

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 21, 2019

Findings Date: June 21, 2019

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11682-19

Facility: Wake Forest Dialysis Center

FID #: 041181

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than three dialysis stations for a total of no more than 21 stations upon completion of this project, Project I.D. # J-11311-16 (relocate 10 stations), Project I.D. # J-11152-16 (add one station), Project I.D. # J-11254-16 (add two stations), and Project I.D. # J-11597-18 (add three stations)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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), the applicant, proposes to add no more than three dialysis stations for a total of no more than 21 stations at Wake Forest Dialysis upon completion of this project, Project I.D. # J-11311-16 (relocate 10 stations), Project I.D. # J-11152-16 (add one station), Project I.D. # J-11254-16 (add two stations), and Project I.D. # J-11597-18 (add three stations).

**Need Determination**

The 2019 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a projected surplus of 22 dialysis stations and therefore 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 2019 SDR is 4.05 patients per station per week. This utilization rate was calculated based on 89 in-center dialysis patients and 22 certified dialysis stations as of June 30, 2018 (89 patients / 22 stations = 4.0455 patients per station per week). Application of the facility need methodology indicates up to five additional stations are needed for this facility, as illustrated in the following table.

<b>APRIL 1 REVIEW-JANUARY 2019 SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		101.14%
Certified Stations as of 6/30/18		22
Pending Stations		3
<b>Total Existing and Pending Stations</b>		<b>25</b>
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		89
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		83
<b>Step</b>	<b>Description</b>	<b>Result</b>
	Difference (SDR2 - SDR1)	6
(i)	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17(SDR1)	0.1446
(ii)	Divide the result of Step (i) by 12	0.0120
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.0723
(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	95.4337
(v)	Divide the result of Step (iv) by 3.2 patients per station	29.8230
	and subtract the number of certified and pending stations to determine the number of stations needed (rounded)	<b>5</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five stations. 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 three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2019 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.”*

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 52; 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), pages 10-11; Section L, pages 45-49; 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 Section B.4(c), page 11; and Section N, page 51. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2019 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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 no more than three dialysis stations for a total of no more than 21 stations at Wake Forest Dialysis upon completion of this project, Project I.D. # J-11311-16 (relocate 10 stations), Project I.D. # J-11152-16 (add one station), Project I.D. # J-11254-16 (add two stations), and Project I.D. # J-11597-18 (add three stations).

The following table illustrates the current and projected number of dialysis stations at Wake Forest Dialysis, per the January 2019 SDR and pending relocations and additions.

Stations	Description	Project ID #
22	Total existing certified stations as of the June 30, 2018	
-10	Relocate 10 stations to Oak City Dialysis	J-11131-16
+1	Add one dialysis station	J-11152-16
+2	Add two dialysis stations	J-11254-16
+3	Add three dialysis stations	J-11597-18
+3	Add three dialysis station in this proposed project	J-11682-19
21	Total stations upon completion of proposed project	

As shown in the table above, upon project completion, Wake Forest Dialysis will be certified for 22 dialysis stations.

**Patient Origin**

On page 369, the 2019 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.” Wake Forest Dialysis is located in Wake County; thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Section C.1, page 13, the applicant provides the current (2018) and projected patient origin for in-center (IC) and peritoneal dialysis (PD) patients at Wake Forest Dialysis for the first two years of operation following completion, as shown in the following table:

<b>Wake Forest Dialysis Current and Projected Patients by County of Residence</b>								
County	Current As of June 30, 2018		OY1 CY2021		OY2 CY2022		County Patients as % of Total	
	IC Patients	PD Patients	IC Patients	PD Patients	IC Patients	PD Patients	OY1 CY2021	OY2 CY2022
Wake	64	9	48	12	51	13	69.0%	69.0%
Durham	1	0	1	0	1	0	1.1%	1.1%
Franklin	13	0	13	0	13	0	14.9%	14.9%
Forsyth	0	2	0	2	0	2	2.3%	2.3%
Johnston	3	0	3	0	3	0	3.4%	3.4%
New Hanover	1	0	1	0	1	0	1.1%	1.1%
Pasquotank	1	0	1	0	1	0	1.1%	1.1%
Vance	2	0	2	0	2	0	2.3%	2.3%
Others States	3	0	3	0	3	0	3.4%	3.4%
State of SC	1	0	1	0	1	0	1.1%	1.1%
<b>Total*</b>	<b>89</b>	<b>11</b>	<b>73 [69]</b>	<b>14</b>	<b>76 [72]</b>	<b>15</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Tables on page 13 and 20 of the application.

