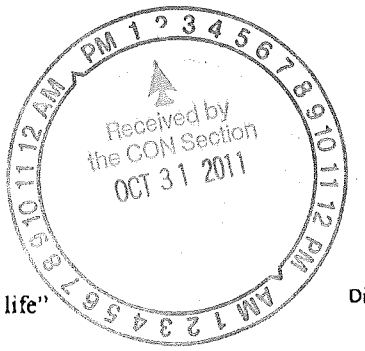

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William L. Hyland
Director of Healthcare Planning

DaVita " he/she that gives life"

October 31, 2011

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

RE: Project #M-8752-11/Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek/Establish a new 11 Station Dialysis Facility Pursuant to the County Need Determination Published in the July 2011 SDR/Harnett County

Dear Mr. Smith:

BMA offers a Certificate of Need application to develop an 11-station dialysis facility in Harnett County. The applicant is planning to offer only 9 of those stations to in-center patients who do not have an infectious disease. The plan is to utilize one station for patients who require isolation and another station for home hemodialysis training. The applicant is proposing to tie up a dialysis station that would provide ongoing in-center dialysis services to 4 patients in order to train two patients each year during the first two years of operation.

The applicant also indicates on page 2 of their application that they will offer Nocturnal Dialysis. As you review their application, you will note that the applicant does not mention Nocturnal Dialysis again in the application. The applicant makes no provisions for the staffing needed for Nocturnal Dialysis – at least one Registered Nurse and one Patient Care Technician.

The applicant fails to have a Notary Public witness the signature of the company officer certifying the application. The applicant fails to offer any capital expenditure for the project on the Invoice – Certificate of Need Application Fee Sheet.

The applicant fails to identify a developer for the project. The applicant fails to identify the owner of the property as the lessor, since the owner will offer to build to suit.

The analyst will note in Section I of the application all of the services the various corporate offices will provide to the facility. However, in Section X.4., operating

expenses, the applicant fails to identify any management fees associated with the provision of all of these identified support services.

There is significant information about the Quality of Care and UltraCare Programs that Fresenius Medical Care offers and promotes. However, there have been serious questions raised recently in Cumberland County about the quality of services that Fresenius facilities provide in some of their Cumberland County facilities. Cumberland County is contiguous to Harnett County. The Anderson Creek facility is proposing to serve some Cumberland County patients. This may mean that the Nephrology practice in Cumberland County will be following patients at Anderson Creek.

In Section II. the applicant is required to provide a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide. The applicant failed to provide either. What the applicant did was provide a couple of emails from David Wells, Fresenius Area Manager. This does not constitute the compliance with the requirement.

The need determination in Harnett County is based on a need for 11 additional dialysis stations to serve the in-center patient population living Harnett County. The applicant proposed to serve 9 out-of-county patients.

On pages 13 and 14 of the application, the applicant presents maps with a bunch of dots that they say identifies where patients live. There is no documentation that supports the dots on the map.

The applicant presents a confusing methodology to justify just enough patients to stay away from having over 100% utilization of the 9 stations dedicated to in-center patients who do not have need for an isolation station. One of the assumptions is that an in-center patient from Harnett County will jump to home hemodialysis training the day the facility is certified. That is an unreasonable assumption the therefore negates the theory that only 36 patients will be receiving in-center dialysis at the end of operating year one.

The applicant fails to provide the required response to the statement in Section II.b.8.

> "(8) A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."

The applicant responds to the issue of training on page 26, indicating that all new employees are required to successfully complete an eight-week training program. Later in the application the applicant indicates that all of the employees at Anderson Creek will be new hires. The Licensure and Certification Section will not certify the program with all new employees who have only had eight weeks to train up. A new employee needs at least a three-month train up period with an additional minimum of three months of close observation in the performance of their duties.

The applicant did not disclose that any new Patient Care Technician must pass a National Certification examination within 18 months of hire.

The applicant notes in Section II. of the application that Duke University Medical Center will provide transplant services. In Section V. of the application, the applicant states that UNC Medical Center will provide transplant services. Neither center provided a transplant agreement or a letter of intent to enter into a transplant agreement. On page 50 of the application, the applicant states that there is a copy of a transplant agreement with UNC in Exhibit 17. Exhibit 17 contains two emails from David Wells, Area Director of Operations with Fresenius Medical Care.

In Section VII. the applicant does not provide sufficient direct care staff to adequately operate an 11-station facility. The applicant will need a total of 180 hours of patient care technician hours to adequately treat the in-center patients. They have only offered 3.5 FTE's, which equates to 140 hours. They understated the PCT FTEs by one full-time position.

The applicant has identified enough RN time to operate two shifts a day, six days a week. However, the applicant has not provided staff for the Nocturnal shift offering stated in Section I. of the application.

The applicant identifies a home training nurse position that will work 8 hours a week. The applicant fails to provide sufficient RN Home Training Nursing hours to train a home hemodialysis patient five days a week for five weeks. In additions, this same nurse will be training PD patients. The hours presented are unreasonable.

On a page with no number, the applicant states that they will plan to operate a third shift when the facility reaches the 37th patient. I assume that will be in additions to the Nocturnal Shift that the applicant proposes, but does not staff.

The applicant states that the Home Training RN will supervise the two home training stations. If that person is to supervise the stations, who will be working to train the patients? If two stations are to be utilized for home training as stated, then there will only be 8 stations for the in-center patients.

On page 62 the applicant states that direct patient care staff will be required to pass an examination at the end of their training period to assure they are qualified to fulfill the requirements of their position. However, passing an examination is no guarantee that the patient care technician can stick patients with accuracy and can competently operate a dialysis machine, setting it up and monitoring the patient.

An RO system for a dialysis facility costs about $90,000. The applicant understated the cost of this required system.

In Section X of the application, the applicant states that the commercial insurance rate identified ($1,375) does not reflect actual reimbursement rates and should not be taken as absolute. The applicant then goes on to calculate the projected commercial treatments at the $1,375 rate. This provides inaccurate and overstated revenue.

The applicant leaves it to the analyst to figure out if there was more revenue than expanses during the first two operating years. The operational revenue has been overstated by the applicant's own admissions concerning the commercial insurance reimbursement.

The operational expenses have been understated based on not accounting for Nocturnal staffing and one PCT FET not identified in Section VII. The applicant also fails to identify management expenses.

The comments above are not all inclusive of the many issues you will find with the FMC Anderson Creek CON application.

Sincerely,

William L. Hyland
Director or Healthcare Planning