

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 22, 2016

Findings Date: April 22, 2016

Project Analyst: Celia C. Inman

Assistant Chief: Martha J. Frisone

Project ID #: J-11131-16

Facility: Oak City Dialysis

FID #: 160068

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new facility by relocating 10 stations from Wake Forest Dialysis Center

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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.

C

Total Renal Care of North Carolina, LLC (TRC or "the applicant") proposes to develop Oak City Dialysis, a new Wake County dialysis facility, by relocating 10 existing certified stations from Wake Forest Dialysis, which is also in Wake County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The applicant proposes to relocate existing dialysis stations within Wake County; therefore, there are no need methodologies in the 2016 State Medical Facilities Plan (2016 SMFP) applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 39 of the 2016 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 39 of the 2016 SMFP is applicable to this review.

POLICY GEN-4 states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN 4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control.”

The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million. In Section B.5, pages 11-13, the applicant provides a written statement describing the proposed project’s plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS on page 33 of the 2016 SMFP is applicable to this review.

POLICY ESRD-2 states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

1. *Demonstrate that the facility losing dialysis stations or moving to a contiguous [sic] county is currently serving residents of that contiguous [sic] county; and*
2. *Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
3. *Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to develop a new 10-station dialysis facility, Oak City Dialysis, in Wake County, by relocating 10 existing dialysis stations from Wake Forest Dialysis Center. Because both facilities are located in Wake County, there is no change in the total dialysis station inventory in Wake County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policies GEN-4 and ESRD-2 in the 2016 SMFP. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (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.

C

The applicant proposes to develop Oak City Dialysis, a new 10-station Wake County dialysis facility, by relocating 10 existing certified stations from Wake Forest Dialysis Center.

Population to be Served

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 14, the applicant provides the projected patient origin for Oak City Dialysis for in-center (IC), home hemodialysis (HH) and peritoneal (PD) patients for the first two years of operation following completion of the project, CY2018 and CY2019, as follows:

County	Operating Year (OY) 1			Operating Year (OY) 2			Percent of Total	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Wake	25	0	2	26	0	3	73.0%	74.4%
Durham	6	0	0	6	0	0	16.2%	15.4%
Johnston	3	0	0	3	0	0	8.1%	7.7%
Pitt	1	0	0	1	0	0	2.7%	2.6%
Total	35	0	2	36	0	3	100.0%	100.0%

The applicant has identified 34 in-center patients who are interested in transferring their care to the proposed facility. The applicant states that each patient is currently receiving dialysis care and treatment at another DaVita HealthCare Partners, Inc. (DaVita) dialysis facility in Wake or Durham County. DaVita is the parent company of TRC. Exhibit C contains copies of signed letters of support from these patients indicating that the proposed facility is located closer to their home and they would consider transferring their care to the new facility upon certification. The letters also state the patients' county of residence and zip code.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, pages 17-18, the applicant discusses the need to relocate stations to the proposed northeast Raleigh facility, stating:

“In doing an analysis of the patients that are served by DaVita operated facilities in Wake and Durham Counties, it was determined that DaVita is serving a total of 34 in-center patients who indicate that a facility in or near the northeastern part of Raleigh would be closer and /or more convenient to them. Additionally, we identified 9 PD patients served by one facility and living in sip codes in or near the northeastern part of Raleigh.”

The applicant states that based on the above analysis and in order to make travel to dialysis more convenient for its patients, it determined a need to provide a dialysis center in the proposed location to provide better access to its patients.

On pages 14-17, the applicant provides the methodology and assumptions used to project utilization as follows:

1. DaVita is the parent company of Southpoint Dialysis and Durham West Dialysis in Durham County, and Wake Forest Dialysis in Wake County.

2. Twenty-four in-center dialysis patients who reside in Wake County and currently receive dialysis treatments at DaVita operated facilities in Wake and Durham counties have signed letters stating they would consider transferring their dialysis care to the proposed facility.
3. Three in-center dialysis patients who reside in Johnston County and currently receive dialysis treatments at DaVita operated facilities in Wake and Durham counties have signed letters stating they would consider transferring their dialysis care to the proposed facility.
4. Six in-center dialysis patients who reside in Durham County and currently receive dialysis treatments at DaVita operated facilities in Wake and Durham counties have signed letters stating they would consider transferring their dialysis care to the proposed facility.
5. One in-center dialysis patients who resides in Pitt County and currently receives dialysis treatments at a DaVita operated Wake County facility has signed a letter stating a willingness to transfer dialysis care to the proposed facility.
6. The 34 patient letters also state that the patient lives closer to the proposed facility and/or that the new facility will be more convenient for them. See Exhibit C. The applicant provides a table on page 15, which the applicant states summarizes the number of in-center patients willing to transfer and the current dialysis facilities from which the in-center patients will transfer.

