FRESENIUS KIDNEY CARE

Certificate of Need
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September 3, 2019

Ms. Martha Frisone, Chief
Ms. Julie Faenza, 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 # J-11743-19, Clayton Dialysis

Dear Ms. Frisone and Ms. Faenza:

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 (1)" – G.S. 131E-183(a)(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."

From the outset, this application is simply not consistent with the State Medical Facilities Plan, and is therefore not consistent with CON Review Criterion 1. The applicant has proposed to relocate 10 dialysis stations from facilities which were serving a combined total of *only three* Johnston County in-center dialysis patients.

Total Renal Care of North Carolina (TRC) has filed an application to relocate a total of 10 dialysis stations to Johnston County 'from two existing Wilson County dialysis facilities—five from Wilson Dialysis and five from Forest Hills Dialysis—to develop a new 10-station dialysis facility in Clayton, Johnston County.

The applicant indicates that it is applying because of the station deficit in the service area and to offer *"a more convenient location to travel to dialysis"*[1].

[1] Section E, Criterion 4, page 32

Consider the definition of "Service area" as codified at NCGS 131E-176 (24a):

> *"Service area" means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*

Chapter 14 of the SMFP includes a series of Basic Principles underlying the projection of need for dialysis stations.

Basic principle #1 of makes the following statement:

> *1. Increases in the number of facilities or stations should be done to meet the* ***specific need for either a new facility*** *or an expansion.*

Dialysis station need is generated by the ESRD patient population residing within the service area. The 12 station deficit in Johnston County in the July 2019 SDR does not mean that a new facility is needed, and certainly the idea of service to only three Wilson County patients does not demonstrate a "specific need for a new facility". DaVita has not demonstrated need for a new facility or to move these stations into Johnston County bi its service to Johnston County patients. To the contrary, under the dialysis station need methodology, an applicant must reasonably project that each dialysis station will be utilized by 3.2 patients, on average. Therefore, three Johnston County patients falls short of demonstrating need for even a single dialysis station, let alone ten.

Moreover, the lack of need for the proposed facility is clear from the nephrologists supporting the application. The nephrology physician is the key to admission at a dialysis facility. Patients cannot self refer for dialysis. The patient's nephrologist must have admitting privileges at the facility in order to refer patients to the facility.

In this application, the Applicant has included letters of support from three nephrologists practicing in Wilson County. The physicians are:

Dr. Will Bynum, Nephrology & Hypertension
Dr. Nirav Jasani, Nephrology & Hypertension
Dr. Anwar Al-Haidary, Wilson Nephrology – Internal Medicine, PA

Drs. Bynum and Jasani have office practices in Wilson and Rocky Mount. A review of their website (www.willbynummd.com) indicates their primary practice focus area is Wilson, and Rocky Mount. Neither of these physicians address Smithfield, Clayton, or any other area of Johnston County. Further, these physicians don't have an office location in Johnston County.

Similarly, Dr. Al-Haidary has an office practice in Wilson. BMA could not locate a website specifically for Dr. Al-Haidary, but an internet search reveals multiple sites with

information about Dr. Al-Haidary. As an example, BMA searched WebMD[2]. This popular website includes the following:

> *Dr. Al Haidary works in Tarboro, NC and 2 other locations and specializes in Internal Medicine and Nephrology. Dr. Al Haidary is affiliated with Nash General Hospital, Vidant Edgecombe Hospital and Wilson Medical Center.*

It appears that the primary practice focus area for Dr. Al-Haidary is not Johnston County. An internet search does address Smithfield, Clayton, or any other area of Johnston County as related to Dr. Al-Haidrary's practice.

To the extent that any of these physicians are serving ESRD patients from Johnston County, they are serving only a very few. On average, they each are treating one Johnston County in-center dialysis patient. The ESRD Data Collection forms for the period ended June 30, 2019 indicate that the DaVita facilities in Wilson County, facilities where these physicians admit and round on patients, were serving a total of only three dialysis patients from Johnston County.

And, this is not new news. The DaVita facilities in Wilson County have traditionally served only a very few patients from Johnston County. A review of patient origin reports from December 2013 through December 2018, and the ESRD Data Collection Forms for the period ended June 30, 2019, all indicate that the number of Johnston County patients served in DaVita facilities in Wilson County has been de minimis at best. Even allowing for service to Johnston County patients by other nearby DaVita facilities, the number of Johnston County residents served in DaVita facilities has not exceeded 15 patients in the past five and one half years, and has fallen dramatically in the past several years.

