. Smith"), is charged with supervising the CON Section's project analysts. (Id. at 602:2-13.) He supervised and assisted Ms. Rupp in her review of the applications at issue in this case. (Id. at 496:5-7, 614:7-10.) Mr. Smith has a B.A. degree in political science and a master's degree in urban and regional planning. (Id. at 602:20-22.) (ALJ Finding 27.)

28. The CON Section issued its decision in this case on February 27, 2008 and issued the Agency Findings on March 5, 2008. (Joint Ex. 3 at 633.) (ALJ Finding 28.)

29. The CON Section determined that TRC's application was nonconforming to Criteria 3, 4, 6, 12, 14, 18a and 10A N.C. Admin. Code 14C.2202(b)(2). (Joint Ex. 3 at 633-680.) (ALJ Finding 29.)

30. The CON Section also determined that BMA's application was conforming or conditionally conforming to all statutory and regulatory review criteria. (Id.) (ALJ Finding 30.)

31. After performing a comparative review of the applications, the CON Section determined that BMA's application was superior and thus conditionally approved BMA's application for a CON to develop a new ten (10) station dialysis center in Brunswick County. (Id. at 672-80.) (ALJ Finding 31.)

32. The CON Section also found TRC's application to add three (3) dialysis stations to its Shallotte facility was conforming or conditionally conforming to all statutory and regulatory review criteria, and thus conditionally approved the application. (*Id.* at 672.) (ALJ Finding 32.)

33. TRC filed a Petition for Contested Case Hearing challenging the CON Section's conditional approval of BMA's application and disapproval of TRC's application on March 28, 2008. (ALJ Finding 33.)

34. BMA filed a Motion to Intervene on April 17, 2008. BMA's Motion was granted on May 1, 2008. (ALJ Finding 34.)

The Isolation Room Issue Has No Impact on the Outcome of this Case

35. Both the TRC application and the BMA application proposed to include isolation station capabilities in their proposed new facilities. (*See, e.g.*, Joint Ex. 1 at 58; Joint Ex. 2 at 65.) Both the TRC Application and the BMA Application made identical proposals regarding isolation station capabilities. (ALJ Finding 35.)

36. The CON Section treated TRC and BMA exactly the same with regard to their proposals for isolation stations. (Tr. at 510:24-511:2.) (ALJ Finding 36.)

37. The CON Section determined that neither TRC nor BMA identified a need under statutory review Criterion 3 for isolation capabilities, since they did not identify any infectious dialysis patients or project an increase in infectious patients. (Joint Ex. 3 at 639, 646.) (ALJ Finding 37.)

38. At the time the CON Section published its decision in this case, March 5, 2008, neither state nor federal regulations required any dialysis facility to have isolation capabilities. (Tr. at 134:23-135:5.) (ALJ Finding 38.)

39. On April 15, 2008, after the CON Section issued the Agency Findings, it was announced that as of February 9, 2009, new dialysis facilities would be required by the Centers for Medicare and Medicaid Services ("CMS"), as a condition of participation, to include isolation capabilities. (Tr. at 136:1-25; Medicare and Medicaid Programs, 73 Fed. Reg. 20476 (Apr. 15, 2008).) CMS also provided a means by which a provider could seek a waiver from this requirement. (73 Fed. Reg. 20460-61.) (ALJ Finding 39.)

40. At the time the CON Section issued its decision in this case, there was no way for the CON Section to know that the CMS regulations would be revised such that isolation capabilities were to be required in new dialysis facilities as of February 9, 2009. (ALJ Finding 40.)

41. Subsequent to the April 15, 2008 CMS announcement, the CON Section adopted a policy that an applicant was not required to identify a specific need for isolation capabilities before an isolation station would be approved. (Tr. at 617:21-618:4.) (ALJ Finding 41.)

42. While the inclusion of an isolation room in a dialysis facility may be best practice, the law at the time the applications were submitted and at the time the CON Section issued its decision did not mandate the inclusion of an isolation room in a new dialysis facility. (Tr. at 134:23-135:5.) Indeed, the CON Section's interpretation of the CON law at the time the applications were submitted required an applicant to show need for isolation capabilities. (Joint Ex. 3 at 639, 646.)

43. Nevertheless, the isolation room issue has no material impact or bearing on the outcome of this case. (ALJ Finding 43.)

The CON Section Properly Convened and Considered the Public Hearing in Accordance with its Statutory Duties.

44. Under N.C. Gen. Stat. § 131E-185(a1)(2), the CON Section is required to ensure that a public hearing is conducted with the appropriate service area if the review to be conducted is competitive. (ALJ Finding 44.)

45. Because the review in this case was competitive, the CON Section held a public hearing in Brunswick County on November 19, 2007. (Joint Ex. 3 at 451.) (ALJ Finding 45.)

The CON Section Did not Err by Failing to Listen to the Recorded Testimony or Read the Transcript of the Public Hearing.

46. In conducting the public hearing, the CON Section must comply with the following requirements:

- (1) Within fifteen (15) days from the beginning of the review of the applications, give notice of the time and place of the public hearing;
- (2) Conduct the hearing in the service area at issue;
- (3) Allow a Department representative to conduct the hearing;
- (4) Allow the proponent of an application to respond to any written comments about the application;
- (5) Allow any person to comment on the applications under review; and
- (6) Maintain a recording of the public hearing and all written submissions received at the public hearing.

N.C. Gen. Stat. § 131E-185. (ALJ Finding 46.)

47. The CON Section gave notice of the time and place of the public hearing in this case. (Joint Ex. 3 at 5, 451.) (ALJ Finding 47.)

48. The CON Section conducted the public hearing in Brunswick County, the service area at issue. (Id. at 451.) (ALJ Finding 48.)

49. A Department representative, CON Section senior project analyst Ron Loftin, conducted the public hearing. (Tr. at 493:6-7.) (ALJ Finding 49.)

50. The CON Section allowed the proponents of each application to respond to any written comments about their respective applications. (See TRC Ex. 28.) (ALJ Finding 50.)

51. The CON Section allowed any person who wished to comment on the applications under review to make such comments. (*Id.*; see also Tr. at 493:19-494:2; Joint Ex. 3 at 453-54.) (ALJ Finding 51.)

52. Ms. Rupp was unable to attend the public hearing in this case because her mother had passed away, a result of which Ms. Rupp had to travel out of state. (Tr. at 151:3-152:5.) Mr. Loftin thus appeared for Ms. Rupp at the public hearing in her absence. (Tr. at 493:6-7.)

53. The CON Section maintained a recording of the public hearing and all written submissions received at the public hearing. (Tr. at 494:24-495:1.)

54. Although it may be best practice, there is no statutory, regulatory, or other requirement that the recording of a public hearing be reviewed by the project analyst performing the review of a CON application, or that that particular project analyst attend the public hearing.

55. The CON Section gave due regard to the events of the public hearing in this case. Ms. Rupp spoke with Mr. Loftin about the public hearing, reviewed the public hearing sign-in sheet, and read all 386 pages of public comments that were submitted. (Tr. at 147:21-24; 149:17-150:5; 493:8-494:23; Joint Ex. 3 at 34-450.) Ms. Rupp took all of these materials into consideration when she made her decision on the TRC and BMA applications. (Tr. at 494:9-23.)

