

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 21, 2016

Findings Date: June 21, 2016

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: J-11152-16

Facility: Wake Forest Dialysis Center

FID #: 041181

County: Wake

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Add one station to the existing facility for a total of 13 stations upon completion of this project, Project ID# J-11090-15 (add 2 stations) and Project ID #J-11131-16 (relocate 10 stations)

### 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 d/b/a Wake Forest Dialysis Center (“Wake Forest Dialysis” or “the applicant”) proposes to add one dialysis station to the existing facility for a total of 13 stations upon completion of this project, Project ID #J-11090-15 (add 2 stations) and Project ID #J-11131-16 (relocate 10 stations).

#### **Need Determination**

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is

no county need determination for Wake County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for Wake Forest Dialysis in the January 2016 SDR is 3.65 patients per station per week. This utilization rate was calculated based on 73 in-center dialysis patients and 20 certified dialysis stations as of June 30, 2015 (73 patients / 20 stations = 3.65 patients per station per week). Application of the facility need methodology indicates one additional station is needed for this facility, as illustrated in the following table.

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		91.25%
Certified Stations		20
Pending Stations		2
<b>Total Existing and Pending Stations</b>		<b>22</b>
In-Center Patients as of 6/30/15 (SDR2)		73
In-Center Patients as of 12/31/14 (SDR1)		73
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.0000
(ii)	Divide the result of step (i) by 12	0.0000
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.0000
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	73.0000
(v)	Divide the result of step (iv) by 3.2 patients per station	22.8125
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>1</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Wake Forest Dialysis is one station. Step (C) of the facility need methodology states “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add one new station and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing*

*healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9 – 10, Section O, page 51 and referenced Exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section L, pages 44 - 47, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Sections B.4(c) and (d), page 11, and Section N, page 50.

The applicant adequately demonstrates that the proposed project is the least costly or most effective alternative and that the project will not result in the unnecessary duplication of existing health service capabilities or facilities. See Criteria (4) and (6), which are incorporated herein by reference. Therefore, the applicant adequately demonstrates that the proposal will maximize healthcare value.

### **Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2016 SDR and Policy GEN-3. 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 add one station to the existing facility for a total of 13 stations upon completion of this project and two other projects as illustrated in the table below:

FACILITY	PROJECT ID #	#STATIONS TO BE ADDED (DELETED)	END RESULT
Begin with 20 stations as reported in the January 2016 SDR			
Wake Forest Dialysis	J-11090-15	2	22
Wake Forest Dialysis*	J-11131-16	(10)	12
Wake Forest Dialysis	J-11152-16	1	13

\*This project approved a 10-station relocation to develop Oak City Dialysis in Wake County.

The applicant serves both in-center (IC) and peritoneal dialysis (PD) patients at the Wake Forest Dialysis Center, and projects to continue to serve IC and PD patients following the addition of one station as proposed in this application.

**Population to be Served**

On page 369, the 2016 SMFP defines the service area for dialysis stations as “the dialysis station 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 for Wake Forest Dialysis is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 19, the applicant provides the historical in-center (IC) and peritoneal dialysis (PD) patient origin for Wake Forest Dialysis Center as of June 30, 2015, as illustrated in the following table

**Patient Origin Wake Forest Dialysis Center June 30, 2015**

COUNTY	# IN-CENTER PATIENTS	# PERITONEAL DIALYSIS PATIENTS
Wake	52	13
Franklin	12	4
Vance	3	0
Durham	1	1
Johnston	1	0
Rockingham	1	0
Other States	3	0
<b>Total</b>	<b>73</b>	<b>18</b>

In Section C.1, page 13, the applicant projects patient origin for Wake Forest Dialysis for the first two operating years following completion of the project as follows:

