

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 8, 2021

Findings Date: January 8, 2021

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: J-11974-20

Facility: Wake Forest Dialysis Center

FID #: 041181

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 23 stations upon completion of this project and Project ID# J-11847-20 (relocate 10 stations)

### REVIEW CRITERIA

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

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

C

Total Renal Care of North Carolina, LLC (hereinafter referred to as “TRC” or “the applicant”) d/b/a Wake Forest Dialysis Center (WFDC) proposes to add 12 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 23 stations upon completion of this project and Project I.D. #J-11847-20 (relocate 10 stations).

#### **Need Determination**

Chapter 9 of the 2020 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 Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Wake County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for WFDC on page 164 of the 2020 SMFP is 98.86 percent or 3.95 patients per station per week, based on 87 in-center dialysis patients and 22 certified dialysis stations (87 patients / 22 stations = 3.95;  $3.95 / 4 = 98.86\%$ ) on December 31, 2018.

As shown in Table 9E on page 173 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at WFDC is up to 12 additional stations; thus, the applicant is eligible to apply to add up to 12 stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 12 new stations to WFDC, which is consistent with the 2020 SMFP calculated facility need determination for up to 12 dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2020 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on pages 30-31 of the 2020 SMFP, 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.”*

In Section B, pages 13-16, the applicant explains why it believes its application is consistent with Policy GEN-3:

- The applicant describes its safety and quality record and the policies it has to ensure safety and quality in delivering care, including its Quality Management Program.
- The applicant states it will provide care to all patients, describes the ways it accommodates patients with disabilities and those who work or go to school, and states it helps uninsured and underinsured patients with finding and receiving financial assistance.
- The applicant explains the ways it believes its proposed project will maximize healthcare value for resources expended, including its use of a centralized purchasing department to

obtain the best prices for its thousands of facilities nationwide, electronic medical records system, and inventory control.

On pages 15-16, the applicant states:

*“For all its patients - current patients as well as those included in the projected utilization – DaVita is committed to:*

- *promoting a culture of safety;*
- *ensuring industry-leading quality of care;*
- *promoting equitable access; and*
- *maximizing healthcare value.*

*..., established policy and procedure will continue to guide this commitment.”*

The applicant adequately documents how the project will promote safety and quality in the delivery of dialysis services in Wake County, will promote equitable access to dialysis services in Wake County while maximizing healthcare value for resources expended, and how its projected volumes incorporate these concepts in meeting the need identified in the 2020 SMFP as well as addressing the needs of all residents in Wake County. Therefore, the application is consistent with Policy GEN-3.

### **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 demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 because the applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access, and maximum value for resources expended in meeting the need for the proposed services as identified by the applicant.

(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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

### C

The applicant proposes to add 12 dialysis stations to WFDC pursuant to Condition 2 of the facility need methodology for a total of 23 stations following completion of this project and Project I.D. #J-11847-20 (relocate 10 stations).

Table 9C on page 164 of the 2020 SMFP shows WFDC had 22 certified dialysis stations on December 31, 2018. According to WFDC's 2020 ESRD Data Collection Form submitted to the Agency, the facility underwent the following changes during CY 2019:

- May 17, 2019: decertified 10 stations pursuant to Project I.D. #J-11131-16
- May 17, 2019: certified 6 stations pursuant to Project I.D. #J-11254-16
- August 4, 2019: certified 3 stations pursuant to Project I.D. #J-11682-19

As of December 31, 2019, WFDC had 21 certified dialysis stations ( $22 - 10 = 12$ ;  $12 + 6 + 3 = 21$ ).

In Section C, page 19, the applicant states it currently provides peritoneal dialysis (PD) training and support. On page 22, the applicant states it does not project any changes to the types of dialysis modalities it offers as part of this application.

In Section A, page 5, the applicant states its parent company is DaVita, Inc. The applicant uses DaVita, Inc. (DaVita) interchangeably with TRC to refer to itself or its facilities. References to DaVita should be interpreted to mean TRC unless otherwise specified.

