FRESENIUS KIDNEY CARE

Certificate of Need
3390 Dunn Road, Eastover, NC 28312
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December 31, 2019

Mr. Mike McKillip, Project Analyst
Ms. Fatima Wilson, Team Leader
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 # J-11833-19, Downtown Raleigh Dialysis

Dear Mr. McKillip and MS. Wilson:

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

The applicant has filed an application which must be denied for myriad reasons.

"CRITERION (3)": - G.S. 131E-183(a)(3) and G.S. 131E-183(b)

Criterion (3) - *"The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed."*

In-center discussion:

The applicant has identified a population which will not be well served by the proposed facility. The applicant includes letters of support from 31 patients residing in Wake County. A review of the letters indicates that 19 of 31 letters, 61% of the patients, reside further away from the facility than to either Oak City Dialysis or Wake Forest Dialysis.

DaVita has indicated the new location *"was selected because it will allow Total Renal Care of North Carolina, LLC to **provide better access** to the patient population identified and reflected in the patient letters…"*[1] [emphasis added].

- The closest point of 27614 to the Poole Road location is 8.67 miles away.

[1] Application, page 31, last paragraph in response to Section E, Question 2(c).

- The entirety of 27614 is within 8.67 miles of the Wake Forest facility.

- The closest point of 27616 to the Poole Road location is 4.14 miles away.

- Nearly the entirety of 27616 is within 4.14 miles of the Oak City facility; areas of 27616 not within this 4.14 mile radius are east of the Oak City facility and a greater distance from the proposed location.

Traveling further for dialysis is not going to provide better access to care. It is well known within the dialysis community that patients generally prefer to receive dialysis at a facility closest to their residence. It is not reasonable to assume that a patient will drive further for dialysis, especially when the patient would have to bypass another facility which is operated by the same provider with the same physician coverage.

There is nothing in the DaVita application to suggest that the location on Poole Road is more convenient, or will provide better access to care for the 19 patients residing in these two zip codes (27614 and 27616). The applicant has provided no information to support the assumption/assertion that patients will actually travel further for dialysis care at the proposed new location.

If even one patient does not complete the transfer (as projected), then the applicant will not realize 32 patients dialyzing on 10 dialysis stations as of December 31, 2022. Thus, the applicant will fail to satisfy the performance standard at 10A NCAC 14C .2203(a).

It is incumbent upon the applicant to provide reasonable and credible projections of the patient population to be served. In this case, it simply is unreasonable to expect that dialysis patients will travel further for dialysis care.

Home discussion:

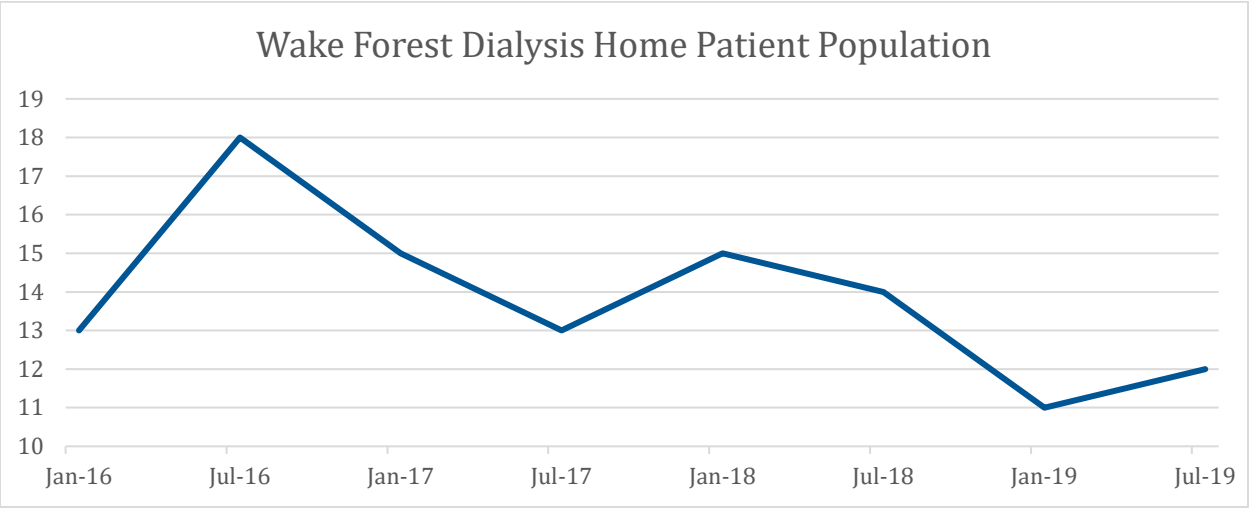
In addition to the unreasonable projections for the in-center patient population, the applicant has also provide unreasonable, an unsupported projections of the home dialysis patient population to be served by the facility. The applicant includes the following statement on page 21 of the application:

