



March 30, 2016

Ms. Martha Frisone, Assistant Chief
Healthcare Planning and Certificate of Need
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Re: Public Witten Comments, CON Project ID # J-11131-16
Total Renal Care of North Carolina, LLC, d/b/a Oak City Dialysis

The application submitted by Total Renal Care of North Carolina, LLC (TRC) presents the CON Section with an incomplete picture, inaccurate information, and an application which is not conforming to the CON Review Criteria and Rules for End Stage Renal Disease Treatment facilities. The application should be not be approved, or conditionally approved. The following information identifies multiple failures within the application.

1. The applicant's projections of patient population to be served are unreasonable. The application should be found non-conforming to CON Review Criterion 3.

The applicant has projected to serve six in-center patients who live in Durham County. It is a road trip of approximately 15 miles from the eastern most edges of Durham County to the primary site for the proposed facility. DaVita, parent to Total Renal Care (TRC), has proposed to develop the East Durham Dialysis facility less than one mile from the Durham-Wake County boundary. It is unreasonable to expect that patients will leave Durham County to seek dialysis at a facility approximately 15 miles distant when patients could very easily obtain dialysis within a mile of the Durham-Wake County boundary, at a facility operated by the same organization.

The letters from the six Durham County residents should be rejected by the Agency. The applicant has proposed to serve a total of 35 patients at the end of the first year, which includes the six Durham County patients. If the six Durham county patients are not counted, then the applicant has projected to serve only 29 patients and is therefore non-conforming to the Performance Standard.

The applicant has included letters of support from six patients dialyzing at Southpoint Dialysis, in Durham County. It is not reasonable to expect that patients dialyzing at Southpoint Dialysis will transfer their care to the new facility. The patients would have to change nephrology physician in order to be admitted at the new facility. The nephrologists admitting patients to Southpoint Dialysis are not identified as nephrologists who will have admitting privileges at Oak City dialysis.

Similarly, it is not reasonable to expect that patients dialyzing at Durham West Dialysis, who reside in Durham County, will transfer their care to the new facility. These patients (1) would have to change nephrology physician in order to be admitted at the new facility, and (2) would have to travel much further for dialysis care. The nephrologists admitting patients to Southpoint Dialysis are not identified as nephrologists who will have admitting privileges at Oak City dialysis.

If the projection to serve Durham County residents is determined to be unreasonable, the applicant fails to meet the performance standard at 10A NCAC 14C .2203. Applications for new facilities must project a minimum of 10 stations with 3.2 patients per station per week at the end of the first year of operations. Absent the patients from Durham County, the applicant can not demonstrate conformity with the Performance Standard Rule.

2. The applicant has assumed on page 17 that at least one of the nine PD patients who signed a letter of support would transfer to the new facility. However, on page 14 the applicant has indicated that the facility would have two PD patients at the end of the first year of operations. The applicant has offered no explanation of how the home PD patient population would increase, other than to say they expect one new patient each year. The question is where does that patient come from? The applicant has not proposed that the new home PD patient would change modality from in-center dialysis. The applicant has not offered any explanation of how, or why a new PD patient is going to present to the facility for home dialysis care.
3. To the extent that the applicant's projections of a patient population to be served are not reasonable, not credible, and unsupported, then the resultant financial projections of revenues to be earned are similarly unreasonable. The application should be found non-conforming to CON Review Criterion 5.
4. The applicant has not relied upon the most current information. On page 19 of the application, the applicant provided information for the Wake Forest Dialysis facility patient census as of June 30, 2015. The applicant had access to more current information and should have reported information for December 31, 2015.
5. The applicant suggests on page 21 that the application was "*submitted to provide geographic accessibility of in-center hemodialysis to a patient population located in and near the northeastern part of Raleigh.*" Patients residing in Durham, Johnston and Pitt Counties do not reside in or near the northeastern part of Raleigh. The applicant has provided misleading information.
6. On page 24 of the application the applicant suggests the services are needed at the proposed location because of the significant number of patients residing in that area of the county. This statement is not credible. The applicant has proposed



to serve only one patient residing in the zip code for the proposed facility: 27616. Of the 26 patient letters from Wake Forest Dialysis facility patients, only one—a single patient—resides in zip code 27616 (see chart on page 23 of the application).