### **Patient Origin**

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin.

<b>WFDC – Current Patient Origin (as of 12/31/2019)</b>				
	<b>In-Center Patients</b>		<b>PD Patients</b>	
<b>County</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Wake	48	60.00%	14	93.33%
Alamance	1	1.30%	0	0.00%
Franklin	16	20.00%	1	6.67%
Granville	3	3.80%	0	0.00%
Halifax	1	1.30%	0	0.00%
Johnston	1	1.30%	0	0.00%
Vance	2	2.50%	0	0.00%
Wayne	1	1.30%	0	0.00%
Other States	7	8.80%	0	0.00%
<b>Total</b>	<b>80</b>	<b>100.00%</b>	<b>15</b>	<b>100.00%</b>

Table may not foot due to rounding.

Source: Section C, page 19

<b>WFDC – Projected Patient Origin – OY 2 (CY 2023)</b>				
	<b>In-Center Patients</b>		<b>PD Patients</b>	
<b>County</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Wake	40	55.60%	18	94.74%
Alamance	1	1.40%	0	0.00%
Franklin	16	22.20%	1	5.26%
Granville	3	4.20%	0	0.00%
Halifax	1	1.40%	0	0.00%
Johnston	1	1.40%	0	0.00%
Vance	2	2.80%	0	0.00%
Wayne	1	1.40%	0	0.00%
Other States	7	9.70%	0	0.00%
<b>Total</b>	<b>72</b>	<b>100.00%</b>	<b>19</b>	<b>100.00%</b>

Table may not foot due to rounding.

Source: Section C, page 20

In Section C, pages 20-22, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following analysis:

- The applicant bases its projected patient origin on its existing patient origin.
- The applicant projects growth of the in-center Wake County patient population according to the Five Year Average Annual Change Rate (AACR) published in the 2020 SMFP for Wake County and does not project growth for the in-center patient population residing in other counties.
- The applicant projects growth of the PD patient population using reasonable and adequately supported assumptions.

**Analysis of Need**

In Section C, page 22, the applicant states these stations will backfill 10 stations approved to be relocated (Project I.D. #J-11847-20) to develop Downtown Raleigh Dialysis. As part of that project, the applicant projected 14 Wake County residents would transfer their care to Downtown Raleigh Dialysis upon certification of the facility (projected to be January 1, 2022).

In Section C, pages 20-21, the applicant projects the Wake County in-center patient population will grow at a Five Year AACR of 3.6 percent as published in the 2020 SMFP and projects no growth for in-center patients residing in other counties. The applicant states that, based on the projected in-center patient population growth, projected utilization during the first two full fiscal years following project completion demonstrates the need to add the 12 stations to WFDC.

The information is reasonable and adequately supported based on the following analysis:

- The applicant projects growth in the in-center patient population based on publicly available and reliable sources of data.
- The applicant’s projected utilization demonstrates a need for the 12 stations at WFDC even after the applicant accounts for the 14 in-center patients that may transfer to Downtown Raleigh Dialysis upon certification of that facility.
- Developing the 12 stations proposed in this application will backfill stations previously approved to be relocated and will not result in physical expansion of the facility.

**Projected Utilization**

In Section C, pages 19-20, and on Form C in Section Q, the applicant provides historical and projected utilization as illustrated in the following tables.

<b>WFDC – Historical Utilization (as of 12/31/2019)</b>				
	<b>In-Center Patients</b>		<b>PD Patients</b>	
<b>County</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Wake	48	60.00%	14	93.33%
Alamance	1	1.30%	0	0.00%
Franklin	16	20.00%	1	6.67%
Granville	3	3.80%	0	0.00%
Halifax	1	1.30%	0	0.00%
Johnston	1	1.30%	0	0.00%
Vance	2	2.50%	0	0.00%
Wayne	1	1.30%	0	0.00%
Other States	7	8.80%	0	0.00%
<b>Total</b>	<b>80</b>	<b>100.00%</b>	<b>15</b>	<b>100.00%</b>

Table may not foot due to rounding.

