Fresenius Medical Care

November 1, 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

Re: Randolph County Dialysis Competitive Review, 10-Station Need Determination Pursuant to the July 2010 SDR

Dear Mr. Smith:

On behalf of Bio-Medical Applications of North Carolina, I am forwarding the attached as Public Written Comments regarding the competing CON Application for the Randolph County Dialysis Need Determination (July 2010 SDR). 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.

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

Attachments: Public Written Comments CON Project ID # G-8583-10

3725 National Drive, Suite 130
Raleigh, North Carolina 27612
Phone: 919-896-7230 FAX: 919-896-7233

Public Written Comments
Re: CON Project ID # G-8583-10
Total Renal Care of North Carolina, Inc.
d/b/a Randolph County Dialysis
Prepared and submitted by: Jim Swann
FMC Director Market Development and Certificate of Need

The TRC (DaVita) application is not the best alternative for the ESRD patients of Randolph County and is therefore non-conforming to Criterion 4. The applicant has provided a more costly plan than the BMA proposal and is therefore not the best alternative. The applicant has not provided sufficient staffing for the project and is therefore not conforming to Criterion 7. The applicant can not add additional staff and has provided inconsistent information with regard to financial projections and is therefore non conforming to Criterion 5 and 7. As a result of these nonconformities, the application should not be approved, nor should it be found conditionally conforming.

1) TRC has proposed that patients of Randolph County would have to travel to Moore County hospital for hospital services, diagnostic services, acute dialysis and emergency care. This is not a suitable alternative for the patients of the county; it is a one way trip of 49 miles from the center of Asheboro to Moore County Regional Hospital. By its own admission, Asheboro is at the approximate center of Randolph County. The Randolph County Hospital is located in the center of Asheboro and is capable of providing the same services as proposed by the TRC application. Why would patients travel 49 miles one way when the services could be obtained within their home county?

BMA has proposed that patients would receive all services locally with the exception of acute dialysis; the Randolph County Hospital does not offer acute dialysis. As a consequence, BMA has proposed that patients needing acute dialysis services would be referred to Moses Cone Hospital, at 1200 N. Elm Street, in Greensboro. This is a one way trip of only 31 miles, and a commute which is 18 miles closer for the one way trip.

It simply is not reasonable to suggest that patients would travel to Moore County Regional Hospital for hospital services when all of the same services can be obtained within the local hospital and for patients needing acute dialysis services, the Moses Cone Hospital is 18 miles closer.

2) The TRC application is a more costly proposal when considered on a dollar per station basis.

TRC has proposed to develop a 10 station dialysis facility at a cost of $1,416,767. BMA has proposed to relocate its entire facility, complete two previously approved CON projects with the relocation, and add 10 stations for a total of 46 stations at a cost of $2,616,129. The TRC proposal is much more expensive and is not the best alternative. Consider the following table:

Applicant	Proposed Stations	Project Cost	Cost per Station
BMA	46	$ 2,616,129	$ 56,872
TRC	10	$ 1,416,767	$ 141,677

The TRC proposal cost nearly 250% more on a per station basis.

3) The July 2010 SDR identifies a need for 10 additional dialysis stations for Randolph County. TRC has proposed within their application that the facility would be offering home hemo-dialysis, an isolation/separation dialysis station and traditional in-center dialysis, with only 10 dialysis stations.

In recent years, the Certificate of Need Section has taken the position that dialysis stations can not be dual purpose stations. In recent efforts by BMA to add home hemo-dialysis training and support at existing facilities, the CON Section has approved BMA requests only when there was a commitment by BMA to utilize a station exclusively for home hemo-dialysis training and support. In other words, a dialysis station dedicated to home hemo-dialysis training can not be used on the dialysis treatment floor when there is not a home hemo-dialysis training patient utilizing the station; that home hemo-dialysis training station is dedicated and committed to the home hemo-dialysis training program. Additionally, because the home hemo-dialysis training station is not connected to the dialysis facility water treatment system (the home training station should be designed to emulate the patient home environment as much as possible) it is not appropriate to utilize the station for in-center treatment. If TRC were to consider such an arrangement, because the home hemo-dialysis training station is contained within a separate room away from the dialysis treatment floor, TRC would have to dedicate one RN to providing treatment for the one patient in the separate room; TRC has not provided any indication that it will have additional staff for such an operation.