\*In the applicant's utilization projections below, the total in-center patients projected to be served in OY1 and OY2 are calculated as 69 and 72 patients, respectively, and not 73 and 76 as listed in the table on page 13 of the application.

As the table above shows, the applicant currently provides peritoneal dialysis home therapies, and the applicant proposes to continue to provide these services following completion of the proposed project.

In Section C, pages 13-14, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.2, page 16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B.2, page 7, the applicant provides its calculation of the facility need methodology showing a need for up to five additional dialysis stations. The information is reasonable and adequately supported for the following reasons:

- As of June 30, 2018, the facility was operating at a utilization rate of 101.14%, serving 89 in-center patients on 22 stations,
- As of June 30, 2018, 64 of the 89 patients were residents of Wake County. The applicant projects that 26 patients, including 21 Wake County residents, currently dialyzing at Wake Forest Dialysis will transfer their care to Oak City Dialysis upon its projected certification date of April 2019. [Note: The applicant’s June 5, 2019 progress report indicates the Oak City Dialysis project is complete and operational.]
- The applicant projects the first full operating year (OY1) of the project will be January 1, 2021 – December 31, 2021 (CY2021) and the second full operating year (OY2) will be January 1, 2022 – December 31, 2022 (CY2022).
- The applicant assumes the Wake County in-center patients population utilizing the facility will increase at the Wake County Average Annual Change Rate (AACR) of 4.3% per year.

Projected Utilization

In Section C.7, pages 17-18, the applicant provides the methodology, based on its stated assumptions, for projecting utilization for the first two years of operation following completion of the project, as summarized in the following table.

	In-Center
The applicant begins with the in-center patients census of Wake County residents dialyzing at Wake Forest Dialysis as of June 30, 2018.	64
The census of Wake County in-center patients is increased by 2.15% to project the census forward six months to December 31, 2018. (4.3%/12*6 = 2.15%)	$64 \times 1.0215 = 65.376$
The applicant deducts 21 Wake County patients projected to transfer to Oak City Dialysis	$65 - 21 = 44$
The census of Wake County in-center patients is increased by 4.3% to project the census forward one year to December 31, 2019.	$44 \times 1.043 = 45.892$
The census of Wake County in-center patients is increased by 4.3% to project the census forward one year to December 31, 2020.	$45.862 \times 1.043 = 47.86536$
The census of Wake County in-center patients is increased by 4.3% to project the census forward one year to December 31, 2021.	$47.86536 \times 1.043 = 49.92357$
The applicant adds the 20 patients from outside Wake County. This is the projected ending census for Operating Year 1 (CY2021).	$49.92357 + 20 = 69.92357$
The census of Wake in-center patients is increased by 4.3% to project the census forward one year to December 31, 2022.	$49.92357 \times 1.043 = 52.07028$
The applicant adds the 20 patients from outside Wake. This is the projected ending census for Operating Year 2 (CY2022).	$52.07028 + 20 = 72.07028$

The applicant rounds patient numbers down.

As the table above shows, the applicant projects to serve 69 in-center patients or 3.3 patients per station per week ( $69/21 = 3.30$ ) by the end of Operating Year 1 and 72 in-center patients or 3.4 patients per station per week ( $72/21 = 3.4$ ) by the end of Operating Year 2 for the proposed 21-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).

Projected utilization for in-center dialysis patients at Wake Forest Dialysis, is reasonable and adequately supported for the following reasons:

- Wake Forest Dialysis was operating at 101.14% of capacity as of June 30, 2018.
- The projection of the future utilization of services is based upon the facility’s historical patient utilization, adjusted for the approved relocation of stations and transfer of patients.
- The growth projections are based on an assumption that the Wake County dialysis patient census will increase annually by 4.3%, which is consistent with the 4.3% five-year AACR for Wake County, reported in the January 2019 SDR, Table D.