	Wake Forest Dialysis	Southpoint Dialysis	Durham West Dialysis
Patients Transferring	26	6	2

7. The project is scheduled for occupancy January 1, 2018.

Operating Year 1 is Calendar Year 2018, January 1 through December 31, 2018.

Operating Year 2 is Calendar Year 2019, January 1 through December 31, 2019.

8. The applicant assumes the 24 Wake County in-center dialysis patients transferring to the new Oak City Dialysis facility will increase at the Wake County Five Year Average Annual Change Rate of 5.0%, as published in the January 2016 SDR. Non-Wake County patients are not projected to increase and are added to the census in a separate step.

Projected Utilization

The applicant's methodology is illustrated in the following tables.

Oak City Dialysis	In-Center
The applicant begins the facility census with the in-center patients projected to transfer care to the proposed facility upon certification on January 1, 2018.	24
Project growth of the Wake County patients by the Wake County Five Year Average Annual Change Rate for one year to December 31, 2018.	$(24 \times 0.05) + 24 = 25.2$
Add the Durham, Johnston and Pitt County patients. This is the end of OY1, December 31, 2018.	$25.2 + 10 = 35.2$
Project growth of the Wake County patients by the Wake County Five Year Average Annual Change Rate for one year to December 31, 2019.	$(25.2 \times 0.05) + 25.2 = 26.5$
Add the Durham, Johnston and Pitt County patients. This is the end of OY2, December 31, 2019.	$26.5 + 10 = 36.5$

Oak City Dialysis	Peritoneal
The applicant begins the facility census with the one PD patient projected to transfer care to the proposed facility upon certification on January 1, 2018.	1
Project growth of the census by one patient each year. This is the end of OY1, December 31, 2018.	$1+1=2$
Project growth of the census by one patient each year. This is the end of OY2, December 31, 2019.	$2+1=3$

The applicant states that the methodology rounds down to the whole patient and projects to serve 35 in-center patients or 3.5 patients per station ($35 / 10 = 3.5$) by the end of Operating Year 1 and 36 in-center patients or 3.6 patients per station ($36 / 10 = 3.6$) by the end of Operating Year 2 for the proposed 10-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The applicant projects two peritoneal patients at the end of the second year of operation. In this application, the applicant assumes a projected annual rate of growth of 5.0% for the Wake County dialysis patient census, which is consistent with the Wake County Five Year Average Annual Change Rate published in the 2016 SMFP. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1(a), pages 50-51, the applicant states that Oak City Dialysis, by policy, will make dialysis services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. Form C in Section R, shows the applicant projects over 71% of its in-center patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that this population has for the proposed project, and adequately demonstrates the extent to which all residents, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (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.

C

The applicant proposes to relocate 10 existing dialysis stations from its Wake Forest Dialysis Center facility to develop a new, 10-station dialysis facility, Oak City Dialysis. Both facilities are in Wake County.

In Section D.1, on pages 26-27, the applicant discusses how the needs of dialysis patients at Wake Forest Dialysis Center will continue to be met after the relocation of stations to the proposed Oak City Dialysis facility. The applicant states the relocation of stations and transfer of patients is projected to occur on January 1, 2018. The development of the proposed facility results in the following changes to the existing Wake Forest Dialysis Center.

	Certified Stations 6/30/15	Stations Approved J-11090-15	Stations Assumed Available 1/1/18	Stations to be Relocated 1/1/18	Stations Remaining 1/1/18
Wake Forest Dialysis Center	20	2	22	10	12

On page 27, the applicant provides a table projecting the in-center patient census at Wake Forest Dialysis Center, after the proposed relocation of stations and transfer of patients, as 54.8 patients on December 31, 2018 and 56.69 patients on December 31, 2019. The assumptions for projecting the Wake Forest Dialysis Center's utilization are provided on pages 26-27 and are summarized below:

- The January 2016 SDR reports the Wake Forest Dialysis Center with 73 in-center patients on June 30, 2015, 20 dialysis stations and a utilization rate of 91.25%.
 - 52 were Wake County residents
 - 21 lived outside of Wake County
- On December 18, 2015, DaVita (TRC) was approved to add 2 dialysis stations to the Wake Forest Dialysis Center for a total of 22 stations. It is assumed those stations

will have been certified before the proposed relocation, which will leave the center with 12 certified dialysis stations.