> *"It is reasonable to assume that the Downtown Raleigh Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth."*

The applicant has not provided any reasonable assumptions regarding growth of the home patient population. Further, an assumption of one new patient each year stands in stark contrast to the realities of the applicant's recent experience with home therapies at the Wake Forest Dialysis facility. Wake Forest Dialysis is the source for the 10 stations projected for relocation. Wake Forest Dialysis is the current dialysis facility for the majority of the patients projected to transfer to the new facility. And, Wake Forest Dialysis is

presumably served by the same attending/referring physicians as would be attending/referring at the new location.

The following chart depicts the overall decline in the home patient population of Wake Forest Dialysis, as reported in the indicated SDR/Patient Origin Report.



In the January 2016 SDR, Wake Forest Dialysis had 13 home patients. In the current SDR, July 2019, Wake Forest Dialysis had 12 home patients. Thus, the Wake Forest Dialysis track record directly contradicts the assumption of the applicant. DaVita has not been increasing their home patient population. Their home patient population has experienced a net decline of one patient over a three and one half year period.

It is not reasonable to project one new home patient each year, and the CON Agency should reject this assumption.

The applicant fails to satisfy the second prong of CON Review Criterion 3.

> *"…the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed."*

ON page 24, the applicant's proposed patient population was largely based on US Census Bureau data, which is not specific to the dialysis population. The applicant failed to utilize available data regarding the actual population of dialysis patients in the service area. Surely, the applicant has access to the patient population of Wake Forest Dialysis (Section L of the application includes demographic information for Wake Forest Dialysis). However, the applicant includes the following statement:

> *"It is reasonable to assume that an estimated percentage of total patients for each group during OY2 would be similar to the percentages reported in Section L, Question 1 and 3."*

Here however, the applicant has included only information from US Census Bureau. That information is not reflective of the ESRD Patient Population of Wake Forest Dialysis. There are striking differences in the percentages of women, elderly, and racial and ethnic minorities, and handicapped persons. The applicant suggests by its own projections that it will **not** be providing adequate access to care for patients of these demographic groups.

- The total of the populations by ethnicity (American Indian, Asian, Black or African American, Native Hawaiian, White or Caucasian, Other, and Declined) does not sum to 100% for the TRC application. The applicant has provided incomplete projections of the population to be served.

- The applicant relied upon the US Census Bureau to project a very low percentage of African American patients to be served by the facility. This is an important factor.

  - DaVita reports a much higher African American percentage of its patient population at Wake Forest Dialysis: 55.2%.

  - In the 2010 Randolph County Competitive Dialysis Review[2], the CON project analyst noted in the discussion of Criterion 13 that *"[I]t is widely held that race impacts the incidence of kidney disease."* This is obviously borne out in the Wake Forest dialysis facility. Why would the percentage be so dramatically different in the Downtown Raleigh facility which is planned to serve the same existing patient population?