The Table at Attachment 1 identifies the DaVita facility by name and provider number, and the number of in-center patients from Johnston County which was reported to DHSR Healthcare Planning and Certificate of Need Section for the period indicated. The Table indicates that DaVita facilities serving Johnston County patients over the past five and one half years have not realized any significant growth in their service to Johnston County patients. At the end of December 2013, DaVita facilities were serving three Johnston County in-center patients, representing 1.23% of the total patient population of the county. That number increased to 15 patients, or 5.068% of the Johnston County ESRD patient population for the period ended December 31, 2016. However, since then the number has been declining. At the end of 2018 the DaVita facilities were serving only nine patients residing in Johnston County, and as of June 30, 2019[3] that number was further reduced to five patients residing in Johnston County. The following graph depicts the rise, and fall of that census.

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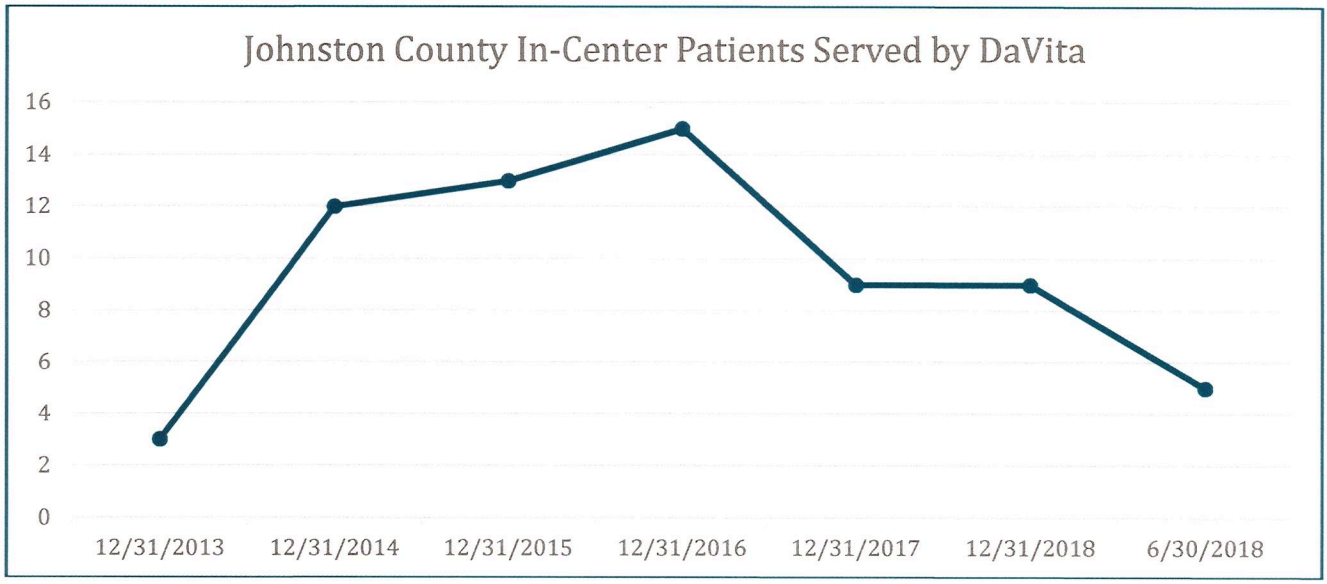
[2] https://doctor.webmd.com/doctor/anwar-al-haidary-8c99227a-8cca-477f-bed9-b453f4b8ad9b-overview

[3] Based on the ESRD Data Collection Forms for June 30, 2019, obtained from DHSR Healthcare Planning.



The applicant has not presented any credible evidence to substantiate service to a significant number of Johnston County ESRD patients. In fact, if the current trend continues, these nephrologists will serve no Wilson County patients at all. The stations that are proposed for relocation overwhelmingly serve a patient population residing primarily in Wilson and other counties.

Not surprisingly, in this application, the applicant has projected that 80% of its patient population would reside in counties other than Johnston.

"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."*

The applicant fails to conform to Criterion 3 on two fronts:

1) The projections of patient population to be served are not reasonable. The applicant has utilized the Johnston County Five Year Average Annual Change rate of 8.3% to project the future Johnston patient population to be served by the facility. However, the reality is that the percentage of Johnston County in-center patients served by DaVita facilities has historically grown at less than 1% annually.

