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DaVita " he/she that gives life"

William L. Hyland
Director of Healthcare Planning

November 1, 2010

Mr. Craig R. Smith, Chief
Certificate of Need Section
North Carolina Department of Health and Human Services
701 Barbour Drive
Raleigh, North Carolina 27603

RE: Project #G-8594-10/Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Asheboro/Relocate entire facility and add 10 stations for a total of 46 stations upon completion of this project and 2 other projects/Randolph County
FID #100968

Dear Mr. Smith:

BMA offers a Certificate of Need application to relocate the current twenty-seven-station facility and add a total of nineteen stations for a total of forty-six stations. They are requesting to expand their existing facility by 41%. BMA presents assumptions that would eliminate any other provider from ever developing a dialysis facility in Randolph County; therefore, continuing the monopoly that the applicant has enjoyed for years in Randolph County.

In Section II.1(b)(7) the applicant provides the following assumptions:

a. BMA assumes that the patient population of Randolph County will continue to increase at a rate commensurate with the Randolph County Five Year Average Annual Change Rate as published in the July 2010 Semiannual Dialysis Report. That rate is 9.3%.

Response:
A year earlier, on December 31, 2008, the rate of 4.2%.
Two years earlier, on December 31, 2007, the rate was negative .1%
Three years earlier, on December 31, 2006, the rate was negative 1.5%
Four years earlier, on December 31, 2005, the rate was negative .8%
Five years earlier, on December 31, 2004, the rate was negative .8%
Six years earlier, on December 31, 2003, the rate was 10.9%

The assumption that Randolph County will continue to increase at a rate commensurate with the Randolph County Five Year Average Annual Change Rate as published in the July 2010 Semiannual Dialysis Report is not a true statement based on past growth experience in Randolph County.

b. Based upon a conversation with Dr. Martin Webb, Medical Director of BMA Asheboro, BMA assumes that the physicians of Carolina Kidney Care will not pursue admitting privileges at another dialysis facility in Randolph County.

Response: The Nephrologists associated with Carolina Kidney Associates and other area Nephrology practices will be offered admitting and rounding privileges at the Total Renal Care of North Carolina, LLC (TRC) facility in Randolph County. If they choose not to secure the privileges, then any of their patients who choose to transfer to the TRC facility will secure a new Nephrologist. The only reason for Dr. Webb makes that statement in his letter and BMA-Asheboro offers as an assumption is to provide the CON Section Project Analyst with a reason to allow BMA Asheboro to continue to operate as a monopoly in Randolph County. Note that none of the other ten physicians associated with Carolina Kidney Associates, P.A. indicated in their letters that they would not pursue admitting privileges at another dialysis facility in Randolph County.

c. BMA assumes that the patients of BMA Asheboro are not likely to change nephrology physicians due to the physician-patient relationship. The nephrology physicians of Carolina Kidney Associates have been providing care for the ESRD patients in Randolph County for many years. Their practice is well established in the community and patients have lengthy relationships with them. The CKA physicians are the only nephrology group with admitting privileges at the BMA Asheboro facility. If patients were inclined to change physicians, another nephrologist, or nephrology practice would already be in existence in Asheboro and would have admitting privileges at the BMA Asheboro facility; BMA Asheboro, like all BMA facilities, is open to other nephrologists to apply for privileges. To the extent that this is not the case, then BMA must assume that other nephrology practices have not established themselves in response to market forces. Thus, the patients of the area are extremely satisfied with CKA and are not going to change physicians.

Response: The July 2010 Semiannual Dialysis Report indicated that there is a need for ten additional dialysis stations in Randolph County. The SDR projected that by December 31, 2010 there would be a need for forty-six dialysis stations, needing to serve 147.6 in-center dialysis patients. BMA Asheboro is the only dialysis provider in Randolph County at present. They are operating only twenty-seven dialysis stations and were serving 111 in-center patients as of December 31, 2009. BMA-Asheboro has a total of thirty-six certified and approved stations. If all of the stations were certified, BMA-Asheboro would have been at a 77% utilization rate.

No one is indicating that any of the patients presently being served by the Carolina Kidney Associates Nephrologists would transfer to a TRC Randolph County facility.

The assumption that TRC Randolph County made was that all patients living in Randolph County would want to dialyze at a facility in Randolph County, which is the same assumption that FMC –Brunswick County used in their approved Certificate of Need application.

d. Based upon the BMA Asheboro facility census, SEKC zip code reports for July 1, 2010, and the July 2010 SDR, it is obvious that some dialysis patients are going out of county for in-center dialysis, and currently all home dialysis patients are going out of county for their care. Three of these patients are going to BMA Greensboro, and have indicated their support for this project.

