



October 31, 2012

Mr. Craig R. Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, N.C. 27603

Re: CON Project ID # J-10038-12, Total Renal Care of North Carolina, LLC d/b/a
Wake Forest Dialysis Center, CON Application to add five dialysis stations /
Wake County
FID #

Dear Mr. Smith:

Please accept this letter as Public Written Comment for the above noted CON application. BMA believes that the application is non-conforming to CON Review Criteria 3, 4, 5, 6, and 18a. Due to the non-conformities as described below, BMA suggests this application should be denied.

- 1) The applicant has "utilized an annual growth rate of 21%". The Wake County Five Year Average Annual Change Rate is only 4.2%. To the extent that the applicant has forecast to serve some patients from Franklin County, BMA notes that the Franklin County Five Year Average Annual Change Rate is only 7.7%. Both of these change rates are published in the July 2012 SDR.

Absent some explanation, it is inappropriate to utilize a growth rate which is so disproportionate to the County Five Year Average Annual Change Rate. In this case, the rate is a magnitude of five times the change rate published for Wake County.

As an additional consideration, this facility is actually located in Raleigh zip code 27614. As of March 31, 2012, there were only 12 ESRD patients residing in 27614. Of these 12 ESRD patients, three were home dialysis patients. In addition, BMA notes that the 27614 zip code has increased by 4 patients over a four year period from March 2008 through March 2012. This is the equivalent of a single patient per year.

As noted in the preceding paragraphs, the growth of the patient population does not support the unreasonably high growth rate of 21% as employed by the applicant. The applicant has used the Facility Need Methodology to

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justify its utilization of 21%. The applicant has not provided any other justification for such an unreasonably high growth rate.

It is not uncommon for small facilities with small patient census to generate high growth rates. Consider for example a small 10 station facility which meets the 80% utilization threshold with 32 patients. The growth of a single patient, from 31 to 32 patients in the six month period typically considered by the methodology, results in a growth rate of 6.5%. This represents a growth rate fully 50% higher than the whole of Wake County as noted in the July 2012 SDR.

BMA suggests that in the case at hand it would have been more appropriate for the applicant to employ a more traditional approach and use the Wake County Five Year Average Annual Change Rate of 4.2%. If the applicant had used such a growth rate, there would be no basis to challenge the growth projections as may have been supplied by the applicant. However, in this case, the applicant has not provided any justifiable rationale for a growth rate of this magnitude, fully five times greater than the County Five Year Average Annual Change Rate. Consequently the applicant has provided projections of patient population to be served which is not based upon reasonable projections. Thus the application is not conforming to Review Criterion 3.

Further, because the applicant's financial projections are based upon unsupported and unreasonable growth rates, the financial projections are likewise questionable and should not be accepted. Consequently the application fails to conform to Review Criterion 5.

To the extent that the application is non-conforming to Review Criteria 3 and 5, then the application is also non-conforming to review criterion 4.

- 2) The applicant has not identified a hospital capable of providing acute dialysis services for the patients of the facility. In the Table of responses at V.1, the applicant has identified Franklin Regional Medical Center as the hospital where patients would be referred for acute dialysis treatment. It is BMA understanding that Franklin Regional Medical Center does NOT offer acute dialysis treatments at this time. Further, the hospital has not offered acute dialysis within the most recent 12 month period. Thus, Franklin Regional Medical Center would be required to obtain a Certificate of Need approving the offering of acute dialysis services.

GS 131E-176 (16)d indicates that dialysis services would be considered a "new institutional health service" if the services have not been provided within the most recent 12 month period by or on behalf of the facility.

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BMA encourages the CON Project Analyst to confirm that Franklin Regional Medical Center has not provided acute dialysis in the most recent 12 months. Consequently, the Application is not conforming to 10A NCAC 14C .2204 (9).

- 3) The application is not conforming to Review Criterion 14. The applicant has not provided any evidence that it meets the clinical needs of health professional training programs in the area. It has not provided an agreement. It has not provided a letter inviting local schools to consider the facility. Thus, the applicant is not conforming to Criterion 14.
- 4) The application is non-conforming to CON Review Criterion 6. The applicant has used an unreasonable growth rate, resulting in unnecessary duplication of health services. Several of the BMA facilities in Wake County are operating with less than 80% utilization. Thus, these facilities have capacity to accept additional stations. BMA notes specifically that the FMC Eastern Wake facility, less than 5 miles from the DaVita Wake Forest facility is operating at 71.43% utilization. To the extent that nearby dialysis facilities are under utilized, and absent any reasonable rationale for utilization of a growth rate of 21%, the application does seek to create excess capacity and unnecessarily duplicate existing health services.
- 5) The applicant has not proposed to serve any Medicaid patients and therefore is non-conforming to Criterion 13C. The applicant has not offered any explanation with regard to it's proposed payor mix. The applicant has not proposed to serve any patients who are dependent upon Medicaid as their primary payor source.
- 6) The applicant has provided incorrect and misleading information in response to CON Application Question V.(b). Wake County is not contiguous to Green, Lenoir, Pitt, Wilson or Wayne Counties. The CON Project Analyst should consider this inaccuracy as representative of the CON application as a whole.
- 7) The applicant has failed to provide adequate staffing for the facility. The applicant has suggested that it offers Home Training for patients dialyzing at home. However, the applicant has failed to identify any staff to provide the home dialysis training and support. Consequently, the applicant has failed to satisfy the requirements of Review Criterion 7.

To the extent that the applicant has failed to provide staffing for home dialysis training and support, the applicants financial projects are consequently questionable. Absent any qualified staff, how will the applicant generate home dialysis revenues? Consequently the applicant should be found non-conforming to CON Review Criterion 5.

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BMA reserves the right to offer additional criticism of the application at the Public Hearing to be conducted by the CON Section on November 19, 2012.

As a consequence of the foregoing, BMA suggests that the DaVita CON application to add five dialysis stations at its Wake Forest Dialysis facility should be denied.

If you have any questions regarding these comments, please contact me at 919.896.7230, or via email, jim.swann@fmc-na.com.

Respectfully,

Jim Swann, via email

Jim Swann, Director
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