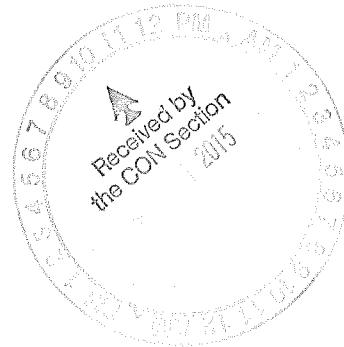




TOPCATS Division
2321 West Morehead Street
Charlotte, NC 28208

April 30, 2014



Ms. Martha Frisone, Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Project #L-11011-15/Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Tarboro/Develop a new 10-station dialysis facility in Tarboro (Edgecombe County) by relocating six stations from BMA East Rocky Mount (Edgecombe County) and four stations from Greenville Dialysis Center (Pitt County)/Edgecombe County

Dear Ms. Frisone:

The Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Tarboro certificate of need application to develop a new facility in Tarboro via transfer of six dialysis stations from BMA East Rocky Mount and four dialysis stations from the Greenville Dialysis Center should be denied for the following reasons:

The applicant provides 39 patient letters that indicate support for the project. Two of the 39 letters indicate that the patient has Stage 5 End Stage Renal Disease and are projected to begin dialysis within the next six months. A lot could happen between now and the time these patients are ready for dialysis. They could relocate, get a transplant, recover kidney function, decide to go on home hemodialysis or peritoneal dialysis, etc. Therefore, the project analyst should discount those two letters. In addition, a Fresenius employee has testified in a hearing before an Administrative Law Judge that the company is working very closely with Nephrologists who treat End Stage Renal Disease patients to encourage the patients to select either home hemodialysis or peritoneal dialysis as their modality of choice.

Two of the remaining 37 letters are signed by patients who treat at the Dialysis Care of Edgecombe County facility that are on peritoneal dialysis. Therefore, the project analyst should discount those two patients. One patient lives in Tarboro and the other patient lives in MacClesfield. Both communities are in Edgecombe County.

One of the remaining 35 patient letters is signed by a patient who is a patient at Dialysis Care of Edgecombe County, but lives in East Rocky Mount in Edgecombe County. This patient lives 3 miles from the East Rocky Mount facility operated by Fresenius and 14 miles from the Dialysis Care of Edgecombe County facility. The letter signed by the patient states, "... is close to my home". The patient already has a Fresenius facility that is close to his home in Rocky Mount. Therefore, the project analyst should discount this letter.

The applicant indicates in Section III.7 on page 51 the patient origin of the facility for the first two operating years. The applicant indicates that 30 of the patients will live in Edgecombe County, two of the patients will live in Halifax County and one patient will live in Martin County.

Two of the remaining 34 patient letters are signed by patients who live in Pitt County. Since the applicant projects that they will not serve any patients who live in Pitt County during the first two years of operation, the project analyst should discount the two letters signed by the patients who indicate they live in Pitt County. One of these two patients indicates that they live in Fountain County. The town of Fountain is located in Pitt County.

One of the remaining 32 patient letters is signed by a patient who lives in Scotland Neck, less than two miles from the Fresenius Halifax County Dialysis. The patient is currently receiving dialysis at Dialysis Care of Edgecombe County. The patient signed a letter that states, "Patients on dialysis have many hardships, especially arranging transportation three days a week. The proposed new BMA dialysis facility in Tarboro will be convenient for me and is close to my home". The patient lives less than two miles from a Fresenius facility and over 22 miles from Dialysis Care of Edgecombe County, which is just over a mile from the proposed Fresenius Tarboro facility. That patient should consider transfer to the facility near to their home. Therefore, the project analyst should discount this letter.

Two of the remaining 31 patient letters are signed by patients who live in the 27843 zip code which is located in the Hobgood Community in Halifax County. The Fresenius dialysis facility where they are currently receiving services is located in Scotland Neck in Halifax County. These two patients live closer to the Scotland Neck facility than to Tarboro. The patients travel about 9 miles to their dialysis now. If they were to transfer to the proposed Fresenius facility in Tarboro, they would be traveling at least 14 miles from their homes. The letters that these two patients signed stated, "Patients on dialysis have many hardships, especially arranging transportation three days a week". The location of the proposed new facility, near the hospital in Tarboro, is closer to my residence location and would be more convenient for me than my current dialysis facility". These patients live in Halifax County and are currently receiving their dialysis treatments at a Fresenius facility in their home county that is closer to their homes than the proposed facility. The applicant does not address the issue of how these two patients would arrange transportation from their home county to another county. Therefore, the project analyst should discount these letters.

All of the letters signed by the patients make the same statements. All of the letters state, "Dialyzing at the new location would mean less time involved in transportation and more time for me and my needs". The primary site for the proposed Fresenius facility is located exactly .96 of a mile from Dialysis Care of Edgecombe County. It is .41 of a mile from the Dialysis Care of Edgecombe County facility to the intersection of Western Boulevard and Hospital Lane. That means that it is .55 of a mile from the intersection of Western Boulevard and the proposed Fresenius Tarboro facility.

These patients signed a letter stating, "The location of the new facility, near the hospital in Tarboro, is closer to my residence location and would be more convenient for me than my current dialysis". Well, there is no way that the site of the proposed Fresenius Tarboro is closer to their residence or more convenient.

