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William L. Hyland
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DaVita “ he/she that gives life”

October 31, 2013

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

RE: Project #N-10178-13/Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Laurinburg/Add four dialysis stations for a total of thirty stations/Scotland County

Dear Mr. Smith:

BMA indicates that they are offering a Certificate of Need application to add four dialysis stations at their BMA Laurinburg dialysis facility in response to the 11-station deficit of stations in Scotland County. However, as your project analyst reviews the application, he or she may end up scratching their head wondering how many stations the applicant is really asking for and how many stations the facility has now. On page 38 the applicant states, “This is an application for two stations. Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to add four dialysis stations to BMA Laurinburg dialysis facility for a total of 14 dialysis stations upon completion of the project”. On page 39 the applicant states, “This application is filed pursuant to a County Need Determination in the July 2013 SDR. The SDR reports a deficit of 11 dialysis stations for Scotland County. This is an application for two stations.” In Exhibit of the application you will find two documents with two typed paragraphs and a number of signatures under the paragraphs. A sentence in the first paragraph of each document states, “I understand that Bio-Medical Applications of North Carolina is submitting an application for a Certificate of Need to add six (6) dialysis stations to the facility.”

The applicant indicates in their application that there will be no capital costs associated with the project. This information can be found in the Letter of Intent that states, “The project does not require a capital expenditure on behalf of BMA”. The same information is also indicated on the Invoice – Certificate of Need Application Fee Sheet. In Section VIII.1.(c) of the application, the applicant responded to the request to list equipment which must be purchased or leased and the cost of each item that is included in the proposed budget. The applicant responded, “Not Applicable. BMA will not incur any capital costs associated with this project. Dialysis machines are leased.” The applicant did not respond to the question.

In Section VIII.2 the applicant failed to respond to the request for a listing of all costs to be incurred to implement this project. The applicant responded, "Not Applicable. BMA will not incur any capital costs associated with this project". In Exhibit 26 of the application, the applicant lists the exhibit as "Sample Dialysis Machine Lease". On page 4 of the lease under paragraph, **"5. INSTALLATION, USE, MAINTENANCE, AND RETURN AND QUIET POSSESSION:**

- (a) Lessee, at its own expense, will provide the required electric current to operate the Equipment and appropriate facilities to house and care for the Equipment as specified by its Supplier"

It is apparent that the applicant failed to provide the necessary capital expense for a two, four or a six-station expansion of BMA of Laurinburg. In order to provide dialysis services to patients in a dialysis station, it is standard for a dialysis station to include a dialysis machine (which the applicant indicated they will lease), a dialysis chair and a patient TV to be used for patient education and entertainment while undergoing dialysis treatments. It is also standard for the machine to have an electrical outlet to plug in the dialysis machine as it is with a TV. It is standard for the dialysis machine to be hooked into a water source. All of this work takes capital when adding dialysis stations to an existing dialysis facility.

In a recent CON application to add four dialysis stations to an existing facility, DaVita estimated the capital cost less dialysis machines to be \$13,040 (\$3,880 for four dialysis chairs, \$4,780 for four patient TVs, \$1,600 for a chair side computer terminal, \$800 for a digi interface, \$680 for Fresenius miscellaneous tubing, check valves, samples ports, \$800 for a Phoenix meter and \$500 for miscellaneous fittings). We are not saying that the capital expenditure for two, four or six stations would be exactly the same as a DaVita expansion of dialysis stations, but we are saying that there is capital expense associated with the expansion of stations within a dialysis facility. The BMA of Laurinburg facility did not provide any funds for the equipment that will be needed for the station expansion of the facility.

In the FMC Scotland County CON application submitted on September 16, 2013, the applicant indicated that they would need \$5,300 capital expenditure for a two-station expansion. This included ancillary water equipment, patient chairs and patient TVs.

The applicant failed to provide a signed written agreement with an acute care hospital. The applicant includes in Exhibit 16 an unsigned affiliation agreement. However, the applicant is required to provide a signed written agreement.

There are a number of issues with the financial assumptions in Section X. of the BMA of Laurinburg CON application. The applicant does not delete the 20% that Medicare does not reimburse for services. Medicare only pays 80% allowable charge. The other 20% has to be paid by either the patient or a secondary source of insurance. The applicant indicates that 78.6% of the in-center patients and 59.43% of the home-trained patients have Medicare. However, the applicant failed to delete the 20% from the \$234 Medicare reimbursement. The applicant provided no other source for the 20% copay.