56. In light of Ms. Rupp's discussion with Mr. Loftin about the public hearing, review of the public hearing sign-in sheet, and review and consideration of all 386 pages of written comments that were submitted at the public hearing, Ms. Rupp's failure to listen to the recording of the public hearing prior to making a determination that BMA was the superior applicant in this case was not error.

Any Error that Resulted from the CON Section's Failure to Listen to the Recording of the Public Hearing or Read the Transcript of the Public Hearing Prior to the CON Section's Decision is Harmless Error.

57. When the CON Section acts contrary to CON law, the error is harmless if there is evidence to support the CON Section's determination and that the same result would have been reached if the CON Section had acted in accordance with CON law. *Britthaven*, 118 N.C. App. at 386, 455 S.E.2d at 461. (ALJ Finding 54.)

58. Ms. Rupp gave her opinion that BMA had the comparatively superior application did not change after she read the transcript of the public hearing. (Tr. at 495:12-18.) (ALJ Finding 55.)

59. Mr. Smith testified that despite the fact that Ms. Rupp did not listen to the recording of the public hearing or attend the public hearing and after hearing all the evidence introduced in this contested case, he still believes that BMA had the comparatively superior application. (Tr. at 611:24-612:3.) (ALJ Finding 56.)

60. Because the CON Section would have reached the same result and determined that BMA's application conformed to all statutory and regulatory criteria and was comparatively superior to the TRC application, even if Ms. Rupp had attended the public hearing or reviewed the recording of the public hearing, any error committed by the CON Section in this regard is harmless. (Britthaven, 118 N.C. App. at 386, 455 S.E.2d at 461.)

61. Moreover, because there would not have been a different result had Ms. Rupp attended or reviewed the recording of the public hearing, TRC has not proven it has been "substantially prejudiced" by the alleged error, as is required by N.C. Gen. Stat. § 150B-23(a).

The CON Section Properly Found That BMA's Application Conditionally Conformed to Criterion 3

62. Criterion 3 is the only statutory review criteria at issue with regard to BMA's application in this case. (ALJ Finding 59.)

63. Criterion 3 requires that an applicant identify the population to be served by the proposed project and that the applicant demonstrates the need that this population has for the services proposed. N.C. Gen. Stat. § 131E-183(a)(3). (ALJ Finding 60.)

64. Therefore, Criterion 3 requires an applicant to set forth its need methodology for determining patient origin. (ALJ Finding 61.)

65. There is no specific methodology that must be used in determining patient origin under CON law. Retirement Villages, Inc. v. N.C. Dep't of Human Resources, 124 N.C. App 495, 500, 477 S.E.2d 697, 700 (1996). Rather, what is required is that all assumptions, including the methodology, must be stated. 10A N.C. Admin. Code 14C.2202(b)(6), .2203(c). (ALJ Finding 62.)

66. The CON Section reviews need methodology for "analytical, procedural, and mathematical correctness" in order to determine whether an application is conforming to the statutory and regulatory criteria. Britthaven, 118 N.C. App. at 388, 455 S.E.2d at 462. (ALJ Finding 63.)

67. The CON Section's determinations of whether an application conforms to statutory or regulatory criteria will be upheld if they are "reasonable." Good Hope, ___ N.C. App. at ___, 659 S.E.2d at 471-472. Further, when the CON Section makes a determination that is consistent with earlier rulings regarding similar issues, the CON Section has acted "reasonably." Good Hope, ___ N.C. App. at ___, 659 S.E.2d at 471. (ALJ Finding 64.)

68. Projections attempt to predict something that will occur in the future; therefore,

the very nature of a projection cannot be established with absolute certainty. Craven, 176 N.C. App. at 52-53, 625 S.E.2d 837, 841. Projections of a patient census made in a CON application thus conform to Criterion 3 as long as the projections are "reasonable." (ALJ Finding 65.)

69. The CON Section's determination that BMA's application conformed to Criterion 3 by identifying the population to be served by its proposed project and demonstrating the need that the population had for the proposed services, with the condition that BMA not develop an isolation station, was reasonable.

BMA's Assumption that Brunswick County Residents would Dialyze in Brunswick County is Reasonable

70. The foundational assumption in BMA's need methodology under Criterion 3 is that dialysis patients residing in Brunswick County will want to dialyze at a facility within Brunswick County. BMA set forth three factors as support for its position for the reasonableness of this assumption. (Joint Ex. 1 at page 20). (ALJ Finding 67.)

71. First, the July 2007 SDR identified a need for thirteen (13) additional dialysis stations for the residents of Brunswick County, and not the surrounding counties. (See July 2007 SDR; TRC Ex. 16; Joint Ex. 3 at 634.) (ALJ Finding 68.)

72. Second, the traffic to and through Wilmington is very congested, such that a New Hanover dialysis facility is unattractive to dialysis patients since they need treatments at least three (3) times per week. (Tr. at 79:5-10; TRC Ex. 28 at 15-16, 18; Joint Ex. 3 at 357.) (ALJ Finding 69.)

73. Third, the available public transportation within Brunswick County only transports patients within the county and will not take patients across county lines. (Tr. at 62:16-18.) The undersigned takes notice that the record is devoid of testimony or other evidence as to what percentage of those patients residing in Brunswick County and receiving dialysis in another County would use public transportation in order to receive treatment in Brunswick County. (ALJ Finding 70.)

74. BMA also presented evidence that TRC's own affiliated physicians testified that they would refer patients to BMA's Supply facility in Brunswick County. (BMA Exhibits 2 and 3). The record is devoid of evidence as to how many patients these two physicians estimate or project they may be able to refer to the Supply facility. (ALJ Finding 71.)

75. It was reasonable for the CON Section to determine that BMA's assumption that dialysis patients residing in Brunswick County will want to dialyze at a facility within Brunswick County was reasonable.

76. BMA projected that its new facility would serve any patients residing in Brunswick County who were not already receiving or projected to receive dialysis services from another facility located in Brunswick County. (Joint Ex. 1 at 20-25.) There is evidence in the record that BMA did not propose to serve a specified set of individual patients that have already

indicated their intent, on the record, to transfer to another facility in a specific location. (Tr. at 453:20-454:13.)

77. While BMA did not specifically project that the thirteen (13) patients who were dialyzing at TRC's Wilmington facility in New Hanover would actually transfer to BMA's new facility in Supply, it was reasonable to project that any patients residing in Brunswick County who were not already receiving or projected to receive dialysis services from another facility located in Brunswick County would transfer to the new BMA facility in Supply. (Tr. at 456:18-457:13.) For any patients living in the Leland area that dialyzed at TRC's Wilmington facility, the Supply facility would pose less travel time due to significant traffic into and out of Wilmington. (Joint Ex. 3 at 357.) In addition, these patients would have the option of public transportation to BMA's Supply facility, whereas the Brunswick County public transportation system will not cross county lines into Wilmington. (Tr. at 62:16-18.)