Response: The three patients dialyzing out of county should be dialyzing in Randolph County if they really want to. Can one deduct that BMA-Asheboro is denying Randolph County patients the opportunity to dialyze in Randolph County? Does BMA-Asheboro have to have a 46-station facility for these three patients to dialyze in their home county? Is it reasonable to assume that these patients should be included in their growth rates for the Randolph County 46-station facility?

e. Based upon the dynamics of the patient population in Randolph County, BMA assumes that patients are NOT likely to change nephrology physicians in order to receive dialysis at an alternate facility in Randolph County.

BMA is affiliated with the Carolina Dialysis – Siler City dialysis facility. That facility is affiliated wit the Renal Research Institute and The University of North Carolina at Chapel Hill. BMA is aware that Carolina Dialysis – Siler City is providing treatment for eight in-center dialysis patients from Randolph County; these patients reside in Asheboro or areas east of Asheboro. It is not likely that these patients will leave the physicians or access to a major medical facility and its teaching institution.

Likewise, zip code 27370 is on the west side of Randolph County (See Map 2, Exhibit 27). This zip code is proximate to High Point, Guilford County, North Carolina. According to the SEKC zip code report there are 17 dialysis patients residing in this zip code; 13 are in-center patients and four are home dialysis patients. BMA Asheboro is serving one of the in-center patients; thus, there are 12 in-center patients and four home patients who are served by another provider. Due to the proximity to High Point, it seems logical to conclude that these patients are not likely to leave Carolina Dialysis-Siler City. The Wake Forest University facilities are linked with a premier teaching institution and the team of nephrologists associated with Wake Forest University Baptist Hospital.

Response: BMA-Asheboro offers no written proof of their assumption that patients are NOT likely to change nephrology physicians. Also, BMA-Asheboro offers no written proof, other than Dr. Webb, that area Nephrologists would not apply for admitting and rounding privileges at a TRC Randolph County facility. BMA-Asheboro has no idea where patients are receiving their dialysis treatments, unless they are patients in a Fresenius-operated facility.

f. With regard to the patient population going out of county for dialysis, and specifically with regard to the discussion above, BMA does not believe that there is a centralized location within the County which could potentially entice these two disparate groups of patients (only 20 in-center patients) to forgo their existing physician-patient relationship and transfer their care ot another facility centrally located within Randolph County.

Response: It is interesting that this was the opposite approach that Fresenius Medical Care took in the Brunswick County 13-station deficit. They indicated that a geographically-located facility in Supply, in Brunswick County, would draw dialysis patients from all corners of Brunswick County. The Certificate of Need Section, the Director of Health Service Regulation and the North Carolina Court of Appeals all agreed with that assumption presented by Fresenius. Now, the same Fresenius would have you reverse tose findings to that they can continue to monopolize Randolph County dialysis services.

g. BMA assumes that the Randolph County patients who were projected to transfer to BMA Asheboro from BMA Southwest Greensboro in CON Project ID #G-8489-10 will continue with their transfer plans, subsequent to development of that project, commensurate with this project, at the new location. Thus, their transfer will essentially be delayed by approximately six months at BMA projects this project to be completed as of June 30, 2010 (G-8489-10 was projected to be completed as of 12.31.11).

Response: Again, is BMA-Asheboro denying transfer of these patients from BMA Southwest Greensboro? Why are they not been offered transfer before now? Why is BMA holding up the development of the G-8489-10 project?

h. BMA does propose to establish a home dialysis program at BMA Asheboro subsequent to relocation and expansion of the facility. BMA necessarily assumes that the home patient population of BMA Asheboro will start with three Randolph County patients currently receiving their home care through BMA Greensboro; BMA does expect the home patient population will increase. BMA also assumes that initial growth of the home patient population will exceed recent Randolph County experience. This will be a result of the additional services becoming available within the County.

Response: BMA Asheboro has been in existence for many years. They are just now thinking about establishing a home training program in Randolph County. Just because the service will be offered in Randolph County, the interest in home training will increase and the number of home-trained patients living in Randolph County will increase.

BMA-Asheboro has it all wrong. The ability to grow a home program begins with education. Patients need to know all of the modality alternatives before going on dialysis or while they are on hemodialysis. The Nephrologists, along with the patient, make the modality decision. The provider has the responsibility, working

with the Nephrologist, to continually educate the hemodialysis patient, on other alternative modalities.

One may question why BMA did not include the establishment of home modalities and nocturnal dialysis options in one of their prior CON applications. Or one might wonder why BMA did not request relocation of their existing facility in one of the other CON applications. The only reason they are doing this now is to try to keep their monopoly of being the only dialysis provider in Randolph County.

Beginning on page 14 of the BMA-Asheboro application, BMA –Asheboro provides their methodology. This continues through page 18. Since BMA-Asheboro did not use the assumption that they used in Brunswick County, which was that ESRD patients residing in Brunswick County will want to dialyze at a facility in Brunswick County, they had to come up with a methodology utilizing and manipulating their current patient population at their Asheboro facility.