- DaVita has not projected any handicapped persons to be in the facility. The US Census Bureau reports under the heading of "Health", "With a disability, under age 65 years, percent, 2013-2017". The US Census Bureau includes this definition on its website:

> ***Definition***
> *In an attempt to capture a variety of characteristics that encompass the definition of disability, the ACS identifies serious difficulty with four basic areas of functioning – hearing, vision, cognition, and ambulation. These functional limitations are supplemented by questions about difficulties with selected activities from the Katz Activities of Daily Living (ADL) and Lawton Instrumental Activities of Daily Living (IADL) scales, namely difficulty bathing and dressing, and difficulty performing errands such as shopping. Overall, the ACS attempts to capture six aspects of disability: (hearing, vision, cognitive, ambulatory, self-care, and independent living); which can be used together to create an overall disability measure, or independently to identify populations with specific disability types. For the complete definition, go to ACS subject definitions "Disability Status."*

[2] See Attachment 3, extracts from the Required State Agency Findings.

The US Census Bureau reports that 5.8% of the Wake County population under the age of 65 has a disability as defined above. These persons would be considered as handicapped.

Based upon these factors, the applicant failed to adequately address the extent to which underserved groups will have access to dialysis services, and therefore has not appropriately satisfied the second prong of CON Review Criterion 3.

Taken as a whole, the Applicant has provided an application which fails to conform to Criterion 3. The projections of patients to be served include a patient population which does not reside proximate to the proposed location of the new facility, and does reside closer to other facilities operated by the applicant. Further, the applicant has grossly exaggerated growth rate for its home patient population.

"CRITERION (3a)" - G.S. 131E-183(a)(3a)

"In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care."

The applicant has failed to adequately address the needs of the population which will remain at the Wake Forest Dialysis facility after relocation of 10 stations to the Downtown Raleigh facility. By its own calculations, the applicant projects utilization rates greater than 140% on the 11 stations remaining at Wake Forest Dialysis.

"CRITERION (4)" - G.S. 131E-183(a)(4)

"Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed."

The applicant has proposed to develop a facility which is not central to the overwhelming majority of patients projected to transfer their care. It is not reasonable to suggest this location is more convenient for the projected patient population identified by the applicant.

The information provided by the applicant is inaccurate. For example, the applicant suggests is census at Wake Forest Dialysis on December 31, 2018 was 88 patients[3]. However, the SDR, which is comprised of provider self-reported information, indicates the census of Wake Forest Dialysis on December 31, 2018 was only 87 patients[4].

[3] Application, page 31
[4] See July 2019 SDR, Table B, page 52 of the SDR.

In addition, the applicant has provided misleading assumptions with regard to its patient census growth in its Wake County facilities. The applicant suggests that its growth rate has been 9.1%.

However, this is not representative of a five year average. The following table contains information extracted from recent SDRs and provides an indication of the Wake Forest Dialysis facility census for December 31 of the years indicated. This information will demonstrate that the growth of the Wake Forest Dialysis patient census is not 9.1% when calculated as a five year average. The Agency should not rely upon a one-time measurement to justify a growth rate of 9.1% when the Wake County Five Year Average Annual Change Rate is only 3.6%.

Wake Forest Dialysis	July 2015 SDR	July 2016 SDR	July 2017 SDR	July 2018 SDR	July 2019 SDR
	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
Census	73	75	77	83	87
Raw Change		2	2	6	4
% of Change		0.0274	0.0267	0.0779	0.0482

The average change for the five years reported above is only 4.50% not 9.1% as suggested by the applicant.

Even if the Agency were to accept the applicant's reported census for October 30, 2019 as an annual number, the average annual change does not rise to the level of 9.1%.

Wake Forest Dialysis	July 2016 SDR	July 2017 SDR	July 2018 SDR	July 2019 SDR	Provider Reported
	12/31/2015	12/31/2016	12/31/2017	12/31/2018	10/30/2019
Census	75	77	83	87	96
Raw Change		2	6	4	9
% of Change		0.0267	0.0779	0.04829	0.1034

The average change for the five years reported above is only 6.41%, again not 9.1% as suggested by the applicant.