COUNTY	OY 1 (CY 2018)		OY 2 (CY 2019)		COUNTY PTS AS # OF TOTAL	
	IC	PD	IC	PD	OY 1	OY 2
Wake	37	9	39	10	68.7%	70.0%
Franklin	12	4	12	4	23.9%	22.9%
Vance	3	0	3	0	4.5%	4.3%
Rockingham	1	0	1	0	1.5%	1.4%
Other States	1	0	1	0	1.5%	1.4%
<b>Total</b>	<b>54</b>	<b>13</b>	<b>56</b>	<b>14</b>	<b>100.0%</b>	<b>100.0%</b>

\*Totals may not foot due to rounding

The applicant provides the assumptions and methodology used to project patient origin on pages 13 - 15. The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section B.2, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2016 SMFP, utilizing data from the January 2016 SDR. The applicant proposes to add one dialysis station to Wake Forest Dialysis Center. The applicant’s assumptions, from Section C.1 pages 13 – 15, are summarized below.

The applicant states on page 13 that as of June 30, 2015, Wake Forest Dialysis had 73 in-center patients dialyzing on 20 stations, which is 3.65 patients per station per week, or 91% utilization [ $73 / 20 = 3.65$ ;  $3.65 / 4 = 0.91$ ]. The applicant states 52 of those patients were Wake County residents and 21 patients were residents of other counties, as shown in the table above. On April 15, 2016, the applicant filed an application, Project ID #J-11131-16, which proposed relocating ten existing stations from Wake Forest Dialysis to develop a new facility (Oak City Dialysis) in Wake County. That application was approved on April 22, 2016. The applicant projects that when Oak City Dialysis is certified in 2017, 26 total patients from Wake Forest Dialysis will transfer their care to the new facility; 22 patients from Wake County and four from outside Wake County.

After the 26 patients transfer their care to Oak City Dialysis, Wake Forest Dialysis will be left with 36 in-center Wake County patients. The applicant projects patient growth in its facility using the 5.0% Wake County Five Year Average Annual Change Rate (AACR) published in the January 2016 SDR. See the following table which summarizes the applicant’s projections, beginning with the patient census of 52 as of June 30, 2015:

TIME PERIOD	# SERVICE AREA PTS. X WAKE COUNTY AACR = SERVICE AREA END CENSUS	# PTS. OUTSIDE SERVICE AREA	TOTAL PATIENT CENSUS
7/1/15 – 12/31/15	$52 \times 1.025 = 53.30$	+ 21	74.3
1/1/16 – 12/31/16	$53.3 \times 1.05 = 55.97$	+ 21	76.97
1/1/17 – 12/31/17*	$55.97 \times 1.05 = 58.77$	+ 21	79.77
1/1/18 - 12/31/18 (OY 1)	$58 - 22 = 36 \times 1.05 = 37.80$	+ (21 - 4) = 17	54.8
1/1/19 – 12/31/19 (OY 2)	$37.8 \times 1.05 = 39.69$	+ 17	56.69

\*At the end of CY 2017 the 22 Wake County patients and the 4 patients from outside Wake County are projected to transfer their care to Oak City Dialysis.

The applicant’s methodology rounds down to the nearest whole number. The project is scheduled for certification on January 1, 2018. Thus, Operating Year One is CY 2018, and Operating Year Two is CY 2019. The applicant projects that in OY 1, 54 in-center patients will dialyze on 13 stations, which is 4.15 patients per station, or 103% utilization [ $54 / 13 = 4.15$ ;  $4.15 / 4 = 1.03$ ]. In OY 2, the applicant projects 56 in-center patients will dialyze on 13 stations, which is 4.31 patients per station, or 107% utilization [ $56 / 13 = 4.31$ ;  $4.31 / 4 = 1.07$ ]. 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). 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 of in-center dialysis patients is based on reasonable and adequately supported assumptions regarding continued growth.

