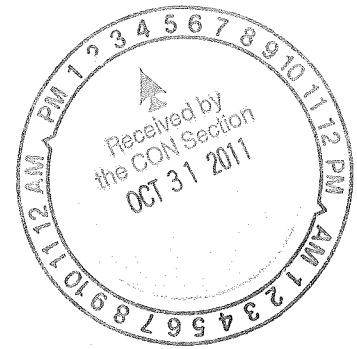




Fresenius Medical Care



October 31, 2011

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

Re: Public Written Comments, CON Project ID #M-8743-11

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 DaVita to develop a new 11 station dialysis facility in Harnett County. BMA is pleased to have the opportunity to submit comments, and hope that the CON Project Analyst will consider these comments during the review process.

As the following comments will demonstrate, BMA believes the CON application to be fatally flawed on both its patient projections, Criterion 3 and financial projections, Criterion 5. In addition, the application is non-conforming to Criterion 7. A non-conformity in these areas will necessarily result in a non-conformity in Criterion 4. BMA believes the application can not be conditioned to a level of conformity. Therefore, BMA suggests that the CON Section should deny this application.

If you have any questions, or I can be of further assistance, please contact me at 919-896-7230.

Sincerely,

Jim Swann, via email

Jim Swann
Director, Market Development and Certificate of Need

Attachment: Public Written Comments

3725 National Drive, Suite 130
Raleigh, N.C. 27612
Phone: 919-896-7230 FAX: 919-896-7233

Public Written Comments

Re: CON Project ID # M-8743-11

Total Renal Care of North Carolina, LLC.

d/b/a Spring Lake Dialysis

Prepared and submitted by: Jim Swann

FMC Director, Market Development and Certificate of Need

1. The applicant has provided an unreasonable need methodology in its representations of patients to be served. An applicant for a Certificate of Need must provide reasonable estimates of the patient population to be served. BMA notes the following Findings of Fact from the Final Agency Decision, 08 DHR 0818, (the BMA Brunswick County contested case hearing).

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).*

In the case at hand, BMA believes the "analytical" approach by TRC to be unreasonable, overreaching, and not approvable.

- a. The applicant suggests on Page 16 (this is repeated several times throughout the application) that the SEKC has counted patients from zip codes which cross county lines as being residents of Harnett County. Specifically, the applicant identifies the zip codes for Spring Lake, Sanford and Cameron. Further the applicant suggests that all patients from these zip codes then are residents of Harnett County. The zip code boundary is obviously not the county boundary. It is not reasonable to suggest that the patients of a zip code are necessarily the patients of any particular county.
- b. The applicant proposes on page 18 that eight home trained patients would transfer their care to the new facility. However, the applicant has not provided any reasonable methodology for such an assertion. The applicant could just as easily have said that patients from South Carolina would transfer their care to the facility. It is incumbent upon the applicant to provide some rationale and methodology to support such an assertion. Absent any rationale, then the methodology is unsupported. To the extent that this then calls in to question the applicant's projection of patient population to be served, the resultant revenue generation must also be questionable. Therefore the applicant should be deemed non-conforming to Review Criterion 5.

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To the extent that this foundational assumption of the applicant is unreasonable, then the subsequent patient treatment and revenue projections must also be deemed unreliable. Therefore, this application is non-conforming with Review Criterion 3, 4 and 5.

2. On page 35 the applicant has suggested in response to 10A NCAC 14C. 2204 (4) that home patients would be trained in its Moore County facility and only the home follow-up services would be provided from the new location. BMA on the other hand proposed a full complement of home training services for both Peritoneal Dialysis and Home Hemo-dialysis patients.
3. The applicant has not provided any response to Policy Gen 3.
4. The applicant proposes that Drs. Shah and Chandra would be the attending nephrologists and that Dr. Chandra would be the Medical Director. However, both Drs. Shah and Chandra already have admitting privileges at four dialysis facilities in Cumberland County, one in Robeson County, and the DC Hoke County facility. Further, DaVita has identified Drs. Shah and Chandra as having privileges in its proposed Lumbee River Dialysis facility (CON Project ID #N-8725-11. With only two nephrologists in their practice, and both with admitting privileges at six existing facilities and one other proposed new facility, it is not reasonable to expect that these two physicians can stretch their day to add yet another facility to their rounding responsibilities.
5. The applicant's projected payor source is not reasonable. While Moore County is contiguous to Harnett, the patient population to be served is not the same. BMA's projected payor mix is based upon actual experience in Harnett County. In 2010 the CON Section determined in the Randolph County competitive review that a payor source must be based upon the population of the county, or one that is more similar in nature. In this case, the applicant has projected only 0.7% Medicaid. BMA experience is that Medicaid should account for 8.8% of the ESRD patient population in Harnett County. The applicant's projection is exceptionally low. Medicaid reimbursement is lower than most other payors. To the extent that the projection of Medicaid patients to be served is low, then it is reasonable to suggest that the applicant has a higher than probable projection of revenues. If revenue projections are overstated then the applicant should be found non-conforming to Review Criterion 5.