78. The undersigned also finds that patients residing in a particular service area may choose to change providers upon the opening of a new facility in their service area has been previously recognized as valid and reasonable by the Agency in a Final Agency Decision issued in 2004 in the TRC St. Pauls contested CON case. This fact was specifically referenced on Page 24 of BMA's application to further support the reasonableness of its patient projections under Criterion 3. (Joint Ex. 1 at 24, citing to Finding of Fact #72 in Final Agency Decision for TRC St. Pauls.) Further, the undersigned finds that TRC has previously acknowledged the possibility that patients will transfer to a new provider entering an area where only other providers offer dialysis services. In an application filed by TRC on September 15, 2008, in which TRC proposed to develop a new ten (10) station dialysis facility in Davie County, TRC projected that out of thirty-nine (39) Davie County patient-residents currently dialyzing out of county at one of four different facilities operated by providers other than TRC, thirty-five (35), or approximately ninety percent (90%) would transfer to TRC's new facility. (BMA Ex. 8, Tr. at 364:11-365:10.) (ALJ Finding 74.)

79. The undersigned also finds that the proposal set forth by BMA and discussed in the Anson County Dialysis Review findings from March 2007 (the "Anson County findings") are substantively and materially different than BMA's proposal in this case. In the Anson County findings, fourteen (14) patients living in Anson County were currently dialyzing at a TRC facility in Monroe, Union County. (TRC Ex. 11 at 6; Tr. at 643:13-644:13.) In an application filed approximately one (1) year prior to the date of the Anson County findings, TRC specifically identified these fourteen (14) patients as having expressed a desire to transfer to a proposed facility in Marshville, Union County. (TRC Ex. 11 at 6; Tr. at 644:18-24.) When BMA filed an application to develop a new facility in Anson County, TRC claimed that BMA's need methodology improperly attempted to usurp those fourteen (14) patients that had already expressed an intention to transfer to the proposed Marshville, Union County facility. (TRC Ex. 11 at 5-6; Tr. at 572:6-13; 645:3-15.) The undersigned finds the facts of the CON cases set forth in paragraphs 78 and 79 herein to be distinguishable from this case, and while considered by the undersigned, are not determinative of the ultimate decision reached in this case. (ALJ Finding 75.)

80. In this case, BMA has not proposed to serve a specified set of individual patients that have already indicated their intent, on the record, to transfer to another facility in a specific location. Rather, BMA solely projected to serve patients residing in Brunswick County who were not already receiving or projected to receive dialysis services from another facility located in Brunswick County at some point in the future. While this may include Brunswick County residents who were previously choosing to dialyze in another county or even another state, BMA's projections do not specifically single out any individual patients, and certainly do not single out any patients who have already expressed an intent to transfer to another facility.

81. Projections, by their very nature, cannot be established with absolute certainty. See Craven, 176 N.C. App. at 53, 625 S.E.2d at 837. Therefore, projections need only be "reasonable" to conform to Criterion 3. It was reasonable for BMA to project to serve thirteen (13) Brunswick County patient-residents who are not currently receiving dialysis services in Brunswick County because these thirteen (13) patients could then dialyze in their home county. In addition, in contrast to the Anson County findings, these thirteen (13) patients have not identified a different site at which they intend to dialyze once BMA's Supply facility is operating.

82. It was reasonable for the CON Section to find BMA's application conditionally conforming to Criterion 3 when the BMA application assumed that Brunswick County dialysis patients would choose to dialyze in Brunswick County.

83. 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. (Tr. at 646:9-15.) 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. (Tr. at 648:25-649:9.) 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. (Tr. at 646:9-15.) (ALJ Finding 77.)

BMA's use of the Five Year Annual Change Rate was Reasonable

84. BMA projected the dialysis patient population of Brunswick County by using the Five Year Annual Change Rate published within the July 2007 SDR. 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. (Tr. at 455:14-21.) (ALJ Finding 80.)

85. Even though there was a decrease in the Brunswick County patient population during the six (6) month period between December 2006 and July 2007, it was reasonable to use the Five Year Annual Change Rate because it was based on a greater sample of patients over a longer period of time. (ALJ Finding 81.)

86. The North Carolina Court of Appeals has recognized, in an unpublished opinion, that it is reasonable to rely on the data that formed the basis of the SDR that originally identified the relevant need. Bio-Medical Applications of N.C., Inc. v. N.C. Dep't of Health and Human

Servs., 177 N.C. App. 286, 628 S.E.2d 258, 2006 WL 997667 at *3-4 (2006) (unpublished opinion). (ALJ Finding 82.)

87. The Court further recognized that a six-month fluctuation in patient population is not reliable enough to indicate an actual overall change in patient population. Id. at *4. Instead, “years’ worth of data” is required to get a fair and accurate reading of patient population growth. Id. (ALJ Finding 83.)

88. Therefore, even though some data indicated a decrease in the Brunswick County patient population between December 2006 and July 2007, it was reasonable for the CON Section to find the BMA application conditionally conforming to Criterion 3 when the BMA Application relied on the Five Year Annual Change Rate as published by the July 2007 SDR. (ALJ Finding 84.)

The CON Section Properly Determined that BMA’s Application Conformed to the Performance Standard Rule.

89. The Performance Standard Rule, 10A N.C. Admin. Code 14C.2203, is the only regulatory review criteria at issue with regard to BMA’s application in this case. The Performance Standard Rule requires that an applicant proposing to establish a new dialysis treatment facility document the need for at least ten (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). An applicant must also provide all assumptions, including the methodology, by which patient utilization is projected. Id. at (b). (ALJ Finding 86.)

90. The BMA application clearly set forth all of its assumptions. (Joint Ex. 1 at 20-21.) (ALJ Finding 87.)

91. As set forth supra, the CON Section reasonably found that the BMA application demonstrated the need the population had for the proposed services.

92. To calculate utilization under the Performance Standard Rule, the total number of patients is divided by the total number of stations. (See Joint Ex. 3 at 638.)

93. The BMA application projected that it would serve 32.6 in-center patients by the end of the first operating year. (Joint Ex. 1 at 23.)

94. The BMA application proposed to develop ten (10) dialysis stations.

95. The division of 32.6 in-center patients by ten (10) dialysis stations equals a utilization rate of 3.26.

96. By proposing a utilization rate of 3.26, the BMA application conformed to the Performance Standard Rule.

The CON Section Correctly Determined that the TRC Application was Not Approvable

97. An applicant may not obtain a CON unless the CON Section determines that the application is conforming, or conditionally conforming, to all statutory and regulatory criteria. N.C. Gen. Stat. § 131E-187; Dialysis Care of North Carolina, LLC v. N.C. Department of Health and Human Servs., 137 N.C. App. 638, 649, 529 S.E.2d 257, 263 (2000). (ALJ Finding 89.)

98. Because the TRC application did not conform to all statutory and regulatory criteria, the CON Section properly disapproved the TRC application. (ALJ Finding 90.)

The TRC Application did not Conform to Criterion 3

99. Criterion 3 requires, *inter alia*, that an applicant identify the population to be served by the proposed project and demonstrate the need that this population has for the services proposed.

100. An application for a CON cannot be conditioned upon the showing of need for a proposed project. Need must be adequately accounted for on the face of an application.

101. TRC projected January 1, 2009 as the proposed Leland facility's start date. (Joint Ex. 2 at 30.)

102. TRC projected that 29 of its in-center patients would transfer to its proposed Leland facility from various facilities in the surrounding area. (*Id.* at 29.) Specifically, TRC identified two (2) patients dialyzing at its Elizabethtown facility, one (1) patient dialyzing at its Shallotte facility, nine (9) patients dialyzing at its Whiteville facility, and seventeen (17) patients dialyzing at its Wilmington facility. (*Id.*) TRC stated that it projected those patients would transfer to the proposed Leland facility because the facility would be closer to their homes and they could continue to see their current nephrologists. (*Id.*)

103. TRC also projected an annual growth rate for Brunswick County of five percent (5%). (*Id.* at 30.) It based its projection 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. (*Id.* at 29-30.)