Home Therapy Programs

The applicant does not currently provide home hemodialysis (HHD). On page 15, the applicant provides the following table showing its projections of peritoneal dialysis (PD) patients through the first two operating years of the project.

<b>PD Patient Projections</b>	<b>Start Date</b>	<b># of Patients Start of Year</b>	<b># of Patients End of Year</b>	<b>Average # of Patients in Year</b>
Interim Period	7/1/2018	11	11	11
Current Year	1/1/2019	11	12	11.5
Interim Period	1/1/2020	12	13	12.5
Operating Year 1	1/1/2021	13	14	13.5
Operating Year 2	1/1/2022	14	15	14.5

Source: Table on page 15 of the application.

On page 18, the applicant describes its assumptions as follows:

*“Wake Forest Dialysis Center had 11 PD patients as of June 30, 2018 based on information included in Table C of the January 2019 SDR. ... The period of growth begins July 1, 2018 and is calculated forward to December 31, 2022. It is reasonable to assume that the Wake Forest Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth.”*

Projected utilization for PD training and support is based on reasonable and adequately supported assumptions regarding continued growth.

**Access**

In Section C.3, page 16, the applicant states:

*“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation. ... Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped person, elderly and other under-served persons.”*

The applicant projects payor mix for the second operating year following completion of the project in Section L.1(b), page 46, by percent, as summarized below:

**Projected Payor Mix OY2**

<b>Payor Source</b>	<b>Total Patients</b>	<b>In-center Patients</b>	<b>HH Patients</b>	<b>PD Patients</b>
Private Pay	0.0%	0.0%	0.0%	0.0%
Medicare	13.5%	15.1%	0.0%	9.7%
Medicaid	13.5%	19.2%	0.0%	0.0%
Commercial Insurance	8.7%	9.6%	0.0%	6.5%
Medicare / Commercial	41.3%	39.7%	0.0%	45.2%
Medicare / Medicaid	21.2%	16.4%	0.0%	32.3%
VA	1.9%	0.0%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>0.0%</b>	<b>0.0%</b>

Totals may not sum due to rounding

In Section L.1(b), page 46, the applicant states that the projected payor mix is based upon the the patient payments received by the existing facility during the last full operating year. The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.



- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (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

The applicant does not propose a reduction or elimination of a service, or the relocation of a facility or a service; therefore, Criterion (3a) is not applicable to this review.

- (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

The applicant proposes to add no more than three dialysis stations for a total of no more than 21 stations at Wake Forest Dialysis upon completion of this project, Project I.D. # J-11311-16 (relocate 10 stations), Project I.D. # J-11152-16 (add one station), Project I.D. # J-11254-16 (add two stations), and Project I.D. # J-11597-18 (add three stations).

In Section E, page 24, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application. The alternatives considered were:

- Maintain status quo – The applicant states that this alternative was dismissed given the growth rate at the facility.
- Apply for three stations based on the facility need methodology – The applicant states this alternative meets the growing demand for services at Wake Forest Dialysis.

On page 23, the applicant states that the project as proposed is the most effective alternative because it ensures that the facility will proactively address the issues of growth and access at the facility. The applicant further states:

*“As calculated in Section B-2, there is a need for additional stations. ... We are committed to ensuring that all patients referred by our admitting nephrologists have convenient access to the facility and the chosen alternative does that effectively.”*

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the January 2019 SDR, Total Renal Care of North Carolina, LLC shall develop and operate no more than three additional dialysis stations at Wake Forest Dialysis Center for a total of no more than 21 certified stations upon completion of this project, Project I.D. # J-11311-16 (relocate 10 stations), Project I.D. # J-11152-16 (add one station), Project I.D. # J-11254-16 (add two stations), and Project I.D. # J-11597-18 (add three stations), which shall include any home hemodialysis training or isolation stations.**
  - 3. Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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 no more than three dialysis stations for a total of no more than 21 stations at Wake Forest Dialysis upon completion of this project, Project I.D. # J-11311-16 (relocate 10 stations), Project I.D. # J-11152-16 (add one station), Project I.D. # J-11254-16 (add two stations), and Project I.D. # J-11597-18 (add three stations).