- The Wake County patient population is projected forward using the 5.0% Wake County Five Year Average Annual Change Rate as published in the January 2016 SDR.
- No growth rate is applied to the 21 patients who reside outside of Wake County.
- The applicant expects at least 26 current in-center patients from Wake Forest Dialysis will transfer to Oak City dialysis upon its certification: 22 Wake County residents and four non-Wake residents.

Based on the above assumptions, the Project Analyst calculates projected utilization at Wake Forest Dialysis Center as follows:

Wake Forest Dialysis Center	In-Center
The methodology begins with the facility census with the in-center Wake County patients June 30, 2015	52
Project growth of the Wake County patients by the Wake County Five Year Average Annual Change Rate for 6 months to December 31, 2015.	$(52 \times 0.05/2) + 52 = 53.3$
Project growth of the census by the Wake County Five Year Average Annual Change Rate for 1 year to December 31, 2016.	$(53.3 \times 0.05) + 53.3 = 55.96$
Project growth of the census by the Wake County Five Year Average Annual Change Rate for 1 year to December 31, 2017.	$(55.96 \times 0.05) + 55.96 = 58.76$
The methodology deducts the 22 Wake County residents who will transfer to Oak City Dialysis.	$58.76 - 22 = 36.76$
Project growth of the Wake County patients by the Wake County Five Year Average Annual Change Rate for 1 year to December 31, 2018.	$(36.76 \times 0.05) + 36.76 = 38.60$
The methodology adds back 17 non-Wake County patients (21 – 4 who will transfer to Oak City Dialysis) for the total Wake Forest Dialysis Center patients as of December 31, 2018.	$38.6 + 17 = 55.6$
Project growth of the Wake County patients by the Wake County Five Year Average Annual Change Rate for 1 year to December 31, 2019.	$(38.6 \times 0.05) + 38.6 = 40.53$
The methodology adds back 17 non-Wake County patients (21 – 4 who will transfer to Oak City Dialysis) for the total Wake Forest Dialysis Center patients as of December 31, 2019.	$40.53 + 17 = 57.53$

Thus, as of December 31, 2018, the end of the first full operating year following the relocation of stations and transfer of patients, Wake Forest Dialysis Center is projected to

have 56 patients (55.6 rounded up, following traditionally accepted rounding methodology) and 12 stations, which is a utilization rate of 117% (56 patients / 12 stations = 4.66 / 4 = 1.17).

On page 27, the applicant states:

“Given this projected growth of the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility’s patients will continue to be met.”

The applicant demonstrates that the needs of the population presently served at Wake Forest Dialysis Center will continue to be adequately met following the proposed relocation of 10 dialysis stations from Wake Forest Dialysis Center to Oak City Dialysis.

In Section D.2, page 27, the applicant states:

“The transfer of stations from Wake Forest dialysis will have no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved group [sic] and the elderly to obtain needed health care.

Wake Forest Dialysis, by policy, will continue to make dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age religion, or disability.”

Conclusion

The applicant demonstrates that the needs of the population presently served at Wake Forest Dialysis Center will continue to be adequately met following the proposed relocation of 10 dialysis stations from Wake Forest Dialysis Center to Oak City Dialysis and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (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.

CA

In Section E, page 28, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo – The applicant states that maintaining the status quo is not an effective alternative because Wake Forest Dialysis is at station capacity and has experienced substantially higher growth than Wake County’s five year annual change rate of 5%.

- Locate a facility in another area of Wake County - The applicant states that the sites selected for the new facility were selected to allow better geographic access to the identified patient population, as reflected in the patient letters in Exhibit C. The applicant further states that a facility in another area of Wake County would not address the needs of the identified patients. Therefore, this alternative was rejected.
- Develop the project as proposed – Relocate 10 Wake Forest Dialysis center stations to develop Oak city Dialysis in Northwest Raleigh.

