

May 1, 2018

Ms. Lisa Pittman, Assistant Chief  
Ms. Gloria Hale, Team Leader  
Mr. Mike McKillip, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
809 Ruggles Drive  
Raleigh, North Carolina 27603

Re: Public Written Comments,  
CON Project ID # L-11495-18, Whitakers Dialysis

Dear Ms. Pittman, Ms. Hale, and Mr. McKillip:

Bio-Medical Applications of North Carolina, Inc. offers the following comments on the above referenced Certificate of Need application filed by Total Renal Care of North Carolina, LLC.

Total Renal Care of North Carolina (TRC) has filed an application to relocate a total of 10 dialysis stations from Dialysis Care of Edgecombe County to develop a new 10-station dialysis facility in Whitakers, Edgecombe County. The applicant has filed an application which does not conform to multiple CON Review Criteria, and therefore must be denied.

The application by TRC quite simply can not be approved.

1. The application fails to conform to Review Criterion 3 and should be denied. The applicant provided 39 patient letters of support—34 patient letters from patients residing in zip code 27886—all stating that the new facility would be more convenient.

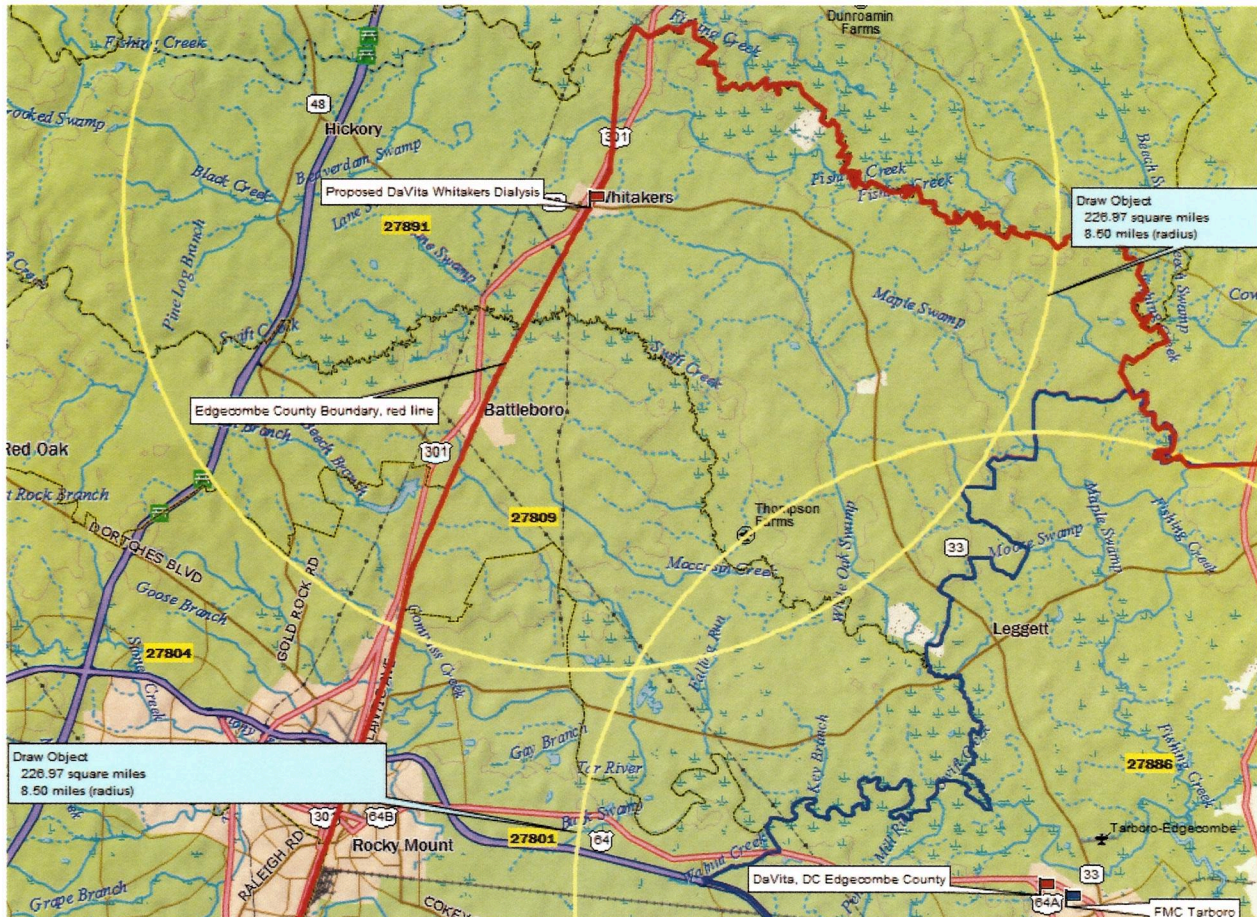
The letters are a form letter. Each of the letters is identical. BMA is not suggesting that there is something wrong with using a form letter; in fact BMA frequently uses form letters in its own CON applications. Form letters serve to convey the same sentiment, in the same manner, in the same language. Form letters are simple, straight forward, and in large measure assist with communicating a consistent message to the dialysis patient population.