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

In Section F.1, page 25, the applicant shows that it will not incur any capital costs to develop this project. In Sections F.10-F.12, pages 27-28, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project, because Wake Forest Dialysis is an existing facility.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In 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.

<b>Projected Revenues and Operating Expenses</b>		
<b>Wake Forest Dialysis</b>	<b>Operating Year 1 CY2021</b>	<b>Operating Year 2 CY2022</b>
Total Treatments	12,079	12,597
Total Gross Revenues (Charges)	\$3,799,733	\$3,960,185
Total Net Revenue	\$3,719,130	\$3,876,287
Average Net Revenue per Treatment	\$308	\$308
Total Operating Expenses (Costs)	\$3,213,457	\$3,332,212
Average Operating Expense per Treatment	\$266	\$265
<b>Net Income/Profit</b>	<b>\$505,673</b>	<b>\$544,075</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R 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.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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 no more than three dialysis stations for a total of no more than 21 stations at Wake Forest Dialysis upon completion of this project, Project I.D. # J-11311-16 (relocate 10 stations), Project I.D. # J-11152-16 (add one station), Project I.D. # J-11254-16 (add two stations), and Project I.D. # J-11597-18 (add three stations).

On page 369, the 2019 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 is Wake County. Facilities may serve residents of counties not included in their service area.

Currently, there are 18 existing and approved dialysis facilities in Wake County, 16 of which are owned by Fresenius Medical Care (FMC). The applicant, DaVita, operates one dialysis facility in Wake County, and has one approved but not yet operational, as shown in the following table:

WAKE COUNTY DIALYSIS FACILITIES				
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 6/30/18	UTILIZATION AS OF 6/30/18
FMC New Hope Dialysis	FMC	Raleigh	36	84.72%
BMA of Fuquay Varina Kidney Center	FMC	Fuquay Varina	28	82.14%
BMA of Raleigh Dialysis	FMC	Raleigh	50	92.50%
Cary Kidney Center	FMC	Cary	28	78.57%
FMC Apex	FMC	Apex	20	81.25%
FMC Central Raleigh	FMC	Raleigh	19	69.74%
FMC Eastern Wake	FMC	Rolesville	17	60.29%
FMC Millbrook	FMC	Raleigh	17	79.41%
FMC Northern Wake	FMC	Wake Forest	16	59.38%
Southwest Wake County Dialysis	FMC	Raleigh	30	93.33%
Wake Dialysis Center	FMC	Raleigh	50	99.00%
Zebulon Kidney Center	FMC	Zebulon	30	77.50%
FMC Morrisville	FMC	Morrisville	10*	NA
FMC White Oak	FMC	Garner	12*	NA
FMC Rock Quarry	FMC	Raleigh	10*	NA
FKC Holly Springs	FMC	Holly Springs	10*	NA
Wake Forest Dialysis Center	DaVita	Raleigh	22	101.14%
Oak City Dialysis	DaVita	Raleigh	10*	NA

Source: Table B, January 2019 SDR.

\*Indicates dialysis stations at facilities that were approved but not operational as of June 30, 2018.

As shown in the table above, Wake Forest Dialysis, which is the applicant’s only operational dialysis facility in Wake County, operated at a utilization rate of 101.14% of capacity as of June 30, 2018.

In Section G, page 31, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states that the application utilizes the facility need methodology and addresses the specific needs of patients who chose to receive service from DaVita. The applicant further states:

*“In Section B-2 and Section C of this application, we demonstrate the need that Wake Forest Dialysis Center has for adding stations. While adding stations at this facility does increase the number of stations in Wake County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists.*

*The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant demonstrates the need for the stations based on the Wake Forest Dialysis facility’s patients’ needs.
- The applicant adequately demonstrates that the proposed stations are needed in addition to the existing stations in Wake County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 32, the applicant provides current and projected OY2 staffing for the proposed services in full-time equivalent (FTE) positions, as summarized in the following table.