The CON Section has consistently stated that home hemo-dialysis training must occur on a dialysis station. Unlike Peritoneal Dialysis where the training equipment is not considered a “station”, home hemo-dialysis training necessarily requires a dialysis station. As a result of proposing home hemo-dialysis training, TRC has effectively said that one of the 10 stations will be dedicated to home hemo-dialysis. This leaves nine dialysis stations.

The isolation/separation station likewise should not be utilized as a multipurpose dialysis station. Current CDC and CMS guidelines clearly suggest that isolation stations should be utilized to dialyze hepatitis B patients should be in a separate room and not utilized to dialyze other patients.

TRC has indicated that the facility will have an isolation/separation capability. While BMA will agree that non hepatitis B positive patients could dialyze on the isolation/separation station, BMA also reminds the CON Section and Project Analyst that once a single patient is identified as Hepatitis B Positive, that isolation/separation station can not be utilized for routine dialysis of other patients. CDC guidelines necessarily require that patients who are positive for hepatitis B must be dialyzed on separate equipment and that equipment can not be utilized for dialysis of the general patient population. TRC could have applied for a waiver for the isolation/separation station; however, no such waiver request was included in the application, nor was there any

indication of an intent to apply for a waiver. TRC clearly communicated its intent to develop the isolation/separation capability. The Table at V.1 indicates TRC intent to provide isolation on site.

On page 24 of the application, TRC indicates its intent to provide an "isolation area". This could be interpreted to say that TRC plans to operate nine dialysis stations in the treatment area, and then when the facility is treating a patient who is positive for hepatitis B, TRC would move a machine into the isolation area. Surely, TRC does not intend to operate in this manner.

First and foremost, if TRC were the approved applicant in this review, one of the standard Conditions of approval would require TRC to provide "plumbing and wiring through the wall" for only 10 stations. Thus, it simply is not realistic to plan move a station within the center; if the facility is constructed in a manner consistent with a CON approval, then there is no acceptable way in which a station could be moved to the isolation area.

However, BMA does not suggest that TRC intends to provide "plumbing and wiring through the wall" for more than 10 stations. A review of the proposed facility floor plan included in Exhibit 25 clearly indicates only eight dialysis on the floor and one station in isolation (plus one station in home training). TRC has effectively reserved one of the 10 stations for isolation/separation, leaving a net of eight dialysis stations for use by the general patient population.

The CON Section has clearly indicated that dialysis stations can not "swing" between various types of utilization. For example, a home hemo-dialysis station can not be utilized for in-center dialysis when a patient is not performing home hemo-dialysis training. Likewise, the isolation/separation station can not be in isolation/separation on one shift, and then utilized on the in-center treatment area when an isolation/separation patient is not dialyzing.

The State of North Carolina calculates utilization of dialysis stations based upon four patient shifts—Monday-Wednesday-Friday morning and afternoon, and Tuesday-Thursday-Saturday morning and afternoon. Dialysis providers across the State typically schedule patients on shifts of this nature. Eight dialysis stations can thus provide treatment for 32 dialysis patients on traditional shift schedules.

The TRC application has indicated that the facility would be providing treatment for 32 in-center patients at the end of the first year of operations. The eight dialysis stations on the treatment floor can certainly accommodate 32 patients.

However, the TRC application also indicated that the facility would be providing treatment for 35 dialysis patients at the end of the second year. However, 100% capacity

for the eight dialysis stations is only 32 patients. How does TRC propose to provide dialysis treatment for the remaining three patients?

