**Fresenius Medical Care**


October 3, 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 #N-8725-11

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 Hoke 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
Director, Market Development and Certificate of Need

Attachment: Public Written Comments

3725 National Drive, Suite 130
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Phone: 919-896-7230 FAX: 919-896-7233

Public Written Comments
Re: CON Project ID # J-8725-11
Total Renal Care of North Carolina, Inc.
d/b/a Lumbee River Dialysis
Prepared and submitted by: Jim Swann
FMC Director, Market Development and Certificate of Need

1. The applicant has provided conflicting information with regard to the property developer for the project. In response to I.10, the applicant suggests that RGHC Investments, LLC will develop the project. However, Exhibit 9 includes a letter to Hill Gray Seven, LLC regarding the availability of utilities at the site.

2. 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. The applicant has suggested that 31 patients would transfer to the new Lumbee River Dialysis facility. The applicant has suggested that these patients would receive their nephrology care from the physicians at Pinehurst Nephrology Associates. According to information contained within the application these physicians do not have admitting privileges at the DaVita Dialysis Care Hoke County facility (see response to VII.7, page 40). Absent admitting privileges at DC Hoke County, these physicians are not providing care for the patients projected to transfer to the new DaVita Lumbee River facility. It is unreasonable to expect a wholesale change of physician by the patients projected to transfer to the new facility. Have the patients been informed of the need to change physicians? Have the current attending physicians been apprised of the plan for these patients to transfer to the new facility and thus also change nephrology physicians?

   Based upon BMA experience (BMA is the leading provider of dialysis in North Carolina), patients do not change nephrology physicians on a wholesale basis. Certainly some patients will occasionally change nephrologists; however this is generally a function of patient relocation, and not because the patient is changing facilities within the same county.

   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 Hoke County would seek privileges at the new facility. The applicant has identified only the physicians of Pinehurst Nephrology as having admitting privileges at the new facility.

The applicant did include letters of support for the project from Drs. Shah and Chandra of Sandhills Nephrology in Fayetteville. However, the letters from Drs. Shah and Chandra do not provide any indication of their intent to seek admitting privileges at the new facility. Furthermore, it does not seem reasonable to conclude that Drs. Shah and Chandra will seek admitting privileges at the new facility. Both Drs. Shah and Chandra already have admitting privileges in the four dialysis facilities in Cumberland County, the DaVita St. Pauls facility and the DC Hoke County facility; furthermore, Drs. Shah and Chandra have indicated that they would serve as Medical Director for the proposed DaVita facility in Harnett County (CON Project ID# M-8743-11). 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.

In addition to Drs. Shah and Chandra, the nephrology physicians of Carolina Kidney Care (a Fayetteville and Lumberton based nephrology practice) also have admitting privileges at DC Hoke County. The applicant has not provided any letters of support from even one physician of Carolina Kidney Care.

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.

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.

3. The applicant has incorrectly applied the Hoke County Five Year Average Annual Change Rate of 8.8% to the overwhelming majority of the patients projected to transfer to the new facility. In its projections of patients to be served by the facility, the applicant has suggested that 31 patients would transfer to the new facility upon certification of the stations at the new location. It its methodology, the applicant begins with 29 patients of the DC Hoke County dialysis facility and increases this patient population at the Hoke County Five Year Average Annual Change Rate of 8.8%. In response to III.7 the applicant suggests that only two of the patients projected to be served by the facility at the end of the first year of operations would be Hoke County patients. The applicant does not identify the home county of the patients projected to transfer to the facility. However, based upon the information in III.7 one must conclude that the overwhelming majority of patients projected to transfer are Robeson County residents.

   In its mathematical projections of patients to be served, the applicant has incorrectly applied the Hoke County Five Year Average Annual Change Rate of 8.8% to the entire patient population projected to transfer. The applicant has projected that 87.8% of the patients to be served at the end of the first year of operations would be Robeson County patients. The Robeson County Five Year Average Annual Change Rate is only 1.9% according to the July 2011 SDR (applicant exhibit 6). The patient population residing in Robeson County should be increased at a rate commensurate with the Robeson

County Five Year Average Annual Change Rate as published within the July 2011 SDR. Or 1.9%. The patients of Scotland County should likewise be increased at a rate commensurate with the Scotland County Five Year Average Annual Change Rate. That change rate is only 0.3%. To the extent that the applicant has applied an incorrect growth rate to the overwhelming majority of the patients projected to be served, the financial projections must also be questionable.

