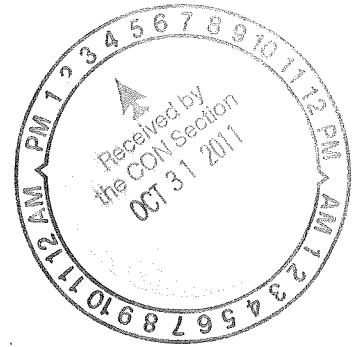




**Fresenius Medical Care**



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 #L-8750-11

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 10 station dialysis facility in Northampton 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 Rule 10A NCAC 14C .2203 (a), and financial projections, Criterion 5. 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

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DVA Healthcare Renal Care, Inc.

d/b/a Northampton Dialysis

Prepared and submitted by: Jim Swann

FMC Director, Market Development and Certificate of Need

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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 has suggested that BMA was serving 54 patients at its East Northampton County dialysis facility as of December 31, 2010. The applicant suggests that five of these patients were residents of counties other than Northampton. However, the applicant has no basis for such an assumption. BMA has dialysis facilities in Bertie, Halifax and Warren Counties, all of which are contiguous to Northampton. The applicant does not know where dialysis patients reside (other than those which the applicant is serving in its Ahoskie facility). The applicant can not make such an assumption of patient residence location and use this as a basis for its need methodology.
- b. The applicant makes an incomplete suggestion regarding 70% of patients residing in zip codes 27831, 27845, 27876, and 27832. It is unclear what the applicant is suggesting.
- c. Assuming that the applicant has intended to suggest that 70% of the dialysis patient population residing in these zip codes would transfer to their facility, BMA notes that it has included eight letters of support from patients residing in Garysburg and nine patients residing in Gaston in its application to add three dialysis stations to its FMC East Northampton County. Each of these patients has indicated that they do NOT desire to transfer to another facility.

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- d. The applicant has incorrectly assumed that 27 patients who are receiving their care at a BMA facility on December 31, 2010 would agree to transfer their care. The applicant begins its calculations based upon a census of patients changing providers more than nine months before the application was filed. It is inappropriate to "reach back" in time to project a future patient population when the applicant does not have any indication from the patients that they would agree to such a transfer.
- e. The applicant's math is incorrect on page 15 (and other locations within the application where this is repeated). Specifically, the last two calculations reported on the page are either incorrect, or inconsistent. To the extent that these are inconsistent, one must conclude that the projections of future patients and resultant financial projections are likewise inconsistent and unreliable.
- f. On page 16 of the application (and other locations within the application where this is repeated) the applicant suggests that it will also provide treatment for three home dialysis patients. However, the applicant has not provided any basis for such an assumption. This is therefore unreliable.

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. The applicant has not provided the most reasonable alternative, and is therefore non-conforming to Review Criterion 4. The applicant has suggested that it would refer patients to Albemarle Hospital for acute dialysis, x-ray services, blood bank services and emergency care. It is approximately 88 miles from the site of the proposed facility to the Albemarle Hospital. Conversely, the Halifax Regional Hospital in Roanoke Rapids is less than 10 miles from the proposed location. It is not reasonable to expect that dialysis patients would, or should, travel nearly 90 miles when a fully capable hospital is less than 10 miles from the proposed location.
3. The applicant has suggested on page 29 that patients desiring to perform home hemo-dialysis would have to travel to its Elizabeth City dialysis facility. This is again an approximately 88 mile trip for each training visit and monthly clinic visit. This is unreasonable for the patients who may desire to perform home hemo-dialysis.
4. The applicant has suggested that they would invite other nephrologists to seek admitting privileges at the new facility? There is nothing in the application to suggest that the physicians admitting to DC Northampton County would seek privileges at the new facility. The applicant has identified only the physicians of Albemarle Nephrology as having admitting privileges at the new facility.

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Based upon the absence of any indication that other physicians will seek privileges at the new facility, BMA suggests that it is unreasonable to expect all of the patients projected to transfer to the new facility to also change their nephrology physician.

5. The applicant has not provided any response to Policy Gen 3.
6. The applicant has not provided a complete response to Policy ESRD 2. While BMA would agree that ESRD 2 is not applicable to an application of this nature, the absence of a complete response is indicative of the inconsistencies within the application.
7. The applicant has not adequately planned for staffing at the facility. In Operating Year 2 the applicant is proposing to serve 41 dialysis patients. However, a 10 station dialysis facility can provide treatment for only 40 patients on traditional shifts. The applicant thus fails to adequately propose staffing for the care of the patients projected to be served. The applicant is non-conforming to Review Criterion 7.
8. The applicant has not provided a letter from any physician indicated an intent to serve as Medical Director. The letter from Dr. Branspigel does not say that he will serve as Medical Director. In 2004 BMA provided a similar letter from its proposed Medical Director for the proposed FMC Gates County dialysis facility (see Required State Agency Findings, R-7158-04, page 14). The CON Section determined this letter was not sufficient in as much as the letter did not clearly indicate the physician intent to serve as Medical Director. The application is therefore non-conforming to Review Criterion 7.
9. The applicant's projected payor source is not reasonable. While Hertford County is contiguous to Northampton, the patient population to be served is not the same. BMA's projected payor mix is based upon actual experience in Northampton 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 a commercial mix of 8.4%. Compare that to BMA experience and projections of only 3.3%. The applicant's projection is more than twice the actual rate of Northampton County ESRD patients. Consequently, the applicant has overstated its projected revenues.
10. The applicant has suggested that patients who are candidates for transplantation would have to travel to Charlotte, a distance of some 230 miles from the facility. There are at least three other transplant programs in much closer proximity: Pitt County Memorial Hospital, Duke University, and the University of North Carolina Medical Center in Chapel Hill. Proposing

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to send patients to Carolinas Medical Center in Charlotte is not the best alternative for the patients of the area.

11. 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 pre 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 1. That calculation is:

$$\$912,960 / 5,706 = \$160 \text{ per treatment for EPO and Other Ancillaries}$$

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:

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Dialysis Treatment Revenue						
Private Pay	6006	5706				
Medicare	6006	5706	23.0%	1312	\$234.00	\$ 307,097
Medicaid	6006	5706	2.4%	137	\$136.00	\$ 18,624
Medicate/Medicaid	6006	5706	36.1%	2060	\$234.00	\$ 482,009
Commercial	6006	5706	8.4%	479	\$520.00	\$ 249,238
VA	6006	5706	2.4%	137	\$136.00	\$ 18,624
State Kidney Program	6006	5706				
Other-Specify:	6006	5706				
Medicare/Commercial	6006	5706	27.7%	1581	\$234.00	\$ 369,852
						\$ 1,445,444
EPO and Other Ancillary				616	\$160.00	\$ 98,600
TOTAL PROJECTED REVENUE						\$ 1,544,044
TOTAL PROJECTED EXPENSES (Table X.4)						\$ 1,781,615
NET PROJECTED OPERATING PROVIT / (LOSS)						\$ (237,571)

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.