The applicant states that given the Wake Forest Dialysis Center capacity issues and high growth rate, the project represented in the application is the more effective alternative to better serve a large patient population that are currently receiving services at Wake Forest Dialysis. The applicant further states, *“This action will provide both Wake Forest Dialysis and Oak City Dialysis space for future growth.”*

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center shall materially comply with all representations made in the certificate of need application.**
2. **Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center shall relocate no more than 10 dialysis stations from Wake Forest Dialysis Center.**
3. **Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
4. **Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center shall take the necessary steps to decertify 10 dialysis stations at Wake Forest Dialysis Center for a total of no more than 12 dialysis stations at Wake Forest Dialysis Center upon completion of this project and Project I.D. #J-11090-15 (add two dialysis stations for a total of 22 stations).**
5. **Total Renal Care of North Carolina, LLC d/b/a Wake Forest Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**

- (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.

C

The applicant, TRC, proposes to develop Oak City Dialysis, a new 10-station Wake County dialysis facility, by relocating 10 stations from Wake Forest Dialysis Center.

Capital and Working Capital Costs

In Section F.1, page 29, the applicant projects \$2,433,324 in capital costs to develop this project, as itemized below.

Projected Capital Costs

Site Costs	\$ 38,500
Construction	1,637,500
Machines	150,000
RO Equipment	146,065
Other Equipment/Furniture	358,759
Architect/Engineering Fees	102,500
Total Capital Costs	\$ 2,433,324

In Sections F.10-F.12, page 32, the applicant states that start-up expenses and initial operating expenses incurred for this project will be \$191,283 and \$759,604, respectively, for a total estimated working capital of \$950,887.

Availability of Funds

In Section F.2, page 30, F.13, pages 32-33, and Exhibit F, the applicant states DaVita, TRC parent company, will finance the capital costs and working capital costs with accumulated reserves, as shown below.

DaVita Accumulated Reserves / Owner's Equity

	Total
Capital Costs	\$ 2,433,324
Working Capital	\$ 950,887
Total	\$ 3,384,211

Exhibit F contains a letter dated February 15, 2016, from DaVita Chief Accounting Officer and signed by William Hyland, authorizing and committing \$3,384,211 in capital costs and working capital for the project. Exhibit F also contains a letter dated February 15, 2016, from William Hyland, stating authority to sign the above letter on behalf of DaVita's Chief Accounting Officer, who was made aware of the commitment but was unavailable to sign the

letter. Exhibit F-7 contains the Securities and Exchange Commission Form 10-K for DaVita which indicates that it had \$965 million in cash and cash equivalents as of December 31, 2014.

The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	CY2018	CY2019
Total Net Revenue	\$2,728,906	\$2,881,091
Total Operating Expenses	\$1,519,208	\$1,563,750
Net Income	\$1,209,698	\$1,317,341

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicant, TRC, proposes to develop Oak City Dialysis, a new 10-station Wake County dialysis facility, by relocating 10 stations from Wake Forest Dialysis Center.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service

area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates just one dialysis center in Wake County. Bio-Medical Applications of North Carolina, Inc. (BMA) is the only other provider of dialysis services in Wake County, and operates 12 dialysis centers, as shown in the table below.

**Wake County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2015**

Dialysis Facility	Certified Stations 6/30/15	# In-center Patients	Percent Utilization	Patients/Station
BMA Owned/Operated Facilities				
BMA of Fuquay-Varina Kidney Center	20	77	96.25%	3.8500
BMA of Raleigh Dialysis	50	163	81.50%	3.2600
Cary Kidney Center (BMA Cary)	28	80	71.43%	2.8571
FMC Apex	20	49	61.25%	2.4500
FMC Central Raleigh	19	55	72.37%	2.8947
FMC Eastern Wake	14	61	108.93%	4.3571
FMC Millbrook	17	57	83.82%	3.3529
FMC New Hope Dialysis	36	110	76.39%	3.0556
FMC Northern Wake*	0	0	0.00%	0.0000
Southwest Wake County Dialysis	31	115	92.74%	3.7097
Wake Dialysis Clinic	50	198	99.00%	3.9600
Zebulon Kidney Center	30	99	82.50%	3.3000
Davita Owned/Operated Facilities				
Wake Forest Dialysis Center	20	73	91.25%	3.6500

Source: 2016 SMFP

*Project ID #J-10152-13 / Relocate 10 dialysis stations from BMA Wake (BMA of Raleigh Dialysis) and 3 stations from BMA Southwest Wake (Southwest Wake County Dialysis) to develop a new 13-station facility in North Raleigh

As shown in the table above, eight of the Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station), and 11 of the 13 facilities are operating at or above 70% utilization (2.8 patients per station). Furthermore, FMC Northern Wake is a new facility and was not certified until January 11, 2016.