The reality of Wake Forest Dialysis is that its average annual growth does not comport with the suggested 9.1%. This is critically important when the Agency considers the following statement from page 31 of the application:

> *"Giving [sic] this current growth and the potential for a similar trend in the future, maintaining the status quo may result in a scenario where patients …would have a third shift as their only option of dialyzing at a DaVita facility in Wake County…"*

Patients choosing dialysis with DaVita are not going to be forced to a third shift. The applicant has a total of 32 CON approved stations (10 stations at Oak City, and 22 stations at Wake Forest Dialysis). Application of the Wake County Five Year Average Annual Change Rate of 3.6% would produce a census of only 107 patients at DaVita facilities. This equates to a utilization rate of only 3.34 patients per station. The following calculations are used to arrive at this projected utilization.

Assumptions:

A. Oak City has a census of 20 patients as of October 30, 2019.

B. Wake Forest has a census of 96 patients as of October 30, 2019.

C. For purposes of this calculation, BMA has relied upon the Patient Origin Report from the July 2019 SDR. That report indicates that of the 87 patients at Wake Forest Dialysis on December 31, 2018, only 49 were Wake County residents; the remaining 27 patients resided in other counties.

D. Assuming the 27 patients residing in other counties is a constant, the 69 patients residing in Wake County are increased by application of the Wake County Five Year Average Annual Change Rate of 3.6%. The 27 patients are added at appropriate points in time.

Begin with the combined census of Oak City and Wake Forest patients residing in Wake County as of October 30, 2019.	69
Add the 27 patients residing in other counties.	69 + 27 = 96
Project the Wake County patient census forward for 2 months to December 31, 2019.	69 X 1.006 = 69.4
Add the 27 patients residing in other counties.	69.4 + 27 = 96.4
Project the Wake County patient census forward for 12 months to December 31, 2020.	69.4 X 1.036 = 71.9
Add the 27 patients residing in other counties.	71.9 + 27 = 98.9
Project the Wake County patient census forward for 12 months to December 31, 2021.	71.9 X 1.036 = 74.5
Add the 27 patients residing in other counties.	74.5 + 27 = 101.5
Project the Wake County patient census forward for 12 months to December 31, 2022.	74.5 X 1.036 = 77.2
Add the 27 patients residing in other counties.	77.2 + 27 = 104.2
Project the Wake County patient census forward for 12 months to December 31, 2023.	77.2 X 1.036 = 80.0
Add the 27 patients residing in other counties.	80.0 + 27 = 107.0

Thus the following utilization rates are calculated for years indicated:

2020 98.9 patients dialyzing on 32 stations = 3.09 patients per station

2021 101.5 patients dialyzing on 32 stations = 3.17 patients per station

2022 104.2 patients dialyzing on 32 stations = 3.26 patients per station

2023 107.0 patients dialyzing on 32 stations = 3.34 patients per station

Thus, using the Wake County Average Annual Change Rate of 3.6%, the applicant continues to have capacity to accept additional patients at its existing facilities.

Even if the Agency accepts a higher utilization rate, 6.41%, the calculated census would be 116 patients and a resultant utilization rate of 3.64 patients per station.