<b>WFDC – Projected Utilization – OY 2 (CY 2023)</b>				
	<b>In-Center Patients</b>		<b>PD Patients</b>	
<b>County</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Wake	40	55.60%	18	94.74%
Alamance	1	1.40%	0	0.00%
Franklin	16	22.20%	1	5.26%
Granville	3	4.20%	0	0.00%
Halifax	1	1.40%	0	0.00%
Johnston	1	1.40%	0	0.00%
Vance	2	2.80%	0	0.00%
Wayne	1	1.40%	0	0.00%
Other States	7	9.70%	0	0.00%
<b>Total</b>	<b>72</b>	<b>100.00%</b>	<b>19</b>	<b>100.00%</b>

Table may not foot due to rounding.

In Section C, pages 20-22, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

**In-Center Projected Utilization**

- The applicant begins its in-center utilization projections with the in-center patient facility census on January 1, 2020. On page 20, the applicant states that, on January 1, 2020, its in-center patient census was comprised of 48 Wake County patients and 32 patients from other North Carolina counties and other states.
- The applicant projects the in-center Wake County patient population will grow at an annual rate of 3.6 percent, which is the Five Year AACR for Wake County as published in the 2020 SMFP.
- The applicant assumes that, as part of Project I.D. #J-11847-20 (relocate 10 stations to develop Downtown Raleigh Dialysis), 14 in-center patients residing in Wake County will transfer their care to Downtown Raleigh Dialysis on January 1, 2022, when Downtown Raleigh Dialysis is projected to be certified.
- The applicant assumes no population growth for the patients residing in other North Carolina counties and other states dialyzing in-center at WFDC but assumes the patients will continue to dialyze in-center at WFDC and adds them to the calculations when appropriate.
- The project is scheduled to begin offering services on January 1, 2022. OY1 is CY 2022. OY2 is CY 2023.

In Section C, page 21, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the in-center patient census for OY1 and OY2, as summarized in the table below.

<b>WFDC In-Center Projected Utilization</b>	
Starting point of calculations is Wake County patients dialyzing at WFDC on January 1, 2020.	48
Wake County patient population is projected forward by one year to December 31, 2020, using the 3.6% Five Year AACR for Wake County.	$48 \times 1.036 = 49.728$
Wake County patient population is projected forward by one year to December 31, 2021, using the 3.6% Five Year AACR for Wake County.	$49.728 \times 1.036 = 51.518$
14 Wake County patients are projected to transfer care to Downtown Raleigh Dialysis on January 1, 2022, when the 10 stations to be relocated from WFDC (Project I.D. #J-11847-20) are projected to be certified.	$51.518 - 14 = 37.518$
The patients from other NC counties and other states are added. This is the projected census on January 1, 2022 and the starting census for this project.	$37.518 + 32 = 83.518$
Wake County patient population is projected forward by one year to December 31, 2022, using the 3.6% Five Year AACR for Wake County.	$37.518 \times 1.036 = 38.869$
The patients from other NC counties and other states are added. This is the projected census on December 31, 2022 (OY1).	$38.869 + 32 = 70.869$
Wake County patient population is projected forward by one year to December 31, 2023, using the 3.6% Five Year AACR for Wake County.	$38.869 \times 1.036 = 40.268$
The patients from other NC counties and other states are added. This is the projected census on December 31, 2023 (OY2).	$40.268 + 32 = 72.268$

In Section C, page 21, the applicant states it rounds the number of projected patients to the nearest whole number. The applicant projects to serve 71 patients on 23 stations, which is 3.1 patients per station per week ( $71 \text{ patients} / 23 \text{ stations} = 3.1$ ), by the end of OY1 and 72 patients on 23 stations, which is 3.1 patients per station per week ( $72 \text{ patients} / 23 \text{ stations} = 3.1$ ) by the end of OY2. This exceeds the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