<b>POSITION</b>	<b>Current FTE Positions</b>	<b>OY2 PROJECTED FTE POSITIONS</b>
RN	3.0	3.0
Technician (Patient Care)	9.0	9.0
Administrator	1.0	1.0
Dietician	1.0	1.0
Social Worker	1.0	1.0
Home Training RN	1.0	1.0
Administrative Assistant	1.0	1.0
Bio-med Technician	0.5	0.5
<b>Total</b>	<b>17.5</b>	<b>17.5</b>

Source: Table on 32 of the application.

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section R. In Section H, pages 33-34, the applicant describes the methods used to recruit or fill new positions and DaVita’s existing training and continuing education programs. Exhibit H contains DaVita training documentation. The Medical Director is a contract service, not an FTE position. In Section H.2, page 33, and Section I.3, page 37, the applicant identifies the Medical Director. In Exhibit I-3, the applicant provides a letter from the Medical Director expressing his commitment to continue to serve in that position following completion of the proposed project.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

In Section I-1, pages 36-37, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 36, as summarized below.

**Wake Forest Dialysis Center  
 Ancillary and Support Services**

Services	Provider
(a) In-center dialysis/maintenance	Wake Forest Dialysis
(b) Self-care training (performed in-center)	Wake Forest Dialysis
(c) Home training	
(1) Hemodialysis	Durham West Dialysis
(2) Peritoneal dialysis	Wake Forest Dialysis
(3) Accessible follow-up program	Wake Forest Dialysis
(d) Psychological counseling	Wake Forest Dialysis
(e) Isolation-hepatitis	Wake Forest Dialysis
(f) Nutritional counseling	Wake Forest Dialysis
(g) Social work services	Wake Forest Dialysis
(h) Acute dialysis in an acute care setting	WakeMed
(i) Emergency care	WakeMed
(j) Blood bank services	WakeMed
(k) Diagnostic and evaluation services	WakeMed
(l) X-ray services	WakeMed
(m) Laboratory services	DaVita Laboratory Services, Inc.
(n) Pediatric nephrology	WakeMed
(o) Vascular surgery	WakeMed
(p) Transplantation services	Duke University Medical Center
(q) Vocational rehabilitation counseling & services	NC Division of Vocational Rehabilitation Services
(r) Transportation	Wake Human Services

In Section I, pages 37-38, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

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.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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

The project does not require any construction or more than minor renovation; therefore, Criterion (12) is not applicable to this review.



- (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.7, page 48, the applicant provides the historical (CY2018) payment source for the patients dialyzing at Wake Forest Dialysis, as shown below.

<b>Payment Source</b>	<b>Total Patients by Percent of Total</b>
Medicare	13.5%
Medicaid	13.5%
Commercial Insurance	8.7%
Medicare/Commercial	41.3%
Medicare/Medicaid	21.3%
VA	1.9%
<b>Total</b>	<b>100.0%</b>

The table above shows that 76.1% of the patients who received treatments at Wake Forest Dialysis had some or all of their services paid for by Medicare or Medicaid in CY2018.

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**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Wake	11%	51%	40%	11%	6%	10%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

\* Excludes "White alone, not Hispanic or Latino"

\*\* "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26<sup>1</sup>) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

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<sup>1</sup><https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(d), page 48, the applicant states:

*“Wake Forest Dialysis Center 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. The facility has no obligation under the Hill Burton Act.”*

In Section L.6, page 48, the applicant states that there have been no civil rights access complaints filed against any facilities owned by the applicant or the parent company and located in North Carolina within the last five years.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L.1(b), page 46, the applicant projects the following payor mix for the proposed services during the second full calendar year of operation following completion of the project, as summarized in the table below.