Using the information from the application, BMA has calculated the projected patient population to be served using the appropriate County Annual Change Rate. The following table illustrates a more correct methodology using the appropriate county change rates.

| | % of Census | Beginning Census | Probable Pt Population | Projected OY 1 | Projected OY 2 | County 5 Yr Average Annual Change Rate |
|---|---|---|---|---|---|---|
| Hoke | 6.1% | 31 | 2 | 2.2 | 2.4 | 0.088 |
| Robeson | 87.8% | 31 | 27 | 27.5 | 28.0 | 0.019 |
| Scotland | 6.1% | 31 | 2 | 2.0 | 2.0 | 0.003 |
| TOTAL | 100% | | 31 | 31.7 | 32.4 | |

The above table assumes that the beginning patient population is a function of the same percentages as the beginning census. In the case of the two patients projected to be from Hoke and Scotland Counties, BMA has actually rounded up to provide a whole number (0.61 X 31 = 1.89), giving the applicant the benefit of doubt. However, rounding up is not appropriate for the total number of patients to be served. It is incumbent upon the applicant to prove 3.2 patients per station at the end of the first year of operations. In this case, 31.7 patients divided by 10 stations is 3.17 patients per station. The applicant has failed to prove 3.2 patients per station.

4. The applicant has not provided a complete response to III.3, and fails to appropriately address Review Criterion 3a. In its discussion regarding Criterion 3a the applicant fails to account for the one patient reported to dialyzing on the station dedicated to isolation at the DC Hoke County facility. On page 20 of the application the applicant suggests that subsequent to the addition of seven stations (CON Project ID # N-8744-11, assuming approval of that application) that the facility would have 104 dialysis patients and 27 dialysis stations. However, the applicant fails to appropriately allow for the one patient utilizing the isolation station.

The isolation station, when used for a single patient, must not be used to provide dialysis for other patients unless those patients also required isolation/separation (hepatitis B positive). Thus, the DC Hoke facility will effectively have 103 patients dialyzing on 26 stations; this is a utilization rate of 99% or 3.96 patients per station. Under these circumstances, the facility could accept only one additional patient on traditional dialysis shifts. The facility does not plan on a third dialysis shift, nor does the facility offer a third shift. Consequently, given the growth rate of 8.8% for the Hoke County ESRD patient population, approval of this application will necessarily force the facility to develop a third patient shift before the end of the first operating year. The applicant has not provided any

evidence of plans to include a third shift and seems to plan solely for development of the additional seven stations at DC Hoke County. The applicant has not provided any information about future staffing or shift schedules should the third shift requirement become a reality, as it most certainly will.

5. The applicant has failed to provide sufficient funding for this project and is therefore non-conforming to review Criterion 5. The applicant indicates that the new facility will require the acquisition of 10 dialysis machines at a cost of $13,600 per machine. The acquisition of only 10 machines does not allow for any equipment failure. Furthermore, the applicant has indicated that it has planned capital expenditure of only $130,250 for 10 dialysis machines. By its own information the new machines would cost at least $136,000 before any taxes or freight. The project is under-funded and should therefore be found non-conforming to Criterion 5.

6. 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 $180 per treatment for ancillary medications. This $180 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:

   $853,560 / 4742 = $180 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 by more than $340 thousand.

   The following Table offers a corrected version of Revenue Projections:

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| Dialysis Treatment Revenue | | | | | | |
|---|---|---|---|---|---|---|
| Private Pay | 4,992 | 4,742 | | | | |
| Medicare | 4,992 | 4,742 | 25.0% | 1186 | $234.00 | $ 277,407 |
| Medicaid | 4,992 | 4,742 | 3.1% | 147 | $136.00 | $ 19,992 |
| Medicate/Medicaid | 4,992 | 4,742 | 31.3% | 1484 | $234.00 | $ 347,314 |
| Commercial | 4,992 | 4,742 | 9.3% | 441 | $520.00 | $ 229,323 |
| VA | 4,992 | 4,742 | | | | |
| State Kidney Program | 4,992 | 4,742 | | | | |
| Other-Specify: No INS | 4992 | 4,742 | | | | |
| Medicare/Commercial | 4,992 | 4,742 | 31.3% | 1484 | $234.00 | $ 347,314 |
| | | | | | | $ 1,221,350 |
| Ancillary Revenue | | | | | | |
| EPO and Other Ancillary | | | | 588 | $180.00 | $ 105,841 |
| TOTAL PROJECTED REVENUE | | | | | | $ 1,327,191 |
| TOTAL PROJECTED EXPENSES (Table X.4) | | | | | | $ 1,623,877 |
| NET PROJECTED OPERATING PROVIT / (LOSS) | | | | | | $ (296,686) |

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 1. Similarly Operating Year 2 will demonstrate a loss.

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.