*Peritoneal Dialysis Patients*

As of June 30, 2015, Wake Forest Dialysis was serving 18 PD patients. The applicant projects to serve one additional peritoneal dialysis patient each year. The analyst examined historical ESRD Data Collection Forms, which providers submit to Healthcare Planning for use in the Semi-Annual Dialysis Reports twice per year. The Data Collection Forms from December 31, 2013 to December 31, 2015 show the PD patient population at Wake Forest Dialysis Center grew from 10 patients to 24 patients in two years, or five total reporting periods, as shown in the following table:

DATE OF DATA COLLECTION	# PD PATIENTS	NUMERICAL GROWTH	PERCENT GROWTH
December 31, 2013	10	--	-
June 30, 2014	14	4	40%
December 31, 2014	18	4	29%
June 30, 2015	18	0	0%
December 31, 2015	24	6	33%

The data shows that the PD patient population at Wake Forest Dialysis Center increased by eight patients from December 31, 2013 to December 31, 2014; and by six patients from December 31, 2014 to December 31, 2015.

At the time the Oak City Dialysis Center is certified, the applicant projects nine PD patients will transfer their care from Wake Forest Dialysis to Oak City Dialysis. See the following table, which illustrates the applicant's assumptions:

TIME PERIOD	# PERITONEAL DIALYSIS PATIENTS	# PD PATIENTS TO BE ADDED	TOTAL PATIENT CENSUS
Start Date - 7/1/15	18	+ 1	19
CY 2016	19	+ 1	20
CY 2017*	20	+ 1	21
CY 2018 (OY 1)	21 - 9 = 12	+ 1	13
CY 2019 (OY 2)	13	+ 1	14

\*At the end of CY 2017 the 9 PD patients are projected to transfer their care to Oak City Dialysis.

By OY 1, Wake Forest Dialysis Center will serve 14 PD patients. Projected growth of one PD patient per year, and projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

**Access**

In Section L.1(a), pages 44 - 45, the applicant states that Wake Forest Dialysis, by policy, makes dialysis services available to all persons without qualification, including low-income, racial and

ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.7, page 48, the applicant states that in CY 2015, 71.1% of its services at Wake Forest Dialysis Center were provided to recipients of Medicare and Medicaid. In addition, in Section R, Form C, and in Section L, page 45, the applicant projects that 71.1% 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.

NA

- (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 23, the applicant describes the alternatives considered prior to submitting this application for a one-station addition, which include:

- Maintain Status Quo – The applicant states that maintaining the status quo is not an effective alternative, because the facility is currently at maximum capacity, which could cause patients to locate another facility for their dialysis needs.
- Add a Third Shift – The applicant states that adding a third shift is not an effective alternative, it is inconvenient for the patients if that becomes their only option to remain at Wake Forest Dialysis Center.
- Develop the Project as Proposed – The applicant states that adding one station to the existing facility is the most effective alternative to ensure that all patients referred by their admitting nephrologists have adequate access to the dialysis services at Wake Forest Dialysis.

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 develop and operate no more than one additional dialysis station for a total of no more than 13 certified stations upon completion of this project, Project ID #J-11090-15 (add two stations) and Project I.D. # J-11131-16 (relocate 10 stations), which shall include any isolation or home hemodialysis stations.**
  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 one dialysis station, 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 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 proposes to add one dialysis station to the existing facility for a total of 13 in-center dialysis stations at Wake Forest Dialysis Center.

### **Capital and Working Capital Costs**

In Section F.1, page 24, the applicant projects no capital costs are required to develop this project. In Sections F.10-F.12, pages 26 - 27, the applicant states projects there will be no start-up expenses or initial operating expenses incurred for this project, since it is currently an operational facility.

### **Financial Feasibility**

In Section R, the applicant provides pro forma financial statements for the first two operating 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.



	CY 2018	CY 2019
Total Net Revenue	\$4,941,418	\$5,126,968
Total Operating Expenses	\$2,597,763	\$2,669,168
Net Income	\$2,343,656	\$2,457,799

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable and adequately supported assumptions, including the number of projected treatments. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization 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 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 proposes to add one station to the existing facility for a total of 13 stations upon completion of this project and two other projects as illustrated in the table below:

FACILITY	PROJECT ID #	#STATIONS TO BE ADDED (DELETED)	END RESULT
Begin with 20 stations as reported in the January 2016 SDR			
Wake Forest Dialysis	J-11090-15	2	22
Wake Forest Dialysis*	J-11131-16	(10)	12
Wake Forest Dialysis	J-11152-16	1	13

\*This project approved a 10-station relocation to develop Oak City Dialysis in Wake County.