104. TRC applied the annual growth rate of five percent (5%) to the 29 patients it had previously identified as those that would transfer to its proposed Leland facility. However, it began "growing" the population of 29 patients in the year 2007. (*Id.* at 30.) Therefore, the projected number of patients that TRC projected would be dialyzing at the proposed Leland facility on the January 1, 2009 start date was 31. (*Id.*)

105. TRC did not account from where the additional two (2) patients came. TRC had specifically identified 29 patients that would transfer to the new facility. (*Id.* at 29.) However, TRC began its population at opening with 31 patients, such that with the application of the five

percent (5%) annual growth rate, the projected number of patients that would be dialyzing at the proposed Leland facility at the end of the first operating year was 33. (*Id.* at 30.)

106. It was improper for TRC to project that its proposed Leland facility would open with 31 patients when TRC had only identified 29 patients that would transfer to the new Leland facility.

107. TRC only provided evidence of 29 patients that would transfer, and therefore it should have started the proposed Leland facility's census at 29.

108. Moreover, TRC sought to retroactively grow the population of 29 patients. The TRC application was filed on September 17, 2007 and the application referred to these 29 patients as currently dialyzing with TRC outside of Brunswick County. The TRC application did not provide any evidence that the 29 patients were in existence on January 1, 2007.

109. Nevertheless, TRC began growing that population of 29 by applying the five percent (5%) growth rate as of January 1, 2007.

110. TRC's attempt to reach back in time to grow its population of 29 patients before the application was even filed is improper.

111. Although the TRC application claimed that its proposed population had a beginning census of 29 patients, in actuality the application projected that the proposed facility would open with 31.9 patients.

112. TRC's methodology and projections are inaccurate and untrustworthy.

113. TRC did not adequately identify the population it sought to serve or demonstrate that population's need for the proposed services.

114. TRC did not adequately state assumptions in support of its projections.

115. TRC's projections were unreasonable and unsupported by the evidence.

116. The TRC application was nonconforming to Criterion 3.

The TRC Application did not Conform to Criterion 14

117. Criterion 14 requires that an applicant demonstrate that its proposal accommodates the clinical needs of health professional training programs in the area. N.C. Gen. Stat. § 131E-183(a)(14). (ALJ Finding 91.)

118. Although the TRC application included a letter of support from Brunswick Community College, the TRC application did not demonstrate that its proposed Leland facility would be available as a health care training site. (Joint Ex. 2 at 219; Joint Ex. 3 at 678.) The fact that TRC's existing Shallotte dialysis facility is available as a clinical rotation site for Brunswick

Community College is not sufficient evidence to establish that TRC would also make its brand new, modern facility in Leland available to students. (ALJ Finding 92.)

119. The burden of establishing that an application meets all CON criteria is placed on the applicant. Good Hope, ___ N.C. App. at ___, 659 S.E.2d at 466. It would be inappropriate to place this burden on the administrative agency and require that the CON Section go out and seek information to make the application conforming for the applicant. (ALJ Finding 93.)

120. The CON Section correctly determined that the TRC application was nonconforming to Criterion 14. (ALJ Finding 94.)

The TRC Application did not Conform to 10A NC Admin. Code 14C.2202(b)(2)

121. The regulatory criterion found at 10A N.C. Admin. Code 14C.2202(b)(2) mandates that an applicant provide a written agreement or a letter of intent to sign a written agreement with a kidney transplantation center describing the relationship and the specific services provided by the transplantation center. The TRC application did not include either a written agreement or a letter of intent to sign a written agreement with a kidney transplantation center. (Joint Ex. 3 at 666.) The fact that TRC's existing Shallotte dialysis facility has a written agreement with a kidney transplantation center is not sufficient evidence to establish that the same transplantation center would enter into an agreement with a new facility in Leland. (ALJ Finding 95.)

122. The CON Section correctly determined that the TRC application did not conform to 10A N.C. Admin. Code 14C.2202(b)(2). (ALJ Finding 96.)

The TRC Application Contained Errors Which are Inconsequential in the Undersigned's Decision

123. Regulatory review criterion 10A N.C. Admin. Code 14C.2202(b)(7) requires that an applicant for a new dialysis facility establish that at least eighty percent (80%) of the anticipated patient population resides within thirty (30) miles of the proposed facility. In the TRC application, TRC represented that no patients from its anticipated patient population would travel more than thirty (30) miles one way either to or from Leland for their treatments. (Joint Ex. 2 at 31.) However, TRC projected that four (4) of its patients live in Riegelwood and Chadbourn. (Joint Ex. 2 at 29.) It is a round trip of almost ninety (90) miles between Chadbourn and Leland. (Joint Ex. 3 at 305.) Therefore, TRC's statement that none of the patients from its anticipated patient population would travel more than thirty (30) miles one way for a treatment is false. (Tr. at 656:5-15.) However, the undersigned gives little weight to the errors as set forth in this paragraph and are inconsequential with respect to the undersigned's Recommended decision in this case. (ALJ Finding 97.)

The CON Section Correctly Determined that the BMA Application was Comparatively Superior to the TRC Application

124. In a competitive review, the Agency may conduct a comparison of the

applications, but no particular points of comparison must be used. Craven, 176 N.C. App. at 58, 625 S.E.2d at 845. A comparison can provide the CON Section with the ability to make “additional findings and conclusions [that] give the [CON Section] the opportunity to explain why it finds one applicant preferable to another on a comparative basis.” Id. at 58, 625 S.E.2d at 845 (quoting Britthaven, 118 N.C. App. at 385, 455 S.E.2d at 459.) The comparative factors are considered equal in value and are not weighted. (ALJ Finding 99.)

125. In this review, the CON Section compared the BMA application and the TRC application on the following factors: SMFP Principles, facility location, service to Brunswick County patients; access to alternative providers; access by underserved groups, access to support services; operating costs; revenue; charges to insurers; and direct care staff salaries. (Joint Ex. 3 at 672-78.) (ALJ Finding 100.)

126. With regard to the CON Section’s selection of these particular factors, [t]he correctness, adequacy, or appropriateness of criteria, plans, and standards shall not be an issue in a contested case hearing.” 10A N.C. Admin. Code 14C.0402. (ALJ Finding 101.)

The CON Section Correctly Determined that BMA and TRC were Equally Effective with Regard to SMFP Principles and Direct Care Staff Salaries

127. The CON Section determined that the BMA application and the TRC application were equally effective alternatives with regard to SMFP principles and Direct Care Staff Salaries. (Joint Ex. 3 at 673, 678.) Neither party takes issue with this determination. Based on the evidence of record, the CON Section correctly determined that the BMA application and the TRC application were equally effective alternatives with regard to SMFP principles and direct care staff salaries. (ALJ Finding 102.)