7. The information on page 26 of the application is inconsistent with other representations within the application. The applicant suggests that only 22 Wake County patients will transfer from Wake Forest Dialysis Center. Yet, the applicant provided only 21 letters from Wake County patients.
8. The applicant has not provided funding for all of the staff projected to be a part of the facility. The chart on page 26 fails to account for the Regional Operations Director. However, the applicant has suggested Ms. Lauren Coyle, ROD, will be the CEO for the facility. Certainly Ms. Coyle is compensated for her services. Consequently the application financial projections are incomplete and should not be accepted as reasonable and credible.
9. The applicant fails to provide accurate information for Ancillary Services, CON Review Criterion 8. The applicant suggests that Wake Med Hospital would be responsible for pediatric nephrology. Pediatric Nephrology is not listed on the Wake Med website as a service offering by the hospital.
10. The applicant has not provide an agreement with a hospital for Acute dialysis as required by Criterion 8. There is an unsigned letter in Exhibit I-1 for such services but this appears to be a draft letter and not executed by any party.
11. The applicant has not identified any physician with a medical practice in Raleigh, or Wake County who will admit patients to the facility. In response to Question #3 on page 41-42, the applicant suggests Dr. Lateef will provide medical coverage for the patients. However, a review of the website for Dr. Lateef indicates his office practice is in Burlington, Alamance County, and not in Wake County. In fact, his website does not include any indication of his affiliation with the facility, or any other facility in Wake County.

It is a distance of greater than 60 miles from Burlington to the proposed facility. It is not reasonable to expect that dialysis patients from Raleigh, or northeast Raleigh will travel 60 miles to Burlington to see a nephrologist when there are multiple nephrology physicians in Wake County and there are two internationally acclaimed hospitals with active nephrology practices closer than Burlington (UNC and Duke).

12. The applicant has not provided an accurate response to Criterion 9. The applicant proposes to serve one patient from HSA VI, Pitt County. However, the applicant has suggested that 100% of the patients reside within HSA IV. The CON Agency



should either reject the applicant's representations of serving a patient from Pitt County, or in the alternative, find the application non conforming to CON Review Criterion 9.

13. The applicant has provided ambiguous information related to facility expenses. The applicant suggests several times that it has used *average per tx value for DaVita's North Carolina Facilities*. However, the applicant has direct experience in the Raleigh / Wake County market area, and it has suggested direct experience with the patient population to be served. More detailed information for the Wake Forest Dialysis facility would have been more appropriate for use in this application. Thus the applicant's financial projections are suspect and should be found non conforming to CON Review Criterion 5.
14. The applicant has underfunded its proposed rent expense. The applicant proposed a rental rate of \$120,000 for Operating Year 1. However, the information in Exhibit K-4 suggests the rental rate for 8,000 square feet would be \$15.00 NNN per square foot, plus an additional \$3.00 per square foot for Operating expenses. Thus, rent should be calculated at \$18.00 per square feet. Based on the applicants information, rent for 8,000 square feet would be \$144,000 annual. Thus the applicant failed to adequately fund the rent for the building.
15. The applicant has not provided a signed letter from an officer of the company committing funds for the project. There is no letter from the company authorizing Mr. Hyland to commit funds for the project. Thus, the project is not funded and should be found non-conforming to Criterion 5.
16. Because the applicant has failed to provide reasonable and credible projections of a patient population to be served, the applicant should be found non conforming to CON Review Criterion 4. An applicant providing an unreasonable projection of patient population is not projecting the best alternative.
17. The applicant has not presented an application which is the best alternative and an application which fails to conform to CON Review Criterion 5. The application should be found non-conforming to CON Review Criterion 18a. An application which is not fully conforming to all CON review criteria should not be determined to be cost effective and one which enhances competition.

SUMMARY:

The TRC application to develop Oak City Dialysis facility is replete with non-conformities and should be denied. The application fails to conform to CON Review Criteria 3, 4, 5, 8, 9 and 18a. For these reasons, the application should be denied.

If you have any questions, please contact me at my new office number, 910-354-3712,



Sincerely,

Jim Swann, via email submission

Jim Swann
Director, Certificate of Need