Begin with the combined census of Oak City and Wake Forest patients residing in Wake County as of October 30, 2019.	69
Add the 27 patients residing in other counties.	69 + 27 = 96
Project the Wake County patient census forward for 2 months to December 31, 2019.	69 X 1.0107 = 69.7
Add the 27 patients residing in other counties.	69.7 + 27 = 96.7
Project the Wake County patient census forward for 12 months to December 31, 2020.	69.7 X 1.0641 = 74.2
Add the 27 patients residing in other counties.	74.2 + 27 = 101.2
Project the Wake County patient census forward for 12 months to December 31, 2021.	74.2 X 1.0641 = 79.0
Add the 27 patients residing in other counties.	79.0 + 27 = 106.0
Project the Wake County patient census forward for 12 months to December 31, 2022.	79.0 X 1.0641 = 84.0
Add the 27 patients residing in other counties.	84.0 + 27 = 111.0
Project the Wake County patient census forward for 12 months to December 31, 2023.	84.0 X 1.0641 = 89.4
Add the 27 patients residing in other counties.	89.4 + 27 = 116.4

Thus the following utilization rates are calculated for years indicated:

2020 101.2 patients dialyzing on 32 stations = 3.16 patients per station

2021 106.0 patients dialyzing on 32 stations = 3.31 patients per station

2022 111.0 patients dialyzing on 32 stations = 3.47 patients per station

2023 116.4 patients dialyzing on 32 stations = 3.64 patients per station

The point of this is to say that despite the assertion by the applicant, no patient would be forced to a third shift.

Siting a facility in an area where the overwhelming majority of the patients would travel further for dialysis is not the best alternative.

Developing a facility in an area where more patients will travel further for dialysis care, when sufficient capacity exists, is not the most effective alternative and certainly leads to unnecessary duplication of existing healthcare resources.

"CRITERION (5)" - G.S. 131E-183(a)(5)

"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."

The applicant has filed incomplete pro formas within Section Q of the application. These are directly related to Criterion 5.

The Form C Utilization does not contain any projection of Peritoneal Dialysis treatment volumes.

The Form F.1a Capital Cost is incomplete. There is no way for the CON Project Analyst to determine what project development cost are and how they are allocated.

The Form F.2 Income Statement does not include any Peritoneal Dialysis treatment revenues. This is determined by comparing the total number of projected treatments with the Form C Utilization. Form C Utilization doesn't include the Peritoneal Dialysis treatment volumes and, consequently the Form F.2 does not include Peritoneal Dialysis revenues.

The Form F.3 Patient Services Gross Revenue similarly does not include Peritoneal Dialysis revenues, despite the applicant's patient projections in Section C of the application.

Given the absence of Peritoneal Dialysis treatment revenues, and despite the projections of peritoneal dialysis patients, there is no way for the CON Project Analyst to determine if the peritoneal dialysis supplies are included in the cost of services.

Moreover, the applicant has not included any costs associated with Central Office Overhead. Surely DaVita incurs a cost associated with the overhead management. There is no indication of costs for the DaVita Teammate Recruiter, or DaVita's School of Clinical Education (both discussed on page 39 of the application). There is no indication of costs for any of the corporate staff above the Facility Administrator. The cost for corporate overhead are not insignificant.

Based upon the above noted failures, the applicant has failed to account for peritoneal dialysis revenues (and possibly expenses) and the applicant not included all necessary costs for operation of the dialysis facility.

"CRITERION (6)" - G.S. 131E-183(a)(6)

"The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."

The applicant has proposed to develop *"a new facility at a different location to better serve patients living in the area of the new facility…"*[5] However, 19 of the 31 patients signing letters of support do not reside in the area of the new facility. The applicant proposes to create unnecessary duplication of existing and approved healthcare resources. Notwithstanding the fact that new dialysis stations are not created by this application, the applicant suggests that the location for the new facility will enhance access to care. Yet 19 of the 31 patients signing letters of support will have to travel further for dialysis care.

"CRITERION (12)" - G.S. 131E-183(a)(12)

"Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans."

The applicant has included a floor plan which is not consistent with other representations of the application. For example, the floor plan does not include a dialyzer reprocessing room. Yet, the staffing information provided on page 39 clearly indicates the facility will include dialyzer reprocessing.

The applicant has suggested on page 44 that the new facility will have 9,600 square feet. However, the floor plant indicates only 8,570 square feet. This difference of more than 1,000 square feet is material.