The applicant could easily have reviewed other recent BMA applications for dialysis facilities in Harnett County to arrive at a more reasonable payor mix projection. The applicant has noted within its application that it indeed has reviewed the FMC Angier CON application.

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6. The applicant fails to provide adequate staffing for the patients to be served. The applicant has described the facility as an 11 station dialysis facility with one station dedicated to isolation/separation. Thus, in a practical sense the applicant will have 10 stations available for the general patient population receiving treatment at the facility. The applicant suggests that it will be serving 41 patients at the end of the second year of operation. However, the applicant has not provided staffing or any indication of a third dialysis shift which would accommodate the 41st patient.

7. The applicant's revenue projections are not consistent with the reality of Medicare reimbursement today and fail to account for the "bundle". In 2010 the Medicare "bundle" became the standard for reimbursement. Under the "bundle" Medicare does not reimburse for ancillary medications such as EPO. This is included within the Medicare "bundle" payment for services. It has been BMA experience that the "bundle" is reimbursing approximately \$234 per treatment.

The applicant has projected the Medicare reimbursement at \$136 per treatment coupled with an average of \$160 per treatment for ancillary medications. This \$160 figure is derived by dividing the information provided in Table X.2, EPO and Other Ancillaries by the total number of treatments projected in Operating Year 2. That calculation is:

$$\$1,126,400 / 7040 = \$160 \text{ per treatment for EPO and Other Ancillaries}$$

A more appropriate methodology would have been to correctly reflect the Medicare reimbursement at \$234 per treatment and not demonstrate EPO and Other Ancillary revenue for Medicare patients. As a consequence of this incorrect projection of revenues, the applicant has very likely overstated projected revenue.

The following Table offers a corrected version of Revenue Projections for Operating Year 2:

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Dialysis Treatment Revenue						
Private Pay	7410	7040				
Medicare	7410	7040	11.8%	831	\$234.00	\$ 194,388
Medicaid	7410	7040	0.7%	49	\$136.00	\$ 6,702
Medicate/Medicaid	7410	7040	25.5%	1795	\$234.00	\$ 420,077
Commercial	7410	7040	7.8%	549	\$520.00	\$ 285,542
VA	7410	7040	2.6%	183	\$136.00	\$ 24,893
State Kidney Program	7410	7040				
Other-Specify:	7410	7040	0.7%	49	\$ -	\$ -
Medicare/Commercial	7410	7040	50.9%	3583	\$234.00	\$ 838,506
			100.0%			\$ 1,770,109
EPO and Other Ancillary				598	\$160.00	\$ 95,744
TOTAL PROJECTED REVENUE						\$ 1,865,853
TOTAL PROJECTED EXPENSES (Table X.4)						\$ 2,125,673
NET PROJECTED OPERATING PROVIT / (LOSS)						\$ (259,820)

The applicant projected an operating loss for Operating Year 1. As the Table demonstrates, utilization of the Medicare “bundle” rate, coupled with an appropriate corresponding reduction in EPO and Other Ancillary revenues will necessarily result in an operating loss at the facility for Operating Year 2.

Fresenius Medical Care, parent company to BMA, and DaVita, parent company to Total Renal Care are the two large dialysis providers nationwide. Both companies opted in to the Medicare “Bundle” from its beginning.

Summary:

Based upon the forgoing, BMA suggests the application should be denied.