   In the five and one half years since December 31, 2013, DaVita facilities serving Johnston County in-center patients have increased by a mere two patients. At December 31, 2013, DaVita facilities were serving three in-center patients. DaVita facilities reported serving only five in-center patients from Johnston County for the

period ended June 30, 2019. A change of only two patients over 66 months equates to a 0.149031% growth rate as calculated below:

Step 1: Determine total change in patients served, 6/30/2019 – 12/31/2013
5 – 3 = 2 patients

Step 2: Determine % of raw change
Divide 2 patients by 244 Johnston ESRD Patients as of 12/31/2013
2 / 244 = 0.8196721%

Step 3: Determine monthly change
Divide % of Raw Change by 66 months
0.8196721% / 66 = 0.0124193%

Step 4: Determine annual change
Multiply monthly change by 12
.0124193% X 12 = 0.149031%

In other words, the growth actually realized by DaVita for its Johnston County patient population is only 0.149031%, not 8.3% as utilized by the applicant.

The applicant has overstated its change rate. Consequently projections of future patient populations to be served are similarly overstated. The projected patient population of Johnston County residents is unreliable. If the projected patient population to be served is unreliable, it stands to reason that the resultant financial projections are similarly unreliable.

2) 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."*

The applicant has proposed to serve 33 patients at the end of the first and second years of operations. In its projections of patients to be served, the applicant has projected to serve only seven Johnston County residents.

This second prong of Criterion 3 specifically addresses *"all residents of the area".* The applicant has projected that 80% of its patient population would originate outside of Johnston County. Thus, 80% of its projected patient population is not from "the area" of the projected facility. Consequently, the applicant is proposing that only 20% of its capacity is for patients of the area.

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. BMA filed an application to relocate its FMC Stallings Station dialysis facility on May 15, 2019, for the review to commence on June 1, 2019. This application became public information at the time it was filed, and was certainly available to DaVita for review. It would have clearly offered insight into the patient population of the area. The FMC Stallings Station is currently located approximately two miles from the location of the proposed facility.

The following table offers a comparison of the patient population served by BMA in the area, and the proposed patient population of Clayton Dialysis.

	Clayton Dialysis[4]	FMC Stallings Station[5]
Female	51.0%	35.0%
Male	49.0%	65.0%
Unknown	0%	0%
64 and younger	86.7%	56.7%
65 and older	13.3%	43.3%
American Indian	0.9%	0.0%
Asian	0.9%	0.8%
Black or African American	16.8%	55.9%
Native Hawaiian	0.1%	0.0%
White or Caucasian	79.1%	37.3%
Other	2.2%	5.9%
Decline/Unavailable	51.0%	
Medicare	79.9%	88.1%
Medicaid	6.3%	3.7%
Low income persons		48.3%
Racial and Ethnic Minority		57.5%
Handicapped		30.0%

The above table offers very clear distinctions between the FMC Stallings Station facility, which is already serving patients of the area, and the proposed Clayton Dialysis. Consequently, this publicly available data demonstrate the applicant's failure to adequately address the extent to which underserved groups will have access to services.

- The sum of the populations by ethnicity (American Indian, Asian, Black or African American, Native Hawaiian, White or Caucasian, Other, and Declined) exceeds 100% for the TRC application. On the other hand the

[4] See Application, Pages 24, and 48-49
[5] CON Project ID # J-11709-19

FMC Stallings Station population sums to only 99.9%; this is a result of rounding.

- The applicant has used the US Census Bureau statistical information as its basis for projecting the percentage of women to be served in the facility. However, BMA experience is that a significantly smaller percentage of women dialysis patients are in the area.

- The applicant similarly relied upon the US Census Bureau to project the number of elderly patients (65 and older) who might be served by the facility. The reality is that a great many more elderly dialysis patients reside in the area.

- The applicant relied upon the US Census Bureau to project a very low percentage of African American patients to be served by the facility. BMA experience in the area is that there is a significantly higher incidence of kidney failure among African Americans. This is an important factor.

    - DaVita reports a much higher African American percentage of its patient population in Forest Hills Dialysis, 81.2%, and in Wilson Dialysis, 79.8%[6]. Why would the percentage be so dramatically different in Clayton?