PD Projected Utilization

- The applicant begins its utilization projections with the PD patient facility census on January 1, 2020. On page 21, the applicant states that, on January 1, 2020, its PD patient census was comprised of 14 Wake County patients and one patient from Franklin County.
- The applicant assumes that the PD patient population will increase by one patient per year through the second full operating year following project completion. Based on the projected patient origin on page 20, the applicant projects the new patients will be Wake County residents.
- The project is scheduled to begin offering services on January 1, 2022. OY1 is CY 2022. OY2 is CY 2023.

In Section C, pages 21-22, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the PD patient census for OY1 and OY2, as summarized in the table below.



<b>WFDC PD Projected Utilization</b>	
Starting point of calculations is WFDC PD patients as of January 1, 2020.	15
The PD patient population of WFDC is projected forward by one year to December 31, 2020, at a growth rate of one patient per year.	$15 + 1 = 16$
The PD patient population of WFDC is projected forward by one year to December 31, 2021, at a growth rate of one patient per year.	$16 + 1 = 17$
The PD patient population of WFDC is projected forward by one year to December 31, 2022, at a growth rate of one patient per year (end of OY1).	$17 + 1 = 18$
The PD patient population of WFDC is projected forward by one year to December 31, 2023, at a growth rate of one patient per year (end of OY2).	$18 + 1 = 19$

Projected utilization is reasonable and adequately supported based on the following analysis:

- The applicant projects Wake County in-center patient growth using the 3.6 percent Five Year AACR as published in the 2020 SMFP.
- The applicant projects no growth for the in-center patient population residing outside of Wake County.
- The applicant accounts for the dialysis stations and patients projected to transfer to Downtown Raleigh Dialysis as part of Project I.D. #J-11847-20.

**Access**

In Section C, pages 23-24, 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 [disability]. We will serve patients regardless of ethnic or socioeconomic situation.*

*We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. ...*

*Wake Forest Dialysis Center will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, disabled persons, elderly and other under-served persons.”*

On page 24, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>% of Total Patients</b>
Women	43.9%
People age 65 and older	46.9%
Medicare beneficiaries	82.5%
Medicaid recipients	7.5%
American Indian	1.0%
Asian	2.0%
Black or African-American	65.3%
Native Hawaiian or Pacific Islander	0.0%
Other Race	2.0%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- On page 24, the applicant states it assumes the estimated percentage for the medically underserved groups listed in the following table will be the same as its patient population in CY 2019 and projected patient population in CY 2023.
- The applicant does not project any changes to its current services in this application which would make it unreasonable for the applicant to base its projections on its historical experience.

**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 described above.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or 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 12 dialysis stations to WFDC pursuant to Condition 2 of the facility need methodology for a total of 23 stations following completion of this project and Project I.D. #J-11847-20 (relocate 10 stations).

In Section E, page 29, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states maintaining the status quo was not an effective alternative because of the projected growth rate of in-center patients.
- Relocate Stations from Another DaVita Facility: the applicant states it operates one additional dialysis facility in Wake County (Oak City Dialysis), which has 10 stations and was first licensed in June 2019. The applicant states utilization at Oak City Dialysis is below 75 percent; however, relocating stations from that facility would negatively impact patients served at that facility. Therefore, the applicant determined this was not an effective alternative.

The applicant states its proposal is the most effective alternative because it accounts for the projected growth rate of the in-center patient population and does not negatively impact patients at other facilities in Wake County.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

#### **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. Therefore, the application is approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than 12 additional in-center dialysis stations for a total of no more than 23 in-center stations at Wake Forest Dialysis Center upon completion of this project and Project I.D. #J-11847-20 (relocate 10 stations).**
  - 3. The certificate holder 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 12 dialysis stations to WFDC pursuant to Condition 2 of the facility need methodology for a total of 23 stations following completion of this project and Project I.D. #J-11847-20 (relocate 10 stations).