The CON Section Correctly Determined that TRC was the Comparatively Superior Applicant with Regard to Charges to Insurers

128. The CON Section determined that the TRC application was comparatively superior to BMA’s application with regard to charges to insurers. (Joint Ex. 3 at 677-78.) Neither party takes issue with this determination. Based on the evidence of record, the CON Section correctly determined that the TRC application was comparatively superior with regard to charges to insurers. (ALJ Finding 103.)

The CON Section Correctly Determined that TRC was the Comparatively Superior Applicant with Regard to Service to Brunswick County Patients

129. The CON Section determined that the TRC application was comparatively superior to BMA's application with regard to service to Brunswick County patients. (Joint Ex. 3 at 675.) Neither party takes issue with this determination. Based on the evidence of record, the CON Section correctly determined that the TRC application was comparatively superior with regard to service to Brunswick County patients. (ALJ Finding 104.)

The CON Section Correctly Determined that BMA was the Comparatively Superior Applicant with Regard to Operating Costs

130. The CON Section determined that the BMA application was comparatively superior to TRC's application with regard to operating costs. (Joint Ex. 3 at 677.) Neither party takes issue with this determination. Based on the evidence of record, the CON Section correctly determined that the BMA application was comparatively superior with regard to operating costs. (ALJ Finding 105.)

The CON Section Correctly Determined that BMA was the Comparatively Superior Applicant with Regard to Revenue

131. Based on the evidence of record, the CON Section correctly determined that the BMA application was comparatively superior with regard to revenue. (ALJ Finding 106.)

The CON Section Correctly Determined that BMA was the Comparatively Superior Applicant with Regard to Access to Alternative Providers

132. The CON Section determined that the BMA application was comparatively superior to TRC's application with regard to access to alternative providers. (Joint Ex. 3 at 675.) Neither party takes issue with this determination. Based on the evidence of record, the CON Section correctly determined that the BMA application was comparatively superior with regard to access to alternative providers. (ALJ Finding 107.)

The CON Section Correctly Determined that BMA was the Comparatively Superior Applicant with Regard to Access by Underserved Groups

133. When determining whether and to what degree an applicant is superior with regard to access by underserved groups, the CON Section looks at the percentage of Medicare and Medicaid patients that the applicant proposes to serve. Tr. at 504:25-505:6. The CON Section determined that the BMA application was comparatively superior to TRC's application with regard to access to underserved groups. (Joint Ex. 3 at 676.) The CON Section based its determination on the fact that BMA projected serving a higher percentage of Medicare and Medicaid patients (95.17%) than TRC (90.0%). (Joint Ex. 3 at 675.) BMA based its projections in part on its historical experience in small rural counties, and in part on its experiences at its Loris, South Carolina facility. (Joint Ex. 1 at 34; Tr. at 433:2-15, 533:7-11.) The basis for BMA's projections was reasonable. Conversely, the TRC Application provided no explanation

as to the source of its data or projections regarding payor mix (Joint Ex. 2 at 39-40.) Nor did TRC make any efforts to change, distinguish or adjust the payment projections in Section VI of the Applications for TRC-Shalotte, TRC-Southport and TRC-Leland. (Cf. Joint Ex. 2 at 39 with BMA Ex. 6.) Based on the evidence of record, the CON Section correctly determined that the BMA application was comparatively superior with regard to access by underserved groups. (ALJ Finding 108.)

The CON Section Correctly Determined that BMA and TRC were Comparatively Equal with Regard to Facility Location

134. The CON Section determined that the BMA application and the TRC application were comparatively equal with regard to facility location and improving geographic access to dialysis services in Brunswick County. (Joint Ex. 3 at 673-74.) TRC proposed to place its facility in Leland, Brunswick County, so that each of the three points of the triangular-shaped Brunswick County would have a dialysis facility. (Joint Ex. 3 at 674; Tr. at 310:15-19, 368:9-12.) Leland is near the intersection of U.S. 17 and U.S. 74/76. (Joint Ex. 3 at 674.) (ALJ Finding 109.)

135. BMA proposed to place its facility in Supply, Brunswick County, at the intersection of U.S. 17 and N.C. 211. (Joint Ex. 1 at 18, Joint Ex. 3 at 674.) Supply is essentially at the geographic center of Brunswick County. (Joint Ex. 1 at 18.) Brunswick County Commissioner David Sandifer has indicated that Supply is one of the fastest growing areas of Brunswick County. (*Id.*) BMA and TRC each proposed sites that were most effective for them. (Joint Ex. 3 at 675.) (ALJ Finding 110.)

136. Data from the Southeastern Kidney Council as of December 31, 2006, the same set of data upon which the July 2007 SDR was based, shows that seventeen (17) in-center dialysis patients reside within the zip code associated with Supply and Holden Beach. (Joint Ex. 3 at 674.) The same data shows that fifteen (15) in-center dialysis patients reside within the zip code associated with Belville, Leland and Navassa. TRC's proposed location in Leland would allow TRC to serve its patients in the northern point of the "triangle" that makes up Brunswick County, as well as patients residing in Columbus County. (*Id.* at 675.) BMA's proposed location in Supply would allow BMA to serve the local cluster of patients in Supply as well as patients from all over Brunswick County, due to its central location. (*Id.*) Based on the evidence of record, the CON Section correctly determined that BMA and TRC were comparatively equal with regard to facility location and improving geographic access to dialysis services in Brunswick County. (ALJ Finding 111.)

The CON Section Correctly Determined that BMA and TRC were Comparatively Equal with Regard to Access to Support Services

137. The TRC application proposed to receive diagnostic and evaluation, x-ray, blood bank, emergency care, vascular surgery and acute care support services from New Hanover Regional Medical Center. (Joint Ex. 2 at 34; Joint Ex. 3 at 676.) The TRC application also proposed to receive laboratory support services from Dialysis Laboratories. (Joint Ex. 2 at 34; Joint Ex. 3 at 676.) The BMA application proposed to receive diagnostic and evaluation, x-ray,

blood bank and emergency care support services from Brunswick Community Hospital in Supply and Loris Community Hospital in Loris, South Carolina. (Joint Ex. 1 at 27; Joint Ex. 3 at 676.) The BMA application also explained that with regard to emergency care, all BMA staff members are trained to respond to an emergency, a fully stocked crash cart will be available at the proposed facility, and there will be ambulance service to both Brunswick Community Hospital and Loris Community Hospital. (Joint Ex. 1 at 27.) The BMA application proposed to receive vascular surgery and acute care support services from Loris Community Hospital. (*Id.*; Joint Ex. 3 at 676.) Finally, the BMA application proposed to receive laboratory services from SPECTRA. (Joint Ex. 1 at 27; Joint Ex. 3 at 676.) Based on the evidence of record, the CON Section correctly determined that BMA and TRC were comparatively equal with regard to access to support services. (ALJ Finding 112.)

The BMA Application was Comparatively Superior to the TRC Application on More Factors

138. The CON Section correctly found the BMA application comparatively superior to the TRC application on four factors, whereas the CON Section found the TRC application comparatively superior to the BMA application on only two factors. (Joint Ex. 3 at 672-78.) (ALJ Finding 113.)

139. Furthermore, the TRC application was nonconforming to Criteria 3, 14, and 10A N.C. Admin. Code 14C.2202(b)(2), and also contained errors. (*See supra.*) (ALJ Finding 114.)

140. Therefore, the CON Section correctly found the BMA application comparatively superior overall to the TRC application. (ALJ Finding 115.)