    - In the 2010 Randolph County Competitive Dialysis Review[7], 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 Wilson Dialysis and Forest Hills Dialysis facilities. Again, why would the percentage be so dramatically different in Clayton?

- DaVita has not projected any handicapped persons to be in the facility and has reported that the data on handicapped persons was *"not captured"*. To the contrary, data is/was available.

    - The BMA application to relocate the FMC Stallings Station facility was filed two months before the Clayton Dialysis application. Information regarding handicapped persons in the area was available.

    - Further, 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:

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[6] See pages 48 and 49 of the Clayton Dialysis application.
[7] See Attachment 3

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."

The US Census Bureau reports that 10.5% of the Johnston 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.

The applicant has not satisfied G.S. 131E-183(b) and the rules at 10A NCAC 14C .2203(a).

The rules, in short, are the performance standard. The Agency requires CON applicants to demonstrate need using reasonable and adequately supported utilization projections. In the application for Clayton Dialysis, the applicant failed to do so:

(1) The applicant relied on the Johnston County Five Year Average Annual Change Rate of 8.3%, when the clear facts are that the applicant's patient population from Johnston County has increased at a rate of less than 1% as discussed in the preceding pages. The applicant has not demonstrated any reasonable way in which its patient population from Johnston County will actually increase.

(2) The applicant has failed to adequately identify the population to be served and has failed to reasonably project utilization. The applicant projects 80% of the patients to come from other counties. The proposed facility is on the opposite side of Johnston County, meaning that patients residing in Wilson County will actually travel further for dialysis.

(3) The applicant has failed to demonstrate that its services would be available to all residents of the area. The applicant has first projected that 80% of its patient population would come from other service areas, and secondly, has failed to adequately project to serve the historically underserved populations of Johnston County.

There are other Criterion 3 issues:

- The applicant offers misleading information with regard to its patient population. On page 22 of the application, the applicant says that it has *"identified 40 in-center patients who live in Johnston County or live in a county contiguous to Johnston County that have signed letters…"* The reality is that the applicant has identified only five in-center patients who are residents of Johnston County.

- The applicant has included at least one letter from a patient who has also signed a letter of support for the DaVita proposal for Kenly Dialysis, CON Project ID # L-11438-17. There may be others. Patients should not be double counted. Moreover, if two years ago it was closer for a patient residing in Wilson County to travel to Kenly for dialysis, what has changed to now make it more convenient for the same patient residing in Wilson County to travel further for dialysis in Clayton, Johnston County?

  In the Required State Agency Findings for CON Project ID # G-11606-18[8] the CON Agency found the applicant Non-Conforming to CON Review Criterion 3, in part because the applicant failed to appropriately consider patients who had previously projected to transfer their care to another project (see page 6). This applications should be no different. At least one patient has previously indicated an intent to transfer to the Kenly Dialysis facility upon completion of that project.

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 grossly exaggerated growth rate, and include at least one patient letter wherein the patient has indicated an intent to transfer to a totally different project in Wilson County.

"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 is proposing to develop a facility in Clayton which is by their reckoning, "more convenient" for the patients "to travel to dialysis". With the exception of the five Johnston County residents currently served by DaVita, all of the other patients would have to travel further for dialysis. It is not reasonable to conclude that this proposal would be

[8] Decision and Findings Date, December 3, 2018.

more convenient based on the applicant's suggestion that travel is the key to convenience.

The applicant suggests that the location of the proposed facility would be *"more convenient"* for the dialysis patient as opposed to where the patient is currently receiving their dialysis treatment (see patient letters of support). However, the applicant has not explained how this location would be more convenient. Further, the patient letters of support do not explain how this would be a more convenient location.

The patient letter indicates that the new facility would be more convenient *"[F]or a variety of reasons…"* However, there is nothing in the application or the patient letter of support which would suggest the patient even knows the location of the proposed facility.

The US Census Bureau Quick Facts for Clayton (Attachment 2) indicate that Clayton was comprised of 13.51 miles (in 2010; more current data not available). Does the patient know the location of the proposed facility? How is this location more convenient for the patient?

Aside from the five Johnston County patients, exactly how is this proposed location more convenient? Consider the following:

- Wilson County residents would have to travel much further to dialyze at the proposed facility.
  - Straight line distance, the proposed location of the facility is 19.9 miles from the closest part of Wilson County.
  - Conversely, it is much closer only 11.4 miles from DaVita Wilson to the Wilson-Johnston County line.
  - As an additional consideration, it is less than one mile from the recently approved DaVita facility in Kenly to the Johnston County line.
  - Therefore, patients from Wilson County will travel further for dialysis care if they seek dialysis care in Clayton.