The January 2015 Semiannual Dialysis Report indicates that Dialysis Care of Edgecombe County has 26 certified stations with a utilization rate of 88.46%. However, that calculation does not take into consideration that the facility has nine dialysis stations that have been approved, but are not certified. Taking those nine stations into consideration, Dialysis Care of Edgecombe County has a utilization rate of 65.71%. Fresenius is indicating in their CON application that at least 21 in-center patients dialyzing at Dialysis Care of Edgecombe County will transfer their care to the proposed Fresenius Tarboro facility. Dialysis Care of Edgecombe County had 98 in-center patients as of April 30, 2015. If twenty-one patients were to transfer their care, the facility would have 77 in-center patients and a utilization rate of 55%. This percentage does not take into consideration any growth rate for 2015 or 2016.

The letters signed by patients dialyzing at Dialysis Care of Edgecombe County state, "Continuity of my care is very important to me. My Kidney doctor has told me that Eastern Nephrology Associates will be referring patients to the new facility and seeing patients at the new facility. I understand that the new facility will not involve reuse of dialyzers and that the facility will offer high quality patient care". The applicant proposes to transfer six stations from the BMA East Rocky Mount Kidney Center and four stations from Greenville Dialysis Center.

The first sentence in the paragraph above cites continuity of care and how important it is to the patient. The only continuity of care that the patients will have if they transfer their care to the proposed Fresenius facility is that they will have the same Nephrologist. The patients will have to go through the experience of getting used to a whole new group of employees. They will have to endure someone new sticking them and monitoring their dialysis treatments. This is not continuity of care.

The third sentence in the paragraph indicates that the proposed facility will not involve reuse of dialyzers. As of today, at Dialysis Care of Edgecombe County, 60% of the patients use single use dialyzers (non-reuse). As of June 1, 2015 100% of the patients will be using single use dialyzers (non-reuse).

The last portion of the third sentence indicates that the proposed Fresenius facility will offer high quality patient care. DaVita HealthCare Partners, the entity that owns Dialysis Care of Edgecombe County, is the national leader in quality patient care and patient clinical outcomes. The Centers for Medicare and Medicaid services has established a star rating program for all dialysis centers in the United States. Below is a description of the rating system.

What is the CMS Five-Star rating system and why is it important?

The new Five-Star rating system was created as a way to help patients decide where they want to receive healthcare by providing more transparency about dialysis center performance. The rating system measures dialysis centers on seven different quality measures and compiles these scores

into an overall rating. Stars are awarded for each center's performance. We applaud CMS' intentions of making clinical quality more accessible to dialysis patients and will continue to work with them to improve these measures.

Below is the CMS Five-Star rating for the facilities listed:

Dialysis Care of Edgecombe County – operated by DaVita HealthCare Partners – 3 Stars

BMA East Rocky Mounty Kidney Center – operated by Fresenius Medical Care – 2 Stars

Greenville Dialysis – operated by Fresenius Medical Care – 3 Stars

As you can see, there is no difference between Dialysis Care of Edgecombe County and Greenville Dialysis. BMA East Rocky Mount Kidney Center has a 2-Star rating. BMA East Rocky Mount and Greenville Dialysis have an average rating of 2.5 Star rating as opposed to the 3-Star rating of Dialysis Care of Edgecombe County. See below information about the CMS Five-Star Rating Program:

What does the Five-Star Rating mean?

CMS is using a Five-Star Rating in an attempt to measure patient outcomes at dialysis facilities in order to give consumers a better picture of how the center is performing. The following nine individual quality measures will be considered and rolled up to establish the rating:

1. Standardized mortality ratio (SMR)
2. Standardized hospitalization ratio (SHR)
3. Standardized transfusion ratio (STrR)
4. A measure of spKt/V
5. A measure of hypercalcemia
6. The percentage of patients with an AV fistula
7. The percentage of patients dialyzing with a catheter for more than 90 days
8. The percentage of pediatric hemodialysis (HD) patients who had enough wastes removed from their blood during dialysis
9. The percentage of adult peritoneal dialysis (PD) patients who had enough wastes removed from their blood during dialysis

How is Five-Star calculated?

The Five-Star Rating methodology comes from the distillation of seven data points and forces the data from all centers into an industry-wide bell curve, which will be displayed on Dialysis Facility Compare (DFC). Where dialysis centers fall on the national bell curve will determine whether they receive a five-, four-, three-, two- or one-star rating.

What is a bell curve?

A bell curve is a rating system, that when drawn, is in the shape of a bell. The industry-wide distribution of the bell curve imposed by CMS means:

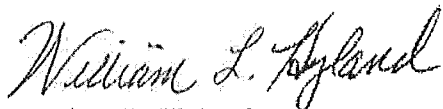
- 10 percent of all centers will receive a five-star rating
- 20 percent of all centers will receive a four-star rating
- 40 percent of all centers will receive a three-star rating
- 20 percent of all centers will receive a two-star rating
- 10 percent of all centers will receive a one-star rating

The letters of support signed by patients who are currently dialyzing at Dialysis Care of Edgecombe County are not fully accurate based on the information above. There is really no reason given in the letter that was written by a Fresenius employee of why a patient who is dialyzing in the Dialysis Care of Edgecombe County would even consider transferring their care to the proposed Fresenius Tarboro facility.

In discounting the letters above for the reasons stated, the applicant has overstated the support for this project and should be denied.

DaVita HealthCare Partners Inc. and Total Renal Care of North Carolina, LLC reserve the right to provide additional comments about the FMC Tarboro CON application at the public hearing.

Sincerely,

A handwritten signature in cursive script that reads "William L. Hyland".

William L. Hyland
Director of Healthcare Planning