The applicant indicates that all treatments provided to in-center and home-trained patients with the exception of the Medicare patient treatments bring in an average additional reimbursement of well over \$300 per treatment. This includes the Medicaid patients with an applicant stated reimbursement rate of \$137.29, patients with commercial insurance with an applicant stated reimbursement rate of \$1,375, patients funded by the Veterans Administration with an applicant stated reimbursement rate of \$146.79 and patients self-funded with an applicant stated reimbursement rate of \$1,375.00. Those additional reimbursements are suspect.

The applicant fails to provide adequate staffing on the treatment floor to cover the hours that the facility will be open. The applicant indicates on page 61 that they will have five full time Registered Nurses during operating years one and two. This equals to 200 RN hours a week. The applicant indicates that they will have eight full time patient care technicians during operating years one and two. This equals to 320 PCT hours a week.

One page 64 the applicant indicates that there will be a total of nine direct care staff for each shift offered in the facility. The applicant indicates that they will have a morning shift that runs from 6 am to noon and an afternoon shift that runs from noon to 5 pm. The applicant indicates that they will operate these shifts six days a week. This means that the facility will be open six days a week for eleven hours a day with nine staff available all open hours. The staffing need indicated by the applicant is a total of 594 hours a week (6 days X 11 hours a day X 9 direct care staff = 594). The total direct care staff available, which includes five Registered Nurses and eight patient care technicians, is a total of 520 hours. The applicant is short 74 hours a week, which equals 1.85 full time equivalent positions.

The applicant failed to provide any indicated or documented Registered Nurse hours for the home training modalities indicated in the application.

The applicant stated on page 56, "BMA has projected a slight decrease in the commercial payor mix at FMC Laurinburg. BMA has proposed (in the CON application for FMC Scotland County, filed September 16, 2013, in response to the July 2013 SDR Scotland County Need Determination) that BMA would redirect one or two of the patients with commercial insurance to the FMC Scotland County facility." The applicant states, "BMA will be working with the admissions team to re-direct one or two new dialysis patients, who reside on the north side of Laurinburg or Scotland County, with commercial insurance, to the FMC Scotland County facility". The applicant is proposing to manipulate patients so that the FMC Scotland County can have enough commercial pay patients to show a profit in operating year two. What happened to patient choice?

Fresenius Medical Care touts that they operate 90 dialysis facilities in North Carolina. Fresenius Medical Care through Jim Swann, their Market Development and Certificate of Need Director in North Carolina, agreed to participate in the gathering of the patient data as of December 31, 2012 by county. That patient data was used in the development of the July 2013 Semiannual Dialysis Report. All of the dialysis providers in North

Carolina agreed to provide this information. All of the providers were given the same amount of time to collect and submit this information to the Division of Health Service Regulation Planning Section. All of the providers were provided a spread sheet prior to the publication of the July 2013 Semiannual Dialysis Report so that they could review the data that they and all other providers had submitted. This was one last chance to correct any errors that the providers may have made in the collection of the data.

As soon as the July 2013 Semiannual Dialysis Report was published indicating a need determination in Nash and Scotland Counties, Fresenius stated that they had made mistakes in the county of residence in three facilities that caused the need determinations. Fresenius has not provided any indication that they made mistakes in reporting data from any of the other 87 facilities, but only facilities in counties where there was a declared need determination.

The applicant goes to great length at several places in the application to explain that the two counties in July 2013 Semiannual Dialysis Report that resulted in a need determination for new dialysis stations by county were a result of errors made by either a Clinical Manager or an Area Manager. In Scotland County, the BMA of Laurinburg patient data was prepared by the Clinical Manager and certified by the Area Manager, who is also identified in the BMA of Laurinburg as the Director of Operations for the facility. This indicates that two professional staff gathered and certified the data. On page 9 of the application the Director of Operations "provides management and oversight for the following facilities:

BMA Lumberton	BMA Laurinburg
FMC Robeson County	FMC Scotland County
BMA Red Springs	FMC Pembroke
FMC St. Pauls"	

The Area Manager/Director of Operations has responsibility for a total of seven facilities. If she reviewed all seven of the ESRD Data Collection documents and certified their accuracy, it seems reasonable to assume that if she saw data at one or more facilities that did not seem right or accurate that she would have asked some questions about the data.

It is apparent that the BMA of Laurinburg CON application is filled with errors, inconsistencies and required documentation. The application is fatally flawed and should be denied.

DaVita HealthCare Partners Inc. and Total Renal Care Inc. reserve the right to provide additional comments about the BMA of Laurinburg application at the public hearing.

Sincerely,



William L. Hyland
Director of Healthcare Planning