- Nash County residents would also have to travel much further to dialyze at the proposed facility.
  - Straight line distance, the proposed location of the facility is 17.6 miles from the closest part of Nash County.
  - Conversely, it is approximately one-third that distance (6.4 miles) from DaVita Wilson to the Wilson-Nash County line.
  - Therefore, Nash County patients will travel further for dialysis care if they seek dialysis care in Clayton

Certainly, travel distance and time are not the only factors associated with convenience. However, the CON Project Analyst has absolutely no way to know what factors are being considered. The patient letters of support are identical form letters, and it is neither reasonable nor believable that thirty-five in-center dialysis patients would voluntarily choose to double or triple their travel distance and travel outside their home county three

times per week for dialysis treatments. There is not a single identified factor which supports the new location being more convenient for non-Johnston County residents/

CON Review Criterion 3 requires an applicant to *"identify the population to be served, and … demonstrate the need that this population has for the services proposed…"* The applicant projects to serve 34 patients in its second operating year, only seven of who would reside in Johnston County. The applicant has not demonstrated any reasonable need that the remaining 27 patients who reside *outside* of Johnston County might have for dialysis services at a facility in Clayton.

"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 appears to have understated its Start-up expenses. The applicant suggests the estimated start-up period is three months. The applicant further suggests the start-up expenses are $166,653.

However, the applicant has not provided any basis for this figure. The applicant suggests on page 36 that start-up expenses *"will include purchasing an inventory of consumable supplies as well as staff labor and training in the timeframe between construction and certification."*

The applicant has not included any expense for rent, housekeeping, depreciation, utilities, insurance, central office overhead, training and travel, and other routine expenses associated with just opening the doors to the facility. It would be reasonable to assume the three months prior to opening would include an amount equal to 25% of the annual operating budget, less a pro rata share of pharmacy and medical supply cost.

1 year	$ 1,308,991.00[9]
25%	$ 327,247.75
Allowance for:	
Pharmacy (first year expense)	$ 127,156.00
Supply (first year expense)	$ 73,359.00
Subtotal	$ 200,515.00
25%	$ 50,128.75
3 months less Allowance above	$ 277,119.00
Budget Amount	$ 166,653.00
Shortfall	$ (110,466.00)

[9] CON Application, Section Q, Form F.4 – Operating Costs

The applicant has not provided adequate funding for the immediate financial needs of the project.

As an additional consideration for Criterion 5, the applicant indicates on Page 9 of the application, in response to Question # 6, that *"[A] subsidiary of DaVita Inc."* will own the building which is to house the dialysis facility. The applicant then follows this with an indication that the owner of the building does not have any joint or common ownership with the applicant.

If the owner of the building is another subsidiary of DaVita Inc., then there is at a minimum a familial relationship. The applicant has failed to fully disclose the relationship between the dialysis facility and the owner of the building. This ambiguity should at a minimum cause the Agency to question veracity of the response provided by the applicant. Further, if there is a relationship, what percentage of the financial burden belongs to the owner of the building? Further, should the related owner be a co-applicant for the project? How can the Agency determine that the project is adequately funded by the un-named building owner?

"CRITERION (8)" - G.S. 131E-183(a)(8)

"The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system."

The applicant has suggested that Johnston County DSS would provide transportation for the patients of the facility. County DSS Transportation does not routinely provide transportation services for out of county residents. It is not likely that Johnston County DSS will send its transportation vehicles for patients residing in Wilson or Nash Counties. Those counties have their own transportation budgets and services. To the extent that Wilson and Nash Counties do have DSS transportation services, it is the same scenario: county transportation agencies do not normally cross county lines.

"Criterion (13)" - G.S. 131E-183(a)(13)

"The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

c. That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services;"

The applicant has not provided reasonable projections of service to the traditionally underserved patient populations of Johnston County. Consider the following examples from the application:

Demographic	DaVita Forest Hills[10]	DaVita Wilson Dialysis[11]	DaVita Clayton Dialysis[12]
65 and Older	60.4%	61.5%	13.3%
Black or African-American	81.2%	79.8%	16.8%
Handicapped	0.0%	0.0%	0.0%

Based upon the above, it would appear that the applicant is proposing to remove services from underserved populations in order to develop the facility in Johnston County. The applicant should be found non-conforming to CON Review Criterion 13c.