The logical way to provide treatment for these three patients is on a third dialysis shift. However, on page 49 of the TRC application, TRC has indicated that the facility will not operate a third dialysis shift. Furthermore, the applicant has not provided sufficient staffing to operate a third dialysis shift. Absent plans for a third shift and absent staffing for a third shift, TRC has not adequately planned for the provision of dialysis treatment for the patients it has indicated. The application is nonconforming to Criterion 7 and therefore must be found nonconforming. The applicant can not be found conditionally conforming to the Ceriteria because adding staff and patient shift schedules should be considered an amendment to the application.

At best,100% capacity for eight dialysis stations as planned by this applicant would be only 32 patients; capacity in this sense is a function of three, eight-patient shifts on M-W-F and two, eight-patient shifts on T-T-S. The application is non-conforming to Review Criterion 5 and 7.

4) The applicant has provided inconsistent information with regard to the number of patients to be served. As a result, the financial projections of the applicant are suspect and can not be relied upon. The application should be denied on the basis of inconsistent financial projections.

At multiple points within the application, the applicant has plainly stated that it "*will use a conservative projection of serving one home training patient during the first two operating years"* (page 14, 18, 22, and 32). However, on page 58 of the application, TRC indicates that it will have "2 home-trained patients being treated" in Operating Year 1 and, "4 home-trained patients being treated" during Operating Year 2. Which number is correct? BMA suggests that neither BMA, the CON Project Analyst possibly rely upon the representations of the Applicant. Such internal inconsistency must render the financial projections of revenues and expenses as unreliable and therefore the application is should be found nonconforming to Criterion 5.

5) On page 50 of the application, the applicant has proposed to that dialysis stations would cost $3,800 per dialysis machine. On page 51of the application, the applicant has proposed capital expenditures of $165,600 for dialysis machines. How many machines does TRC propose to install at this location? At a per machine cost of $3,800, TRC could purchase more than 43 machines for $165,600. Is this information credible and reliable? BMA suggests that the information is not credible, nor is it reliable. As a result, the application should be found non-conforming to Criterion 5 and 12.

6) The applicant has not provided for adequate funding of the project and is non-conforming to Criterion 5.

Section IX of the application indicates the following:

Start-up Expense	$	134,797
First 6 months Operating Expense	$	719,007
Total Working Capital	$	853,804

The applicant indicates the first six months operating expense are equal to 50% of the annual operating expense budget. Yet, on page 59 of the application, the initial operating budget for Operating Year 1 is: $1,446,054. Fifty percent of this figure is: $723,027. Thus, TRC has under budgeted its first six months operating expense by some $4,020.

The applicant has included a funding letter, Exhibit 21, which indicates that DaVita has committed cash reserves for $2,272,004. Of this amount, $1,416,767 is committed to the capital costs of the project, leaving a balance of $855,237. While this figure would seem to be sufficient to cover the proposed working capital in the table above, the figure actually falls short of the correct amount required by $2,587.

The funding letter at Exhibit 21 details yet another internal inconsistency with this application. The funding letter indicates that start-up costs are $136,230; however, the application indicates start-up expenses are $134,797. Which number is correct?

Assuming the Table of Expenses (page 59) is correct in Section X of Application, as noted above the 50% figure for six months operating expense is $723,027. When added to the start up expenses of $134,797, the actual working capital requirement is as follows:

Start-up Expense	$	134,797
First 6 months Operating Expense	$	723,027
Total Working Capital Required	$	857,824

Given the TRC/DaVita commitment for $2,272,004, the project is under funded by $2,587. The following table demonstrates the shortfall:

Capital Expense of Project	$	1,416,767
Total Working Capital Required	$	857,824
Total Required	$	2,274,591

Again, TRC/DaVita has only committed for $2,272,004, leaving a deficit of $2,587. TRC and DaVita have failed to adequately fund this project. Therefore, the application is non-conforming to Criterion 5.