However, the Agency must evaluate patient letters of support more thoroughly, and focus on the veracity of the letter. The Agency frequently uses the phrase, “reasonable and supported”. The Agency must not overlook the “reasonable” prong of this phrase.



Certainly, the applicant provided letters of support. However, there is nothing reasonable about the 34 patient letters from zip code 27886. The question from the Analyst should be, “where is 27886 in relation to Whitakers, NC?”

The following map depicts the northwestern areas of Edgecombe County (red line is the County boundary), Whitakers (noted on the map), the zip code 27886 boundary (blue line) and an 8.5 mile ring (light yellow) around both the proposed location of the facility, as well as an 8.5 mile ring around the location of the DaVita Dialysis Care of Edgecombe County facility in Tarboro.



The map very clearly depicts that the 27886 boundary is closer to the DC Edgecombe County facility, than it might be to Whitakers. In fact, except for the very northern part of 27886, all of the area of 27886, north and west of Tarboro is within 8.5 miles of the DC Edgecombe County facility. On the other hand, absolutely none of 27886 is within 8.5 miles of Whitakers and the location for the proposed new facility.

Thus, one must question the validity of the statements in the patient letters of support:



*"I live in zip code 27886...*

*...Having my dialysis treatments at Whitakers Dialysis would be more convenient for me. I could travel between my home and that location more easily and quickly..."*

Based upon the location of the two facilities, and the distance from Whitakers to the closest point of zip code 27886, it simply is not reasonable to suggest that a facility in Whitakers would be more convenient, or that travel would be quicker, or that one could travel more easily from any point within 27886 to Whitakers as opposed to the DC Edgecombe County dialysis facility.

BMA is not suggesting that there are not 34 patient letters of support.

BMA is suggesting that the statements within the letters simply do not align with reality, and are therefore not reasonable. To the extent that they are not reasonable, the CON Project Analyst must conclude that the patient projections are un-supported. Therefore the application cannot be found conforming to CON Review Criterion 3.

To the extent that the projections of the patient population to be served are unreasonable, then the resultant financial projections are similarly unreasonable and cannot be relied upon. Therefore the application should be found non-conforming to CON Review Criterion 5.

The CON Project Analyst must not overlook the reasonable prong. It is not enough to simply count the letters and conclude that the applicant has met its burden. Surely, there must be some analysis by the Project Analyst with regard to the letters and their statement. It is not as simple as saying the applicant has 39 patient letters of support.

The January 2018 SDR, Table A reports that there were 203 in-center patients residing in Edgecombe County as of June 30, 2017. BMA was serving 119 of these patients. The DC Edgecombe facility was serving 80 Edgecombe County residents at its facilities. The CON Analyst must consider the reasonableness that 34 of these 80 live closer to Whitakers than to DC Edgecombe.

Aside from the 34 patients of 27886, one of the patients resides in 27864, the Pinetops zip code. Pinetops is south of Tarboro, and 27864 is south of the 27886 zip code. Exactly how is it reasonable for the Agency to conclude that a dialysis facility in Whitakers, 27 miles from Pinetops, is more convenient for a patient residing south of 27886?

The Agency must not be misled by the form letters, by the un-reasonable assertions of the applicant!

It is not reasonable to expect patients to travel further for dialysis. Those patients who live in the area of Tarboro and Pinetops, within Edgecombe County are obviously closer to the DaVita DC Edgecombe County facility.

2. The applicant has proposed an unreasonable growth rate for its Peritoneal Dialysis patient population. The applicant suggests that number of PD patients residing in Edgecombe County will increase by 50% in the second year of operations. However, the applicant has not provided any basis for growth rates of this nature.

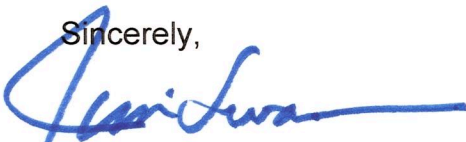
The assertions of the applicant that the home PD patient population would increase by 50% is simply inconsistent with the realities of the patient population of the Edgecombe County. The Edgecombe County ESRD patient population is increasing at a rate of only 0.05%. How can such a projection of 50% increase be deemed reasonable? It is not.

As an additional consideration, consider the Required State Agency Findings for CON Project ID # P-8641-11, an application by Total Renal Care off North Carolina, LLC to add three stations to their Wallace Dialysis Center in Duplin County. On page 8 of the findings, the Project Analyst notes that the applicant *“provides no assumptions, methodology or projected utilization for home dialysis patients.”* The Agency expects the applicant to explain the basis for its projections of patients to be served. In this case, the applicant has failed to provide a basis for its projected patient population to be served, and the application should be denied.

Again, the applicant fails with regard to CON Review Criteria 3 and 5.

The applicant has provided an application which cannot be approved. Therefore the application must be denied. If you have any questions please contact me at 910-568-3041, or email [jim.swann@fmc-na.com](mailto:jim.swann@fmc-na.com).

Sincerely,



Jim Swann  
Director of Operations, Certificate of Need