"CRITERION (18a)" - G.S. 131E-183(a)(18a)

"The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact."

The applicant suggests that the new facility will enhance accessibility to dialysis and reduce the economic and physical burdens on the patients. To the contrary, asking at least 80 of its proposed patients to travel further for dialysis means increased costs of transportation and more time involved in transportation to and from dialysis. Moreover, there is already an existing facility in Clayton (FMC Stallings Station). This proposal does not enhance accessibility, but rather places additional burdens on the patient who have signed letters of support for the proposal.

[10] See application page 48
[11] See application page 49
[12] See application page 24

Comparative Analysis

The Agency has traditionally completed a comparative analysis of competing CON applications. The information following offers a comparison of various factors which the agency has utilized in the past.

Home Training:

Fresenius Kidney Care West Johnston will refer all home training patients to FMC Stallings Station in Clayton. This would be a trip of less than three miles.

Clayton Dialysis proposes to refer patients to Wilson Dialysis for home training. This would be a road trip of nearly 34 miles (one way, NC 42) for home training.

Because Wilson is a significantly further commute for home training, the BMA proposal is the more effective alternative.

Service to Johnston County Residents:

The July 2019 SDR, Table A, Dialysis Data by county of Patient Origin – December 2018 Data, reports that Fresenius Medical Care, parent to BMA, was serving 275 Johnston County residents at facilities within Johnston County, and another 50 Johnston County residents at facilities in another county. On the other hand, DaVita Dialysis, parent to TRC was serving a total of 21 Johnston County residents at facilities in another county.

The BMA proposal is clearly the more effective alternative.

Access to Alternative Providers:

BMA currently operates seven dialysis facilities in Johnston County. TRC does not operate any facilities in Johnston County.

The TRC proposal would represent the more effective alternative if it could be approved.

Access by Underserved Groups:

	BMA	TRC
Medicare	68.62%	79.4%
Medicaid	3.76%	7.9%
Other: Medicare / Commercial	19.39%	
Total	91.77%	87.3%

Both applicants project payor source based upon treatment volumes, and not based upon patients. BMA proposes a higher combined percentage of Medicare and Medicaid treatment volumes. BMA is the more effective alternative.

In addition to the comparison of Medicare and Medicaid populations, In addition, the Project Analyst must also consider the basic principles of the SMFP. Basic Principle #2 address Access to care. The following statement is included in the discussion of "Access Basic Principle":

> *"Barriers to access include, but are not limited to: geography, low income, limited or no insurance coverage, disability, age, race, ethnicity, culture, language, education and health literacy. Individuals whose access to needed health services is impeded by any of these barriers are medically underserved."*

The following chart compares Access projected by the TRC application and the FMC application for West Johnston.

Demographic	DaVita Clayton Dialysis	Fresenius FKC West Johnston
65 and Older	13.3%	43.3%
Racial and ethnic minorities	20.9%	57.5%
Handicapped	0.0%	30.0%

The FMC application projects service to markedly higher percentages of traditionally underserved populations, and is therefore more effective.

Revenues and Operating Costs:

Net Revenues

Fresenius Kidney Care West Johnston	Year One	Year Two
Projected Net Revenue	$1,972,220	$2,135,915
# Dialysis Treatments	6,474	7,011
Average Net Revenue / Tx	$304.64	$304.64

Clayton Dialysis	Year One	Year Two
Projected Net Revenue	$1,811,661	$1,811,611
# Dialysis Treatments	4,891	4,891
Average Net Revenue / Tx	$370.00	$370.00

The BMA proposal projects a much lower (21% lower) net revenue per treatment, and is therefore more effective.

Operating Costs

Fresenius Kidney Care West Johnston	Year One	Year Two
Projected Operating Costs	$1,799,551	$1,880,345
# Dialysis Treatments	6,474	7,011
Average Cost / Tx	$277.97	$268.19

Clayton Dialysis	Year One	Year Two
Projected Operating Costs	$1,308,991	$1,326,266
# Dialysis Treatments	4,891	4,891
Average Cost / Tx	$268.00	$271.00

The TRC proposal projects a slightly lower operating cost in Operating Year One. The BMA proposal projects a slightly lower operating cost per treatment in Operating Year Two. The applications are equally effective.