The CON Section Properly Conditioned the BMA application instead of the TRC application

141. BMA's application was found conditionally conforming to Criterion 3 and 10A N.C. Admin. Code 14C.2202(b)(2). (Joint Ex. 3 at 639, 666.) BMA was conditioned with regard to Criterion 3 because BMA had proposed an isolation station but had not established a need for an isolation station. (Joint Ex. 3 at 639.) BMA was conditioned with regard to 10A N.C. Admin. Code 14C.2202(b)(2) because the BMA application failed to include a letter of intent to sign or a signed transplant agreement with a kidney transplantation center describing the relationship and the specific services provided by the transplantation center. (Joint Ex. 3 at 666.) The TRC application was found nonconforming to Criterion 3 for the same reasons that BMA's application was found conditionally conforming to Criterion 3. (Joint Ex. 3 at 646.) The TRC application was found nonconforming to 10A N.C. Admin. Code 14C.2202(b)(2) for the same reasons that BMA's application was found conditionally conforming to 10A N.C. Admin. Code 14C.2202(b)(2). (Joint Ex. 3 at 666.) The CON Section properly conditioned BMA's application instead of TRC's application because the BMA application was comparatively superior to the TRC application. 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. (Tr. at 507:5-10.) (ALJ Finding 116.)

CONCLUSIONS OF LAW

After examining the official record of this contested case, including the Recommended Decision, and after considering the exceptions to the Recommended Decision and the arguments of the parties, I adopt certain of the Conclusions of Law made by the ALJ. The Conclusions of Law that I have adopted from the ALJ's Recommended Decision are indicated below as "(ALJ Conclusion ____)." I also adopt certain new Conclusions of Law as set forth below.

Based on the foregoing Findings of Fact, the undersigned Administrative Law Judge enters the following Conclusions of Law:

1. To the extent that certain portions of the foregoing Findings of Fact constitute mixed issues of law and fact, such findings of fact shall be deemed incorporated herein by reference as Conclusions of Law. (ALJ Conclusion 1.)

2. BMA is an affected person and has an interest in this contested case, and is thereby entitled to intervene in this contested case hearing by authority of N.C. Gen. Stat. § 131E-188(c), N.C. Gen. Stat. § 150B-23(d) and N.C. Gen. Stat. § 1A-1, Rule 24(a). (ALJ Conclusion 2.)

3. TRC is an affected person entitled to this contested case hearing by authority of N.C. Gen. Stat. § 131E-188(a) and (c). (ALJ Conclusion 3.)

4. The failure of the project analyst and/or supervisor assigned to a review to attend or review the recording of the public hearing for that review prior to rendering a decision was harmless error.

5. The CON Section correctly determined that the BMA application conformed or conditionally conformed to all statutory and regulatory criteria.

6. The CON Section correctly determined that the TRC application was nonconforming with Criteria 3, 4, 6, 12, 14, 18a and 10 N.C. Admin. Code 14C.2202(b)(2). (ALJ Conclusion 6.)

7. The CON Section correctly determined that the BMA application was comparatively superior to the TRC application.

8. The CON Section correctly approved the BMA application.

9. The CON Section correctly disapproved the TRC application. (ALJ Conclusion 9.)

10. BMA is entitled to a certificate of need for a new ten (10) station dialysis facility in Supply, Brunswick County.

11. TRC is not entitled to a certificate of need for a new ten (10) station dialysis

facility in Leland, Brunswick County. (ALJ Conclusion 11.)

REASONS FOR DECLINING TO ADOPT THE RECOMMENDED DECISION IN FULL


After examination of the official record of this contested case, including the evidence produced during discovery and the Recommended Decision, and after considering the exceptions to the Recommended Decision, and the arguments of the parties, I decline to adopt certain of the ALJ Findings of Fact and Conclusions of Law in the ALJ's Recommended Decision. My designations of the specific ALJ Findings of Fact and Conclusions of Law in the ALJ's Recommended Decision that I am declining to adopt and my reasons for declining those ALJ Findings of Fact and Conclusions of Law are set forth in Appendix A which is attached hereto and incorporated herein by reference.

BASED UPON the foregoing Findings of Fact and Conclusions of Law, the Undersigned makes the following:

FINAL AGENCY DECISION

The decision of the CON Section issued on February 27, 2008 to award BMA a CON to develop a new ten (10) station dialysis facility in Supply, Brunswick County is **AFFIRMED**.

This the 10th day of March, 2009.



Jeff Horton
Acting Director
North Carolina Department of Health and Human Services
Division of Health Service Regulation

APPENDIX A

REASONS FOR DECLINING TO ADOPT SELECTED ALJ FINDINGS OF FACT AND CONCLUSIONS OF LAW

After examination of the official record of this contested case, including the evidence presented at the hearing and the Recommended Decision, and after considering the exceptions to the Recommended Decision, and the written and oral arguments of the parties, I decline to adopt certain of the Findings of Fact and Conclusions of Law included in the Administrative Law Judge's ("ALJ") Recommended Decision, as described below. My reasons for declining to adopt these Findings of Fact and Conclusions of Law are set forth in this Appendix A, which is attached to and incorporated by reference into the Final Agency Decision in this matter.

For purposes of clarity, the Findings of Fact included in the ALJ's Recommended Decision are referenced below as "ALJ Finding of Fact," and the Conclusions of Law included in the ALJ's Recommended Decision are referenced below as "ALJ Conclusions."

In additions to the ALJ Findings I have declined to adopt, I have also altered some of the headings as set forth in the Recommended Decision so as to more accurately reflect the Agency Findings and Conclusions.

ALJ FINDINGS NOT ADOPTED

1. ALJ Finding of Fact 52. I am not adopting ALJ Finding of Fact 52 because it is not supported by the record evidence. Specifically, the preponderance of the evidence shows that Ms. Rupp spoke with Mr. Loftin about the fact that some members of the public made comments at the public hearing. (Tr. at 149:17-150:5.) The preponderance of the evidence further shows that when she made her decision on the applications in this case, she did consider the public hearing materials, including the "written statements or written summaries of the comments made at the public hearing." (Tr. at 494:9-23.) The portions of the transcript to which the ALJ refers (pp.527-28) do not support the ALJ's finding that "Ms. Rupp did not review nor take into consideration any oral comments delivered at the public hearing prior to making her decision on these applications."

2. ALJ Finding of Fact 53. I am not adopting ALJ Finding of Fact 53 because it is not supported by the record evidence and erroneous as a matter of law. Specifically, neither the CON statutes nor regulations require that one of the decision makers either attend the public hearing, listen to the tape, or read the transcript of the public hearing. Such requirements simply do not appear in the law and are a creation of the ALJ. Further, the ALJ's statement that "[n]ot fully considering the evidence at the public hearing defeats the underlying purpose of the public hearing" does not apply in this case. The evidence of record establishes that Ms. Rupp did take into consideration certain public hearing materials including the written statements and summaries of comments made at the public hearing. (Tr. at 494:9-23.) Finally, the law is established that if the CON Section acts contrary to CON law, that error is harmless if there is evidence to support the CON Section's determination and the same result would have been reached if the CON Section had acted in accordance with CON law. (Britthaven, Inc. v. N.C. Dep't of Human Res., 118 N.C. App. 379, 386, 455 S.E.2d 455, 461 (1995).) Both Ms. Rupp

and Mr. Smith testified that, after reading the transcript of the public hearing, neither of them would have reached a different conclusion in their review of the applications of this case. (Tr. at 495:12-18; 611:24-612:3; see also ALJ Findings of Fact 55 and 56.) Therefore, any error was harmless and the ALJ erred in finding to the contrary.