SUMMARY:

The applicant has provided an application which cannot and should not be approved. Therefore the application must be denied.

- The TRC application contains questionable representations of the patient population to be served.
- The applicant has not offered the most effective alternative.

[5] See page 37 of the application, response to question 2(a).

- The applicant has not provided adequate information related to determination of capital costs, operational costs, and revenue projections.

- The applicant has proposed an unnecessary duplication of healthcare resources.

- The applicant has provided internally inconsistent information with regard to the projected size of the facility; there is a difference of more than 1,000 square feet in the floor plan and the applicant's planned development.

The TRC application fails to conform to CON Review Criterion 3, 4, 5, 6 and 12 and should not be approved.

If you have any questions please contact me at 910-568-3041, or email jim.swann@fmc-na.com.

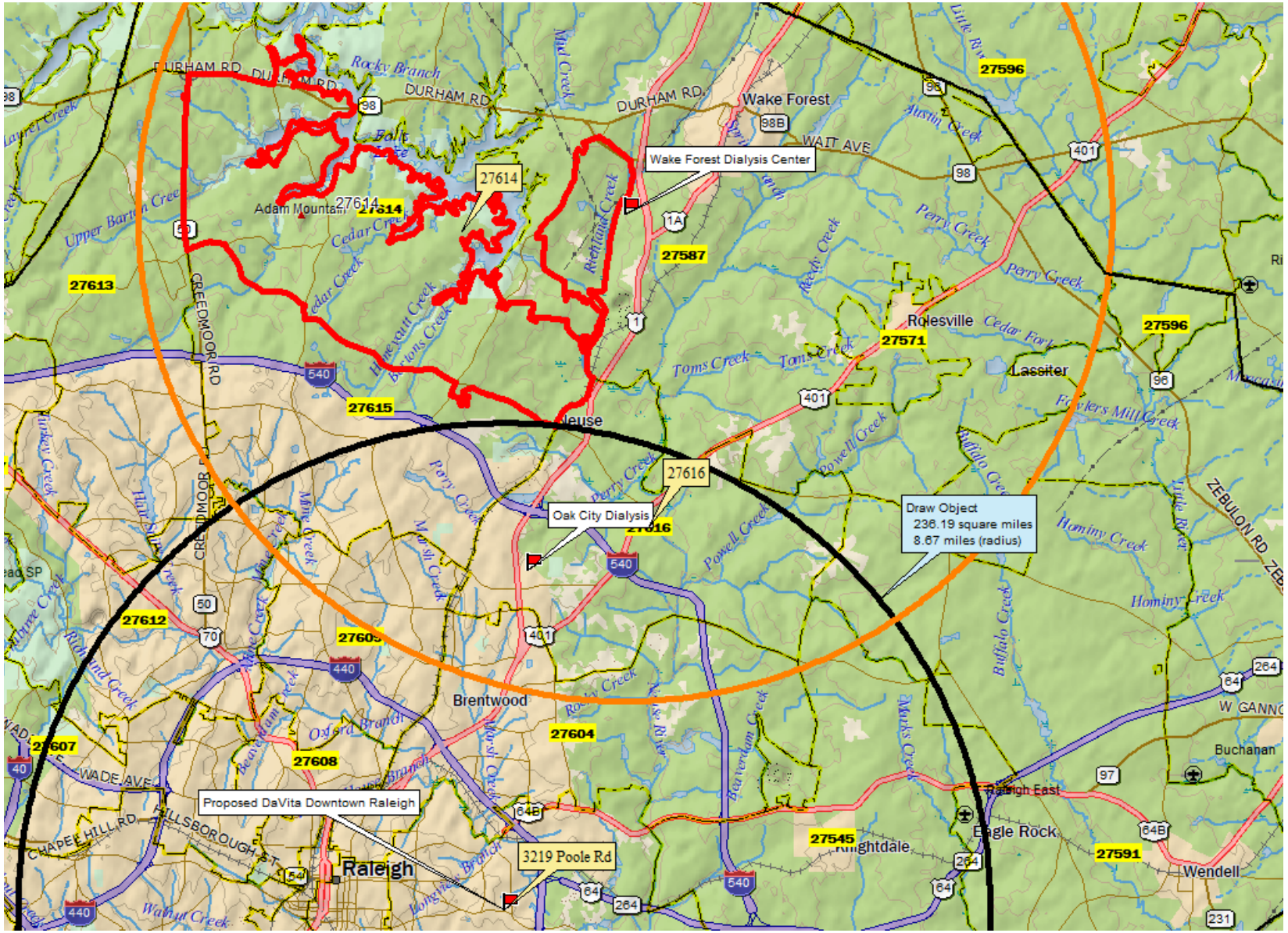
Sincerely,

jim swann via email

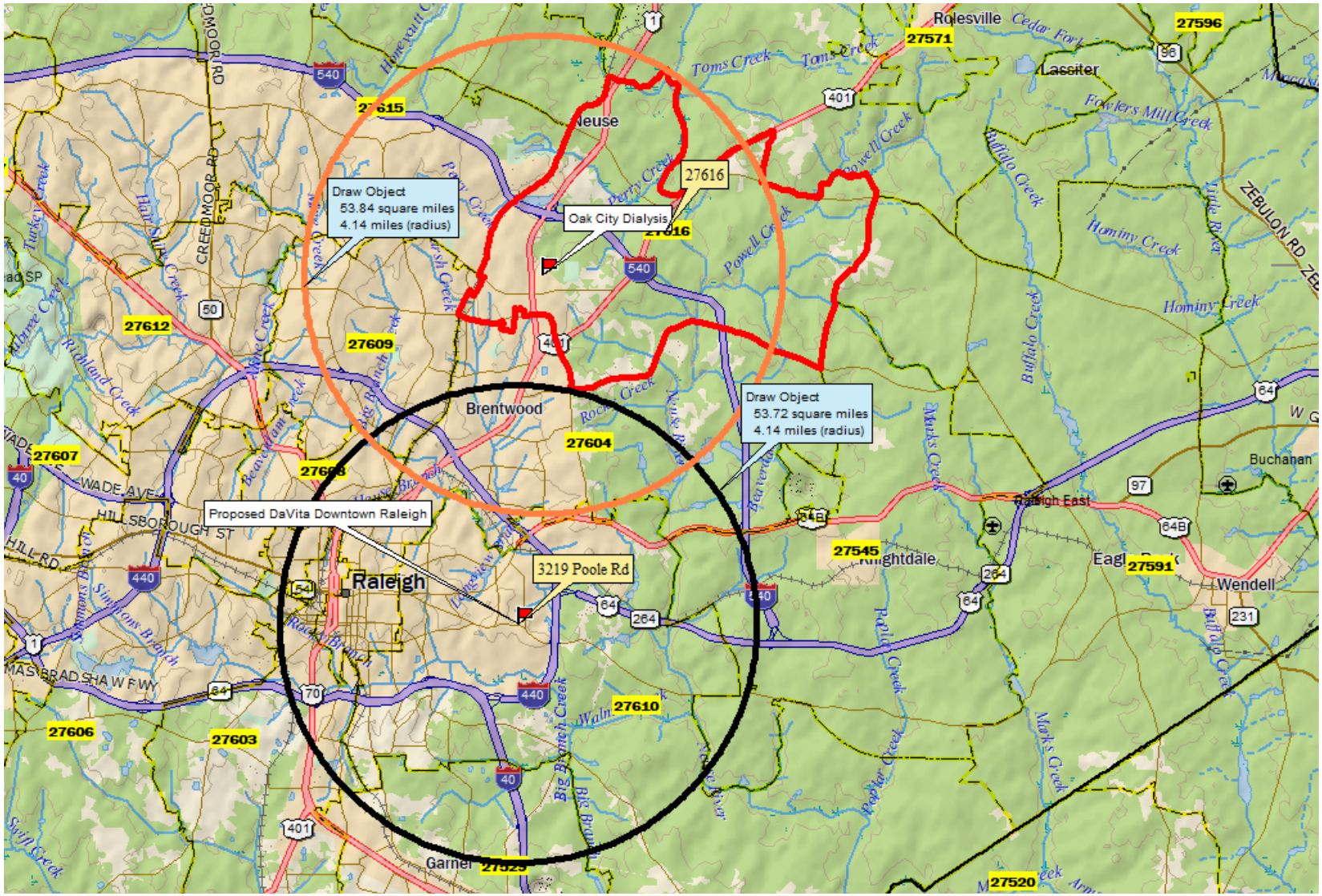
Jim Swann
Director of Operations, Certificate of Need