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 currently operates just one dialysis center in Wake County and in Project ID #J-11131-16 was approved to develop a new 10-station facility, Oak City Dialysis. Bio-Medical Applications of North Carolina, Inc. (BMA) is the only other provider of dialysis services in Wake County, and operates 12 dialysis facilities, as shown in the table below:

FACILITY	# CERTIFIED STATIONS AS OF 6/30/15	# IN-CENTER PATIENTS	PATIENTS PER STATION	% UTILIZATION
<b>DAVITA OWNED FACILITIES</b>				
Wake Forest Dialysis	20	73	3.65	91.25%
Oak City Dialysis*	--	--	--	--
<b>BMA OWNED FACILITIES</b>				
BMA of Fuquay-Varina Kidney Center	20	77	3.85	96.25%
BMA of Raleigh Dialysis	50	163	3.26	81.50%
Cary Kidney Center (BMA Cary)	28	80	2.86	71.43%
FMC Apex	20	49	2.45	61.25%
FMC Central Raleigh	19	55	2.89	72.37%
FMC Eastern Wake	14	61	4.36	108.93%
FMC Millbrook	17	57	3.35	83.82%
FMC New Hope Dialysis	36	110	3.06	76.39%
FMC Northern Wake**	0	0	0.00	0.00%
Southwest Wake County Dialysis	31	115	3.71	92.74%
Wake Dialysis Clinic	50	198	3.96	99.00%
Zebulon Kidney Center	30	99	3.30	82.50%

Source: January 2016 SDR

\*Project ID #J-11131-16 [Relocate 10 stations from Wake Forest Dialysis to develop Oak City Dialysis]

\*\*\*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 add one station to Wake Forest Dialysis Center. Wake Forest Dialysis Center was serving 73 patients weekly on 20 stations, which is 3.65 patients per station per week, 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 13 - 15 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, pursuant to the Wake County AACR. The applicant states that the methodology rounds down to the whole patient and projects to serve 54 in-center patients or 4.15 patients per station per week, a utilization rate of 103% ( $54 / 13 = 4.15$ ;  $4.15 / 4 = 1.03$ ) by the end of OY 1 (CY 2018) and 56 in-center patients or 4.3 patients per station per week, a utilization rate of 107% ( $56 / 13 = 4.3$ ;  $4.3 / 4 = 1.07$ ) by the end of OY 2 (CY 2019). 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 states on page 14 that it will apply for additional stations to reduce the possibility of overcrowding at this facility and ensure continued patient service. The applicant adequately demonstrates the need to add one station to Wake Forest Dialysis Center.

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 31, the applicant provides the existing staffing at Wake Forest Dialysis in Full Time Equivalents (FTEs), as shown in the table below:

POSITION	TOTAL FTEs
RN	3
Patient Care Technician	8
Administrator	1
Dietician	1
Social Worker	1
Home Training RN	1
Administrative Assistant	1
Bio-Medical Technician	1
<b>Total</b>	<b>17</b>

The applicant does not propose additional staffing as a result of this proposal. The applicant states on page 31 that the Medical Director is not an FTE of the facility, but is a contract position.

In Section H.3, pages 32 - 33, the applicant describes its experience and process for recruiting and retaining staff. Exhibit H-3 contains information on DaVita employee benefits. On page 32, the applicant states Munsoor Lateef is the current Medical Director, and Exhibit I-3 provides a copy of a letter from Dr. Lateef, expressing his support for the project and his commitment to continue to serve 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 35, the applicant provides a table to illustrate the providers of the necessary ancillary and support services. The applicant discusses coordination with the existing health care system on pages 36 - 37. Exhibits I-1, 2, 3, and 4 contain documentation for home training, laboratory, transplant services and social services, respectively. 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.