Charge to Insurers:

	BMA	TRC
Insurance	$1,031.09	$1,285.00

TRC proposes a much higher charge to insurance carriers. Therefore, BMA is a more effective alternative.
In the interest of total transparency, the above charges for BMA are net of contractual allowances. It is assumed that the charge reported by TRC is similarly net of contractual allowances.

Staffing:

Position	Fresenius Kidney Care West Johnston	Clayton Dialysis
Administrator	$79,440	$75,000
Registered Nurse	$68,407	$66,000
Patient Care Tech (PCT)	$31,997	$32,000
Dietician	$55,167	$55,000
Social Worker	$55,167	$55,000
Business Office	$29,790	$26,500

BMA proposes a higher salary for each of the above positions with the exception of the Patient Care Technician. There is a $3.00 per year proposed difference; this is negligible.

As an additional consideration, BMA proposes an average 3% annual pay increase. TRC on the other hand proposes a 2.5% annual pay increase.

Because BMA proposes higher staff salaries in five of the six categories above, BMA is the more effective alternative.

Capital Costs:

BMA has proposed to relocate stations to a facility which is under development. BMA has proposed this project would be accomplished for $15,000 capital costs.

TRC has proposed to develop a new facility for a capital cost of $2,518,449

BMA is the more cost effective alternative.

Charity:

BMA has proposed to provide charitable contributions to the American Kidney Fund. It is calculated to be $4.97 per treatment.

TRC indicates it is not able to separate its charitable contributions.

BMA is the more effective alternative.

SUMMARY:

The applicant has provided an application which cannot be approved. Therefore the application must be denied. The TRC application contains questionable representations of the patient population to be served. The TRC application fails to conform to CON Review Criterion 3, 4, 5, 8, and 18a.

Even if the Agency were to find the application conforming to all CON review criteria, the application is not comparatively superior to the BMA application.

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

Sincerely,

Jim Swann
Director of Operations, Certificate of Need

2 Attachments:

1) Chart of Johnston Patients Served by DaVita
2) US Census Bureau Quick Facts Clayton, NC
3) Required State Agency Findings, 2010 Randolph County Competitive Review, pages 1 and 34

Number of Johnston County In-Center patients served by DaVita							
In-Center Patients from Johnston County	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	6/30/2019
34-2507 Wilson Dialysis	1/2/1900	6	5	6	2	1	2
34-2637 Forest Hills Dialysis	2	2	3	2	2	2	1
34-2732 Bull City Dialysis						1	
34-2511 SEDC - Wilmington				1			
34-2685 Cape Fear Dialysis			1				
34-2587 Goldsboro South Dialysis		2	2	3	1		
34-2531 Goldsboro Dialysis		1		1	1	2	1
34-2573 Mt. Olive Dialysis			1			1	
34-2675 Wake Forest Dialysis Center	1	1	1	2	3	2	1
Total	3	12	13	15	9	9	5
Johnston County ESRD	244	253	271	296	315	348	
% of Guilford ESRD Population	1.230%	4.743%	4.797%	5.068%	2.857%	2.586%	

U.S. Census Bureau QuickFacts: North Carolina

QuickFacts

Clayton town, North Carolina

QuickFacts provides statistics for all states and counties, and for cities and towns with a ***population of 5,000 or more***.