3. ALJ Finding of Fact 57. I am not adopting ALJ Finding of Fact 57 because it is erroneous as a matter of law. As stated supra, it is settled law in this state that the CON Section's failure to act in accordance with CON law is harmless error if the CON Section's determination and result would have been the same if the CON Section had acted in accordance with CON law. Both Ms. Rupp and Mr. Smith testified that, after reading the transcript of the public hearing, neither of them would have reached a different conclusion in their review of the applications of this case. (Tr. at 495:12-18; 611:24-612:3; see also ALJ Findings of Fact 55 and 56.) There is no exception to this rule of law and therefore the ALJ's finding that the error in this case was not harmless is erroneous as a matter of law.

4. ALJ Finding of Fact 58. I am not adopting ALJ Finding of Fact 58 because it is not supported by the evidence of record. Specifically, there is no evidence in the record that had Ms. Rupp or Mr. Smith listened to the tape of the public hearing or read the transcript of the public hearing, they would have reached a different result concerning whether BMA met the requirements of Criterion 3 on the population to be served, including the patient origins. Further, there is no evidence in the record to bring Ms. Rupp's or Mr. Smith's testimony into question or to support any finding that it was "self serving" or "not credible." To the extent ALJ Finding of Fact 58 is more properly denominated a conclusion of law, it is not supported by the findings of fact. Specifically, there are no findings of fact supporting a conclusion that Ms. Rupp's or Mr. Smith's testimony was "self serving" or "not credible."

5. ALJ Finding of Fact 66. I am not adopting ALJ Finding of Fact 66 because it is not supported by the evidence of record. Specifically, the evidence of record establishes that BMA's application conformed to Criterion 3 by identifying the population to be served by its proposed project and demonstrating the need that the population had for the proposed services. The evidence of record showed that the July 2007 SDR identified a need for thirteen (13) new dialysis stations in Brunswick County and not the surrounding counties (See July 2007 SDR; TRC Ex. 16; Joint Ex. 3 at 634; ALJ Finding of Fact 68.) In addition, the evidence of record established that the traffic to and through Wilmington is very congested, such that a New Hanover dialysis facility is unattractive to dialysis patients since they need treatments at least three (3) times per week. (Tr. at 79:5-10; TRC Ex. 28 at 15-16; Joint Ex. 3 at 357; ALJ Finding of Fact 69.) The evidence of record further showed that the available public transportation within Brunswick County only transports patients within the county and will not take patients across county lines (Tr. at 62:16-18; ALJ Finding of Fact 70) and that TRC's own affiliated physicians testified that they would refer patients to BMA's Supply facility in Brunswick County (BMA Ex. 2 & 3; ALJ Finding of Fact 71.). Therefore, it was reasonable for the CON Section to determine that BMA's application conformed to Criterion 3 by identifying the population to be served (Brunswick County resident-patients not currently dialyzing in Brunswick County) and demonstrating the need that the population had for the proposed services, and the ALJ's finding to the contrary is unsupported by the evidence of record.

6. ALJ Finding of Fact 72. I am not adopting ALJ Finding of Fact 72 because it is not supported by the evidence of record. Specifically, the evidence of record established that it was reasonable for BMA to project that patients residing in Brunswick County but who were not already receiving or projected to receive dialysis services from another facility located in Brunswick County would transfer to the new BMA facility in Supply. The evidence showed that BMA's proposed Supply facility would require less travel time than TRC's facility in Wilmington, New Hanover County, due to the significant traffic going in and out of Wilmington. (Joint Ex. 3 at 357.) In addition, patients would have the option of public transportation to BMA's Supply facility, whereas the Brunswick County public transportation system would not cross county lines into Wilmington, New Hanover County. (Tr. at 62:16-18.) Finally, the Agency has previously recognized the possibility that patients residing in a particular service area may choose to change providers upon the opening of a new facility in their service area, and this evidence was before the CON Section when it made its decision as set out in BMA's application. (Joint Ex. 1 at 24, citing to Finding of Fact #72 in the Final Agency Decision for TRC St. Paul's.) Therefore, the evidence of record establishes that it was reasonable for BMA to project that patients residing in Brunswick County but not dialyzing in Brunswick County would want to dialyze in Brunswick County and transfer to the BMA facility in Supply, and it was error for the ALJ to conclude otherwise.

7. ALJ Finding of Fact 73. I am not adopting ALJ Finding of Fact 73 because it is not supported by the evidence of record and erroneous as a matter of law. Specifically, there is no evidence to support a finding that all thirteen (13) patients who lived in Brunswick County but dialyzed outside the county and which BMA proposed to serve lived in Leland. Further, although the mileage between Leland and Supply is more than the mileage between Leland and Wilmington, the traffic in and out of Leland can make the commute between Leland and Wilmington take one (1) hour. (Tr. 543: 8-25; Joint Ex. 3 at 357.) In addition, the ALJ improperly compared the distance between the BMA and TRC proposed facilities for the purposes of determining whether BMA conformed to Criterion 3. The ALJ focused on the fact that Leland patients would prefer a Leland facility over one in Supply, and therefore determined that the BMA application was nonconforming with Criterion 3. The proper standard of review is to examine and evaluate an application on its face and not as compared to other applications. The comparative review does not occur until it is determined whether an application is conforming to statutory criteria. Therefore, the fact that Leland patients would be closer to a facility in Leland than in Supply is completely irrelevant for the purposes of determining whether BMA's assumption that patients residing in Brunswick County would want to dialyze in Brunswick County. Rather, the relevant determination is whether BMA reasonably assumed that patients living in Brunswick County would want to dialyze in Brunswick County, and the evidence of record supports the CON Section's determination that BMA's assumption was reasonable. ALJ Finding of Fact 73 is thus not supported by the evidence of record and is erroneous as a matter of law.

8. ALJ Finding of Fact 76. I am not adopting ALJ Finding of Fact 76 because it is not supported by the evidence of record. Specifically, the preponderance of the evidence establishes that it was reasonable for BMA to project to serve thirteen (13) Brunswick County patient-residents who are not currently receiving dialysis services in Brunswick County because these thirteen (13) patients could then dialyze in their home county. The evidence of record

established that the traffic to and through Wilmington is very congested, such that a New Hanover dialysis facility is unattractive to dialysis patients since they need treatments at least three (3) times per week. (Tr. at 79:5-10; TRC Ex. 28 at 15-16; Joint Ex. 3 at 357; ALJ Finding of Fact 69.) The evidence of record further showed that the available public transportation within Brunswick County only transports patients within the county and will not take patients across county lines (Tr. at 62:16-18; ALJ Finding of Fact 70) and that TRC's own affiliated physicians testified that they would refer patients to BMA's Supply facility in Brunswick County (BMA Ex. 2 & 3; ALJ Finding of Fact 71.). Therefore, it was reasonable for BMA to assume that thirteen (13) patients who lived in Brunswick County but were not dialyzing or projected to dialyze at a Brunswick County facility would want to dialyze in their home county. As a result, the projections in the BMA application were reasonable and the ALJ's finding to the contrary is unsupported by the evidence of record.