On page 16 of the BMA application, the applicant begins playing with smoking mirrors. In the fourth block the applicant adds three (3) patients to their census, citing another approved CON application. Again, if BMA-Asheboro were not denying transfer of these patients, they would already be dialyzing in their center. Or is it that the patients do not intend to ever transfer their care?

There is a flaw in the methodology presented by BMA-Asheboro. Here is how the calculations should have been shown:

Begin with 106 in-center patients utilizing the 5-year AACR:

January 1, 2010-December 31, 2010 – 106 in-center patients X 1.093 =115.858
January 1, 2011-December 31, 2011 – 115.858 in-center patients X 1.093 = 126.632794
January 1, 2012-June 30, 2012 – 126.632794 in-center patients X 1.0465 = 132.5211189
July 1, 2012-June 30, 2013 – 132.5211189 in-center patients X 1.093 = 144.8456922

- **Round down to 144 in-center patients residing in Randolph County**
- **Add 5 in-center patients to the 144 in-center patients = 149 in-center patients**
- **Deduct the 3 change of modality home hemodialysis and home peritoneal dialysis patients – the patient base cannot grow at more that 9.3% based on the methodology presented by BMA-Asheboro = 146 in-center patients**
- **Utilization rate for 146 in-center patients based on 46 certified stations = 146/46 = 3.1739 patients per stations or 79.3% utilization.**
- **The CON application fails to meet the threshold of 3.2 patients per station or 80% utilization**

BMA-Asheboro further manipulates the projections based on their statement on page 14, "Note: BMA recognizes that in CON Project ID #G-8489-10 that BMA

reported fewer patients for the December 31, 2009 census. BMA regrets the inconsistency....". A-Asheboro is attempting to justify a methodology that just doesn't work.

BMA-Asheboro states in Section XI.2. "BMS proposes to lease space from a property developer not yet identified. BMA has selected property located at 187 Brower Chapel Road in Asheboro as its secondary site." BMA-Asheboro identifies two secondary sites, but no primary site based on the above statement.

In the response to XI2(f), "Is the site in a flood plain or an area with a probability of flooding? If yes, please explain how this will affect the construction and operation of the facility", BMA-Asheboro looks to the Fresenius Medical Care Project Manager to make the final evaluation of the flood plain issue. There are no credentials identified in the application indicating that Mr. Drye is an expert in the determination of whether a parcel of property in a flood plain zone has a high enough elevation to warrant the determination that "BMA would not be faced with flood issues in the event of a floor in the area". BMA-Asheboro presents no information from any individual associated with Randolph County or Asheboro City government concerning the flood zone issue.

Based on information contained in the CON application, BMA-Asheboro provides no zoning ordinance documentation about how one goes about zoning change in the city or county.

In Section VII.10. the applicant indicates the number of direct care staff for each shift operated in the facility. They begin indicating that the facility will offer two shifts a day, six days a week with 10 direct care staff. To fulfill this requirement, BMA-Asheboro would need 600 hours of direct care staff (patient care technicians).

BMA-Asheboro indicates that they will be offering a third shift three days a week from 5 pm to 10 pm. For these shifts, they indicate that they will have 4 direct care staff working three days a week for 5 hours a day. To fulfill this requirement, BMA-Asheboro would need 60 hours of direct care staff (patient care technicians).

BMA Asheboro indicates that they will be offering nocturnal dialysis three days a week from 9 pm to 5 am. For these shifts, they indicate that they will have 3 direct care staff working three days a week for 8 hours a day. To fulfill this requirement, BMA-Asheboro would need 72 hours of direct care staff (patient care technicians).

In Section VII.1 BMA-Asheboro indicates that they will have 17 direct care staff available to fill the direct care staffing requirements. Based on a work week of 40 hours, they will have available 680 direct care staffing hours each week (40 X 17 = 680)

Based on their staffing of the facility they will need 732 direct care staffing hours each week. BMA-Asheboro has presented available staffing that cannot provide the direct care support in the hours provided each week. They fall 52 hours short.

BMA-Asheboro is also not providing enough direct care staff for the 44 in-center stations it plans to operate six days a week for 10 hours a day. They must provide 11 direct care workers (1 staff to 4 patient ratio) in order to maintain certification. BMA-Asheboro only provides for 10 direct care workers.

In total, base on their staffing pattern, BMA-Asheboro is 112 hours short on direct care staffing of their proposed 46-station facility.

The comments above are not all inclusive of the many issues you will find with the BMA-Asheboro CON application. Total Renal Care of North Carolina, LLC reserves the right to bring up these and other issues in response to any comment by

Sincerely,

William L. Hyland
Director or Healthcare Planning