NA

- (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(b), page 46, the applicant states:

*“... 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 48, the applicant provides the historical payor mix for Wake Forest Dialysis Center in-center patients, showing 71.1% of the patients had some or all of their services paid for by Medicare or Medicaid, as shown below:

Payment Source	% Total IC Patients
Medicare	20.3%
Medicaid	2.9%
Commercial Insurance	27.5%
Medicare/Commercial	43.6%
Medicare/Medicaid	4.3%
VA	1.4%
<b>Total</b>	<b>100.0%</b>

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*<sup>1</sup> provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

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

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
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%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
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(d), page 47, 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 47, 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 served by Wake Forest Dialysis will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected payment source for in-center and PD patients for operating years one and two:

PAYMENT SOURCE	IN-CENTER	PD
Medicare	20.3%	16.2%
Medicaid	2.9%	2.2%
Commercial Insurance	27.5%	27.2%
Medicare/Commercial	43.6%	45.7%
Medicare/Medicaid	4.3%	7.6%
VA	1.4%	1.7%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

\*numbers may not foot due to rounding

In Section L.1(b), page 45, 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 Wake Forest Dialysis 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 (CY 2019) 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 Wake Forest 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 47, the applicant describes the range of means by which a person will have access to the dialysis services at Wake Forest 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 49, 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 proposes to add one station to the existing facility for a total of 13 stations following completion of this project and two other projects as illustrated in the table below:

FACILITY	PROJECT ID #	#STATIONS TO BE ADDED (DELETED)	END RESULT
Begin with 20 stations as reported in the January 2016 SDR			
Wake Forest Dialysis	J-11090-15	2	22
Wake Forest Dialysis*	J-11131-16	(10)	12
Wake Forest Dialysis	J-11152-16	1	13

\*This project approved a 10-station relocation to develop Oak City Dialysis in Wake County.

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 currently operates just one dialysis center in Wake County, and in Project ID #J-11131-16 was approved to develop one more 10-station facility, Oak City Dialysis. 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:



FACILITY	# CERTIFIED STATIONS AS OF 6/30/15	# IN-CENTER PATIENTS	PATIENTS PER STATION	% UTILIZATION
<b>DAVITA OWNED FACILITIES</b>				
Wake Forest Dialysis	20	73	3.65	91.25%
Oak City Dialysis*	--	--	--	--
<b>BMA OWNED FACILITIES</b>				
BMA of Fuquay-Varina Kidney Center	20	77	3.85	96.25%
BMA of Raleigh Dialysis	50	163	3.26	81.50%
Cary Kidney Center (BMA Cary)	28	80	2.86	71.43%
FMC Apex	20	49	2.45	61.25%
FMC Central Raleigh	19	55	2.89	72.37%
FMC Eastern Wake	14	61	4.36	108.93%
FMC Millbrook	17	57	3.35	83.82%
FMC New Hope Dialysis	36	110	3.06	76.39%
FMC Northern Wake**	0	0	0.00	0.00%
Southwest Wake County Dialysis	31	115	3.71	92.74%
Wake Dialysis Clinic	50	198	3.96	99.00%
Zebulon Kidney Center	30	99	3.30	82.50%

Source: January 2016 SDR

\*Project ID #J-11131-16 [Relocate 10 stations from Wake Forest Dialysis to develop Oak City Dialysis]

\*\*\*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 50, 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 expansion of Wake Forest Dialysis will have no effect on competition in Wake County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care of North Carolina, LLC [sic].*

*The expansion of Wake Forest 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.”*

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 Criteria (1) and (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 (1), (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 51, 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 to 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.*
- NA- The applicant is not proposing to establish a new End Stage Renal Disease Facility.
- .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.*
- C- In Section C, pages 13 - 15, the applicant adequately demonstrates the need to add one station to Wake Forest Dialysis Center. At the end of the first operating year, the applicant projects Wake Forest Dialysis will serve 54 in-center patients for a utilization of 4.1 patients per station per week. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 13 – 15, and Section C.7, pages 17 - 19, 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.