9. ALJ Finding of Fact 79. I am not adopting ALJ Finding of Fact 79 because it is not supported by the evidence of record. Specifically, it was reasonable for the CON Section to find BMA's application conditionally conforming to Criterion 3 when the BMA application assumed that Brunswick County dialysis patients would choose to dialyze in Brunswick County. The evidence of record showed that the July 2007 SDR identified a need for thirteen (13) new dialysis stations in Brunswick County and not the surrounding counties (See July 2007 SDR; TRC Ex. 16; Joint Ex. 3 at 634; ALJ Finding of Fact 68.) In addition, the evidence of record established that the traffic to and through Wilmington is very congested, such that a New Hanover dialysis facility is unattractive to dialysis patients since they need treatments at least three (3) times per week. (Tr. at 79:5-10; TRC Ex. 28 at 15-16; Joint Ex. 3 at 357; ALJ Finding of Fact 69.) The evidence of record further showed that the available public transportation within Brunswick County only transports patients within the county and will not take patients across county lines (Tr. at 62:16-18; ALJ Finding of Fact 70) and that TRC's own affiliated physicians testified that they would refer patients to BMA's Supply facility in Brunswick County (BMA Ex. 2 & 3; ALJ Finding of Fact 71.). Therefore, it was reasonable for BMA to assume that patients who lived in Brunswick County would want to dialyze in Brunswick County. As a result, the BMA application was conforming to Criterion 3 and the ALJ's finding to the contrary is unsupported by the evidence of record.

10. ALJ Finding of Fact 88. I am not adopting ALJ Finding 88 because it is contrary to the record evidence. Specifically, the evidence of record supports a determination that the BMA application conformed to the Performance Standard Rule. The need methodology utilized by BMA pursuant to Criterion 3 was conforming, and therefore BMA's projection that it would serve 32.6 in-center patients by the end of the first operating year was reasonable. As a result, the CON Section correctly determined that the BMA application conformed to the Performance Standard Rule and the ALJ's finding to the contrary is unsupported by the evidence of record.

11. ALJ Finding of Fact 98. I am not adopting ALJ Finding 98 because it is contrary to the record evidence and erroneous as a matter of law. Specifically, the evidence of record supports a determination that the BMA application conformed with all statutory and regulatory review criteria, and therefore it was necessary for the CON Section to determine whether the BMA application or the TRC application was competitively superior.

ALJ CONCLUSIONS NOT ADOPTED

1. ALJ Conclusion of Law 4. I am not adopting ALJ Conclusion of Law 4 because it is erroneous as a matter of law and is not supported by the findings of fact. Neither the CON statutes nor regulations require a project analyst and/or the project analyst's supervisor to listen to the tape of a public hearing or read the transcript of the public hearing. Moreover, to the extent any such requirement exists, it was harmless error for Mr. Rupp and Mr. Smith to fail to listen to the tape of a public hearing or read its transcript because they testified that if they had listened to the tape or read its transcript, they would not have reached a different determination in this case. (See Britthaven, 118 N.C. App. at 386, 455 S.E.2d at 461; Tr. at 495:12-18; 611:24-612:3; ALJ Findings of Fact 55 and 56.)

2. ALJ Conclusion of Law 5. I am not adopting ALJ Conclusion of Law 5 because it is erroneous as a matter of law and is not supported by the findings of fact. The CON Section correctly determined that the BMA application conformed or conditionally conformed to all statutory and regulatory criteria. Specifically, the CON Section correctly determined that the BMA application conformed to Criterion 3 and the Performance Standard Rule because the evidence of record showed that the July 2007 SDR identified a need for thirteen (13) new dialysis stations in Brunswick County and not the surrounding counties (See July 2007 SDR; TRC Ex. 16; Joint Ex. 3 at 634; ALJ Finding of Fact 68.) In addition, the evidence of record established that the traffic to and through Wilmington is very congested, such that a New Hanover dialysis facility is unattractive to dialysis patients since they need treatments at least three (3) times per week. (Tr. at 79:5-10; TRC Ex. 28 at 15-16; Joint Ex. 3 at 357; ALJ Finding of Fact 69.) The evidence of record further showed that the available public transportation within Brunswick County only transports patients within the county and will not take patients across county lines (Tr. at 62:16-18; ALJ Finding of Fact 70) and that TRC's own affiliated physicians testified that they would refer patients to BMA's Supply facility in Brunswick County (BMA Ex. 2 & 3; ALJ Finding of Fact 71.). Therefore, it was reasonable for BMA to assume that patients who lived in Brunswick County would want to dialyze in Brunswick County. As a result, the BMA application was conforming to Criterion 3 and BMA's projection that it would serve 32.6 in-center patients by the end of the first operating year was reasonable. By projecting to serve 32.6 in-center patients by the end of its first operating year, the BMA application conformed to the Performance Standard Rule.

3. ALJ Conclusion of Law 7. I am not adopting ALJ Conclusion of Law 7 because it is erroneous as a matter of law and not supported by the findings of fact. The CON Section correctly determined that the BMA application was conforming to all relevant statutory and regulatory criteria. As a result, it was proper for the CON Section to perform a comparative review and find the BMA comparatively superior to the TRC application.

4. ALJ Conclusion of Law 8. I am not adopting ALJ Conclusion of Law 8 because it is erroneous as a matter of law and not supported by the findings of fact. The CON Section correctly approved the BMA application because the BMA application was conforming to all statutory and regulatory review criteria, and was comparatively superior to the TRC application.

5. ALJ Conclusion of Law 10. I am not adopting ALJ Conclusion of Law 10 because it is erroneous as a matter of law. Since the BMA application conformed to all statutory and regulatory review criteria, and was comparatively superior to the TRC application, the CON Section properly approved the BMA application and awarded BMA a CON for a new ten (10) station dialysis facility in Supply, Brunswick County.

CERTIFICATE OF SERVICE

I certify that I have served a copy of the foregoing FINAL AGENCY DECISION on each party, upon each party's counsel of record and upon the Office of Administrative Hearings, at the addresses and by the means indicated below. The address shown for Petitioner is the latest address given to Respondent by Petitioner.

CERTIFIED MAIL

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I certify that a copy of the foregoing Final Decision has been served upon the Office of Administrative Hearings by depositing a copy in an official depository of the United States Postal Service in a first-class, postage prepaid envelope addressed as follows:

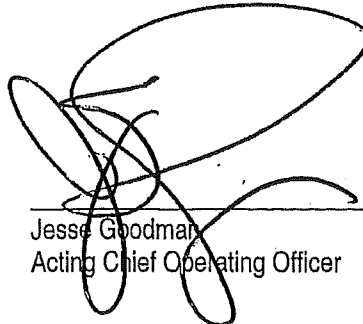
U.S. MAIL

Kim Hausen
Chief Hearings Clerk
Office of Administrative Hearings
6714 Mail Service Center
Raleigh, NC 27699-6714

HAND DELIVERY

I certify that a copy of the foregoing Final Decision has been served upon the Certificate of Need Section by hand delivery.

This the 19th day of March, 2009.



Jesse Goodman
Acting Chief Operating Officer