**Projected Payor Mix OY2**

<b>Payor Source</b>	<b>Total Patients</b>	<b>In-center Patients</b>	<b>HH Patients</b>	<b>PD Patients</b>
Private Pay	0.0%	0.0%	0.0%	0.0%
Medicare	13.5%	15.1%	0.0%	9.7%
Medicaid	13.5%	19.2%	0.0%	0.0%
Commercial Insurance	8.7%	9.6%	0.0%	6.5%
Medicare / Commercial	41.3%	39.7%	0.0%	45.2%
Medicare / Medicaid	21.2%	16.4%	0.0%	32.3%
VA	1.9%	0.0%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>0.0%</b>	<b>0.0%</b>

Totals may not sum due to rounding

As shown in the table above, during the second full calendar year of operation, the applicant projects that 89.6% of the total dialysis patients will have all or part of their services paid for by Medicare and/or Medicaid.

On page 46, the applicant states that the projected payor mix is based on the sources of patient payments that have been received by the existing facility in the last full operating year. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 48, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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, page 50, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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 no more than three dialysis stations for a total of no more than 21 stations at Wake Forest Dialysis upon completion of this project, Project I.D. # J-11311-16 (relocate 10 stations), Project I.D. # J-11152-16 (add one station), Project I.D. # J-11254-16 (add two stations), and Project I.D. # J-11597-18 (add three stations).

On page 369, the 2019 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 is Wake County. Facilities may serve residents of counties not included in their service area.

Currently, there are 18 existing and approved dialysis facilities in Wake County, 16 of which are owned by Fresenius Medical Care (FMC). The applicant, DaVita, operates one dialysis facility in Wake County, and has one approved but not yet operational, as shown in the following table:

WAKE COUNTY DIALYSIS FACILITIES				
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 6/30/18	UTILIZATION AS OF 6/30/18
FMC New Hope Dialysis	FMC	Raleigh	36	84.72%
BMA of Fuquay Varina Kidney Center	FMC	Fuquay Varina	28	82.14%
BMA of Raleigh Dialysis	FMC	Raleigh	50	92.50%
Cary Kidney Center	FMC	Cary	28	78.57%
FMC Apex	FMC	Apex	20	81.25%
FMC Central Raleigh	FMC	Raleigh	19	69.74%
FMC Eastern Wake	FMC	Rolesville	17	60.29%
FMC Millbrook	FMC	Raleigh	17	79.41%
FMC Northern Wake	FMC	Wake Forest	16	59.38%
Southwest Wake County Dialysis	FMC	Raleigh	30	93.33%
Wake Dialysis Center	FMC	Raleigh	50	99.00%
Zebulon Kidney Center	FMC	Zebulon	30	77.50%
FMC Morrisville	FMC	Morrisville	10*	NA
FMC White Oak	FMC	Garner	12*	NA
FMC Rock Quarry	FMC	Raleigh	10*	NA
FKC Holly Springs	FMC	Holly Springs	10*	NA
Wake Forest Dialysis Center	DaVita	Raleigh	22	101.14%
Oak City Dialysis	DaVita	Raleigh	10*	NA

Source: Table B, January 2019 SDR.

\*Indicates dialysis stations at facilities that were approved but not operational as of June 30, 2018.

In Section N, page 51, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote 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.*

*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 others involved in the dialysis process to receive services.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections B, F, and R of the application and any referenced exhibits).
- Quality services will be provided (see Sections B and O of the application and any referenced exhibits).
- Access will be provided to underserved groups (see Sections B and L of the application and any referenced exhibits).

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Section A.11, page 5, the applicant states that DaVita operates over 85 dialysis facilities located in North Carolina. Exhibit A-11 contains a list of DaVita facilities in North Carolina.

In Section O, page 51, the applicant refers to Exhibit O-3, which shows that during the 18-month look-back period immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these DaVita facilities. On page 52, the applicant states that both facilities were back in compliance at the time of application submittal. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, 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. The specific criteria are discussed below.

### **SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

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.*

-NA- Wake Forest Dialysis Center is an existing 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.1, page 15, the applicant projects to serve 69 in-center patients or 4.7 patients per station per week ( $69/21 = 3.3$ ) by the end of Operating Year 1. 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).

*.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C.7, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.