Table

ALL TOPICS	Clayton town, North Carolina
Population estimates, July 1, 2018, (V2018)	**22,850**
PEOPLE	
Population	
Population estimates, July 1, 2018, (V2018)	**22,850**
Population estimates base, April 1, 2010, (V2018)	16,183
Population, percent change - April 1, 2010 (estimates base) to July 1, 2018, (V2018)	41.2%
Population, Census, April 1, 2010	16,116
Age and Sex	
Persons under 5 years, percent	▲ 8.2%
Persons under 18 years, percent	▲ 30.3%
Persons 65 years and over, percent	▲ 10.4%
Female persons, percent	▲ 54.0%
Race and Hispanic Origin	
White alone, percent	▲ 64.7%
Black or African American alone, percent (a)	▲ 28.1%
American Indian and Alaska Native alone, percent (a)	▲ 1.7%
Asian alone, percent (a)	▲ 0.6%
Native Hawaiian and Other Pacific Islander alone, percent (a)	▲ 0.0%
Two or More Races, percent	▲ 3.0%
Hispanic or Latino, percent (b)	▲ 7.4%
White alone, not Hispanic or Latino, percent	▲ 61.4%
Population Characteristics	
Veterans, 2013-2017	1,434
Foreign born persons, percent, 2013-2017	6.8%
Housing	
Housing units, July 1, 2018, (V2018)	X
Owner-occupied housing unit rate, 2013-2017	62.7%
Median value of owner-occupied housing units, 2013-2017	$166,800
Median selected monthly owner costs -with a mortgage, 2013-2017	$1,433
Median selected monthly owner costs -without a mortgage, 2013-2017	$446
Median gross rent, 2013-2017	$1,069
Building permits, 2018	X
Families & Living Arrangements	
Households, 2013-2017	6,618
Persons per household, 2013-2017	2.90
Living in same house 1 year ago, percent of persons age 1 year+, 2013-2017	79.7%
Language other than English spoken at home, percent of persons age 5 years+, 2013-2017	7.4%
Computer and Internet Use	
Households with a computer, percent, 2013-2017	93.7%
Households with a broadband Internet subscription, percent, 2013-2017	82.3%
Education	
High school graduate or higher, percent of persons age 25 years+, 2013-2017	92.1%
Bachelor's degree or higher, percent of persons age 25 years+, 2013-2017	34.4%
Health	
With a disability, under age 65 years, percent, 2013-2017	9.0%
Persons without health insurance, under age 65 years, percent	▲ 13.7%

Economy	
In civilian labor force, total, percent of population age 16 years+, 2013-2017	68.9%
In civilian labor force, female, percent of population age 16 years+, 2013-2017	65.7%
Total accommodation and food services sales, 2012 ($1,000) (c)	41,495
Total health care and social assistance receipts/revenue, 2012 ($1,000) (c)	110,652
Total manufacturers shipments, 2012 ($1,000) (c)	D
Total merchant wholesaler sales, 2012 ($1,000) (c)	64,872
Total retail sales, 2012 ($1,000) (c)	329,958
Total retail sales per capita, 2012 (c)	$19,374
Transportation	
Mean travel time to work (minutes), workers age 16 years+, 2013-2017	29.2
Income & Poverty	
Median household income (in 2017 dollars), 2013-2017	$59,338
Per capita income in past 12 months (in 2017 dollars), 2013-2017	$27,051
Persons in poverty, percent	▲ 8.8%

BUSINESSES

Businesses	
Total employer establishments, 2016	X
Total employment, 2016	X
Total annual payroll, 2016 ($1,000)	X
Total employment, percent change, 2015-2016	X
Total nonemployer establishments, 2017	X
All firms, 2012	1,765
Men-owned firms, 2012	920
Women-owned firms, 2012	684
Minority-owned firms, 2012	510
Nonminority-owned firms, 2012	1,160
Veteran-owned firms, 2012	140
Nonveteran-owned firms, 2012	1,528

GEOGRAPHY

Geography	
Population per square mile, 2010	1,192.8
Land area in square miles, 2010	13.51
FIPS Code	3712860

About datasets used in this table

Value Notes

▲ Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources.

Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable. Click the Q left of each row in TABLE view to learn about sampling error.

The vintage year (e.g., V2018) refers to the final year of the series (2010 thru 2018). *Different vintage years of estimates are not comparable.*

Fact Notes

- **(a)** Includes persons reporting only one race
- **(b)** Hispanics may be of any race, so also are included in applicable race categories
- **(c)** Economic Census - Puerto Rico data are not comparable to U.S. Economic Census data

Value Flags

- **-** Either no or too few sample observations were available to compute an estimate, or a ratio of medians cannot be calculated because one or both of the median estimates falls in t interval of an open ended distribution.
- **D** Suppressed to avoid disclosure of confidential information
- **F** Fewer than 25 firms
- **FN** Footnote on this item in place of data
- **NA** Not available
- **S** Suppressed; does not meet publication standards
- **X** Not applicable
- **Z** Value greater than zero but less than half unit of measure shown

QuickFacts data are derived from: Population Estimates, American Community Survey, Census of Population and Housing, Current Population Survey, Small Area Health Insurance Estimates, Sm Poverty Estimates, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits.

Public Written Comment
CON Project ID# J-11743-19
Clayton Dialysis

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 10 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.1, page 42:

Payor Source	
Medicare/Medicaid	40.7%
Medicare/ 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%. It is 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