Attachments:
1) Map, 27614
2) Map, 27616
3) Extract from RSAF, 2010 Randolph County Competitive Dialysis Review

27614 – 10 patient letters



27616 – 9 patient letters



ATTACHMENT- REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA =Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE:	February 25, 2011
FINDINGS DATE:	March 4, 2011
PROJECT ANALYST:	Jane Rhoe-Jones
TEAM LEADER:	Angie Matthes

PROJECT I.D. NUMBER: G-8583-10/ Total Renal Care of North Carolina, LLC (TRC) d/b/a Randolph County Dialysis/ Develop a new 10-station dialysis facility / Randolph County

G-8594-10/ Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Asheboro/ Relocate existing 27-station dialysis facility and add 10 dialysis stations, for a total of 46 stations upon project completion and completion of Project I.D. #G-8420-09 (add 7 stations) and Project I.D. #G-8489-10 (relocate 2 stations)/ Randolph County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NC - TRC
C-BMA

The 2010 State Medical Facilities Plan (SMFP) and the July 2010 Semiannual Dialysis Report (SDR) provide a county need methodology for determining the need for additional dialysis stations. According to the county need methodology, found on page 333 of the 2010 SMFP, *"If a county's December 31, 2010 projected station deficit is JO or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2010 county station need determination is the same as the December 31, 2010 projected station deficit. If a county's December 31, 2010*

persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. "

The following table illustrates the projected payor mix, as provided by the applicant in Section VI. I, page 42:

Payor Source	
Medicare/Medicaid	40.7%
Medic are/ Commercial	24.1%
Medicare	22.2%
Commercial Insurance	5.6%
Medicaid	3.7%
VA	3.7%
Total	100.0%

On page 42, the applicant states:

" These are average percentages of patients who are currently dialyzing at the Dialysis Care of Montgomery County facility. Montgomery County is contiguous to Randolph County and located to the south of Randolph County.

The applicant is correct that Montgomery County is contiguous to Randolph County, however, the applicant fails to demonstrate that the economic status of residents in Montgomery County is comparable to Randolph County and that the payor mix is comparable, as well. US Census Bureau data show substantial differences in the economic status of the two counties. The poverty level in Montgomery County is 40% higher than in Randolph County. The families living below the poverty level is 37.7% higher in Montgomery County than in Randolph County. The per capita income is 21.2% higher in Randolph County than in Montgomery County. Further, the population in Randolph County is 138,134 and in Montgomery County the population is 26,723. Of that population, the black or African American population in Randolph County is 6%; while in Montgomery County it is 19.5%. tis widely held that race impacts the incidence of kidney disease. These indicators impact the eligibility for Medicaid (source: US Census Bureau, 2005-2009 Survey). The applicant fails to provide any documentation which supports its assertion that the payor mix in Randolph County will duplicate that of Montgomery County. Thus it is not reasonable to assume that these two counties, although contiguous, are comparable in economic status.

The applicant did not demonstrate that the projected payor mix is based upon reasonable and supported assumptions . Therefore, the applicant did not demonstrate