The applicant proposes to relocate 10 Wake Forest Dialysis Center stations to a new facility. Wake Forest Dialysis Center was serving 73 patients weekly on 20 stations, which is 3.65 patients per station, or 91.25% of capacity, as of June 30, 2015. The applicant provides reasonable projections for the patient population it proposes to serve on pages 14-17 of the application. The growth projections are based on a projected 5.0% average annual growth rate in the number of Wake County dialysis patients transferring their care to the proposed facility. The applicant states that the methodology rounds down to the whole patient and projects to serve 35 in-center patients or 3.5 patients per station, a utilization rate of 87.5% ($35 / 10 = 3.5 / 4 = .875$) by the end of Operating Year 1 and 36 in-center patients or 3.6

patients per station, a utilization rate of 90.0% ($36 / 10 = 3.6 / 4 = .900$) by the end of Operating Year 2 for the proposed 10-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The applicant does not propose to increase the number of certified stations in the service area. The applicant adequately demonstrates the need to develop a new 10-station dialysis center by relocating existing Wake County DaVita dialysis stations.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section H.1, page 36, the applicant provides the proposed staffing for the new facility, which includes 9.8 full-time equivalent (FTE) employee positions, as shown below.

Position	Projected # of FTE Positions
Medical Director*	
RN	2.0
Technician	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Home Training RN	0.5
Administrative Assistant	1.0
Biomed Technician	0.3
Total FTE Positions	9.8

*The Medical Director is a contract position, not an FTE of the facility.

In Section H.3, pages 37-38, the applicant describes its experience and process for recruiting and retaining staff. Exhibit H-3 contains information on DaVita employee benefits. Exhibit I-3 contains a copy of a letter from Munsoor Lateef, M.D., expressing his interest in serving as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (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.

C

In Section I.1, page 40, the applicant includes a list of providers of the necessary ancillary and support services. The applicant discusses coordination with the existing health care system on pages 41-42. Exhibits I-1, 2, 3, and 4 contain documentation for home training, laboratory, vascular surgery, transplant, and social services, respectively. Exhibit I-3 contains a letter from the proposed medical director for the facility expressing his support for the proposed project. Exhibit I-2(a) is a copy of an unsigned agreement for acute hospital services by an un-named hospital. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (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.

C

The applicant proposes to develop the new facility in a 7,969 square foot building, per the line drawings, as provided by the applicant in Exhibit K-1(a). In Section F.1, page 45, the applicant lists the project costs, including \$1,637,500 for construction and \$757,324 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees for a total project cost of \$2,433,324. In Section K.1, pages 44-45, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.3(c), pages 52, the applicant states:

"In short, it has been DaVita's practice in North Carolina to accept patients in need of dialysis treatment first, and assist them with insurance and billing issues later. Our goal is to serve the needs of our patient population in accordance with CMS regulations related to billing practices."

In Section L.7, page 54, the applicant provides the historical payor mix for Wake Forest Dialysis Center in-center patients, showing over 71% of the patients had some or all of their services paid for by Medicare or Medicaid, as shown below.

Payment Source	In-Center
Medicare	20.3%
Medicaid	2.9%
Commercial Insurance	27.5%
Medicare/Commercial	43.5%
Medicare/Medicaid	4.4%
VA	1.4%
Total	100.00%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

<http://www.census.gov/quickfacts/table> Latest Data as of 12/22/15

*Excludes "White alone" who are "not Hispanic or Latino"

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. Annual Report*¹ provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3, page 53, the applicant states that it has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.

In Section L.6, page 53, the applicant states that there have been no civil rights access complaints filed within the past five years. Therefore, the application is conforming to this criterion.