Other:

1) TRC has proposed a payor mix based upon its experience in Montgomery County. BMA suggests that Montgomery County is not comparable to Randolph County, and TRC/DaVita has had access to BMA information by way of recently filed CON Applications for its BMA Asheboro facility.

   On September 15, 2009, BMA filed a CON Application to add seven dialysis stations to its BMA Asheboro facility. In that application, BMA provided the following payor mix projections.

IC Payor Source	%
Private Pay	0.0%
Commercial Insurance	17.7%
Medicare	70.7%
Medicaid	8.4%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
State Kidney Program	0.0%
VA	3.2%
Other[Specify] Self/Indigent	0.00%
Total	100.00%

   On March 15, 2010, BMA filed an application to transfer two dialysis stations from its BMA Southwest Greensboro facility (Guilford County) to the BMA Asheboro facility. In that application, BMA provided the following payor mix projections.

IC Payor Source	%
Private Pay	0.0%
Commercial Insurance	20.3%
Medicare	67.2%
Medicaid	8.4%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
State Kidney Program	0.0%
VA	4.1%
Other[Specify] Self/Indigent	0.00%
Total	100.00%

   In its September 15, 2010 CON Application (competitive application with TRC/DaVita), BMA provided the following payor mix projections:

Payor Source	In-center	Home
Private Pay	0.00%	0.00%
Commercial Insurance	14.64%	20.00%
Medicare	75.04%	70.00%
Medicaid	7.71%	7.00%
Medicare/Medicaid	0.00%	0.00%
Medicare/Commercial	0.00%	0.00%
State Kidney Program	0.00%	0.00%
VA	2.57%	3.00%
Other: Self/Indigent	0.03%	0.00%
Total	100.00%	100.00%

TRC has provided payor mix projections which are inconsistent with the ESRD patient population of Randolph County. As the CON Section conducts its review, BMA strongly encourages the Project Analyst to consider the recent and consistent applications of BMA.

The CON Section has consistently utilized payor mix projections as one of the comparative factors when conducting competitive CON reviews. In a case such as this, when other recent CON applications have been filed, it is not appropriate to consider another county population as a basis for payor mix projections.

Clearly, with such recent BMA Applications on file, any applicant could have reviewed those applications and relied upon those payor mix projections as a basis for projections within this competitive review.

In the alternative, another applicant could have reviewed previous recent applications and taken the position that some projection with higher Medicare mix would provide a competitive advantage (as in the case at hand). BMA is not suggesting that TRC/DaVita has "gamed" the system by knowing what BMA projections were likely to be, but, TRC/DaVita had opportunity to review recent filings by BMA and project a payor mix more in line with the current ESRD patient population of Randolph County.

2) On page 33 of the application, TRC/DaVita suggest that BMA has a "monopoly on dialysis services" in Randolph County. This is an old argument by TRC/DaVita and should not sway the Project Analyst. Obviously as the only provider of dialysis services in the County, one could argue that the current provider has a monopoly. However, there are multiple counties across the State in which there is only one provider of dialysis services; this is not a new situation. This situation is simply a result of CON law in North Carolina. BMA, TRC, HSM, DCI, and even Wilkes County Hospital all find themselves in one or more counties as the sole provider. This is not a situation unique to Randolph County or TRC/DaVita.

The CON Project Analyst should not be influenced by inflammatory language such as "monopoly". Rather, the Analyst must consider all elements of each application, and in cases where all applicants are fully conforming to the applicable review criteria and rules, conduct the comparative analysis, and make a decision. In the case at hand, the TRC Application fails on Criterion 4, 5, 7, and 12. The BMA Application is fully conforming to all review criteria and rules.

Summary:

TRC has provided an application which is not conforming to Review Criterion 4.

TRC has provided an application which is not conforming to Review Criterion 5.

TRC has provided an application which is not conforming to Review Criterion 7.

TRC has provided an application which is non conforming to Review Criterion 12.

The multiple failures as identified within these Public Written Comments render the TRC CON Application un-approvable. The applicant should be denied.