- (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; and

C

In Section R, the applicant reports that over 71% of the in-center patients who will receive treatments at Oak City Dialysis will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected payment source for Oak City Dialysis in-center patients for operating years one and two:

Payment Source	In-Center
Medicare	20.3%
Medicaid	2.9%
Commercial Insurance	27.5%
Medicare/Commercial	43.5%
Medicare/Medicaid	4.4%
VA	1.4%
Total	100.00%

In Section L, page 51, the applicant provides the assumptions used to project payor mix, stating that the payor mix is based on the sources of patient payment that have been received by DaVita operated facilities in Wake County during the last full operating year and that no adjustments were applied for the projected payor mix. The applicant's projected payment sources in Section L are consistent with the facility's projected (CY2019) payment sources as reported by the applicant in Section R. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at Oak City Dialysis. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.4, page 53, the applicant describes the range of means by which a person will have access to the dialysis services at Oak City Dialysis, stating that a patient must have a referral from a qualified nephrologist with privileges at the facility. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M.1, page 55, the applicant states that it has offered the proposed facility as a clinical learning site for nursing students from Wake Technical Community College. Exhibit M-1 contains a copy of correspondence from DaVita to Wake Technical Community College

offering the proposed facility as clinical training site. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
 - (16) Repealed effective July 1, 1987.
 - (17) Repealed effective July 1, 1987.
 - (18) Repealed effective July 1, 1987.
- (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.

C

The applicant, TRC, proposes to develop Oak City Dialysis, a new 10-station Wake County dialysis facility, by relocating 10 stations from Wake Forest Dialysis Center.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates just one dialysis center in Wake County. BMA is the only other provider of dialysis services in Wake County, and operates 12 dialysis centers, as shown in the table below.

**Wake County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2015**

Dialysis Facility	Certified Stations 6/30/15	# In-center Patients	Percent Utilization	Patients/ Station
BMA Owned/Operated Facilities				
BMA of Fuquay-Varina Kidney Center	20	77	96.25%	3.8500
BMA of Raleigh Dialysis	50	163	81.50%	3.2600
Cary Kidney Center (BMA Cary)	28	80	71.43%	2.8571
FMC Apex	20	49	61.25%	2.4500
FMC Central Raleigh	19	55	72.37%	2.8947
FMC Eastern Wake	14	61	108.93%	4.3571
FMC Millbrook	17	57	83.82%	3.3529
FMC New Hope Dialysis	36	110	76.39%	3.0556
FMC Northern Wake*	0	0	0.00%	0.0000
Southwest Wake County Dialysis	31	115	92.74%	3.7097
Wake Dialysis Clinic	50	198	99.00%	3.9600
Zebulon Kidney Center	30	99	82.50%	3.3000
Davita Owned/Operated Facilities				
Wake Forest Dialysis Center	20	73	91.25%	3.6500

Source: 2016 SMFP

*Project ID #J-10152-13 / Relocate 10 dialysis stations from BMA Wake (BMA of Raleigh Dialysis) and 3 stations from BMA Southwest Wake (Southwest Wake County Dialysis) to develop a new 13-station facility in North Raleigh

As shown in the table above, eight of the Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station), and 11 of the 13 facilities are operating at or above 70% utilization (2.8 patients per station). Furthermore, FMC Northern Wake is a new facility and was not certified until January 11, 2016.

In Section N.1, page 56, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“The development of Oak City Dialysis will have no effect on any dialysis facilities located in Wake County or in counties contiguous to it. DaVita operates Wake Forest Dialysis. Fresenius Medical Care operates 11 dialysis facilities in Wake County.

The proposed facility will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed.

The bottom line is Oak City Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will

make it easier for patients, family members and other involved in the dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs."

See also Sections B, C, E, F, H, I, L, and N where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Exhibit O-3, the applicant identifies three kidney disease treatment centers (out of a total of 67) located in North Carolina, owned and operated by the applicant, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD Facilities. In Section O.3(c), page 57, the applicant states, "*Each facility is currently in compliance.*" Exhibit O-3 contains copies of letters documenting that the facilities were determined to be back in compliance by the Centers for Medicare and Medicaid Services and the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- C- In Section C, the applicant adequately demonstrates the need to establish the proposed 10-station Oak City Dialysis facility by relocating 10 existing Wake County dialysis stations to the proposed facility. At the end of the first operating year, the applicant projects Oak City Dialysis will serve 35 patients for a utilization of 3.5 patients per station per week. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- NA- The applicant is not proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need. The applicant is seeking to develop a new 10-station dialysis facility.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 14-17, the applicant provides the assumptions and

methodology used to project utilization for the proposed facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.