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

On Form F.1a in Section Q, the applicant projects a total capital cost of \$35,123 to be used for medical equipment, non-medical equipment, and furniture. In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant adequately describes the process it uses on a company-wide basis to determine capital costs for proposed projects.
- The applicant describes a process which is consistent with (to the extent possible) other similar projects.
- Based on the applicant's proposal, it is reasonable for the applicant to use the assumptions and methodology described.

In Section F, page 32, the applicant states there are no projected start-up expenses or initial operating expenses because WFDC is an existing and operational facility.

### **Availability of Funds**

In Section F, page 30, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the applicant on behalf of the Chief Accounting Officer of DaVita, authorizing the use of accumulated reserves for the capital needs and any other needs of the project. Exhibit F-2 also contains a Form 10-K Consolidated Financial Statement from DaVita, Inc., which showed that as of December 31, 2019, DaVita, Inc. had adequate cash and assets to fund the capital costs of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from an appropriate company officer confirming the availability of the funding proposed for the capital needs of the project and a commitment to use that funding accordingly.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. On Form F.2 in Section Q, 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>WFDC</b>	<b>Operating Year 1 CY 2022</b>	<b>Operating Year 2 CY 2023</b>
Total Treatments	12,996	13,348
Total Gross Revenues (Charges)	\$4,679,320	\$4,809,556
Total Net Revenue	\$4,445,129	\$4,569,022
Average Net Revenue per Treatment	\$342	\$342
Total Operating Expenses (Costs)	\$2,587,139	\$2,645,938
Average Operating Expense per Treatment	\$199	\$198
<b>Net Income/(Loss)</b>	<b>\$1,857,991</b>	<b>\$1,923,084</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q with each applicable pro forma financial statement. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

- The assumptions for each pro forma financial statement provided by the applicant are reasonable and adequately supported by information provided elsewhere in the application.

### **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 following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all of the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all of the reasons described above.
  - 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 for all of the reasons described above.
- (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 12 dialysis stations to WFDC pursuant to Condition 2 of the facility need methodology for a total of 23 stations following completion of this project and Project I.D. #J-11847-20 (relocate 10 stations).

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates two dialysis centers in Wake County – Wake Forest Dialysis Center and Oak City Dialysis. However, Oak City Dialysis did not become operational until June 2019. There were 14 additional dialysis facilities, with two more facilities approved but which were not yet operational, as of December 31, 2018. The 18 existing and approved dialysis facilities in Wake County as of December 31, 2018 are shown in the table below.

<b>Wake County Existing/Approved Dialysis Facilities            Certified Stations and Utilization as of December 31, 2018</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
Wake Forest Dialysis Center	DaVita	Raleigh	22	98.86%
Oak City Dialysis*	DaVita	Raleigh	0	NA
BMA of Fuquay-Varina Kidney Center	BMA	Fuquay-Varina	28	84.82%
BMA of Raleigh Dialysis	BMA	Raleigh	50	90.50%
Cary Kidney Center	BMA	Cary	24	89.58%
FMC Eastern Wake	BMA	Rolesville	17	64.71%
FMC Morrisville	BMA	Cary	10	45.00%
FMC New Hope Dialysis	BMA	Raleigh	36	86.11%
FMC Northern Wake	BMA	Wake Forest	14	87.50%
FKC Holly Springs*	BMA	Holly Springs	0	NA
FMC Apex	BMA	Apex	20	82.50%
FMC Central Raleigh	BMA	Raleigh	19	67.11%
FMC Millbrook	BMA	Raleigh	17	76.47%
FMC Rock Quarry*	BMA	Raleigh	0	NA
FMC Wake Dialysis Clinic	BMA	Raleigh	50	98.50%
FMC White Oak	BMA	Garner	12	62.50%
Southwest Wake County Dialysis	BMA	Raleigh	30	95.00%
Zebulon Kidney Center	BMA	Zebulon	30	86.67%

Source: 2020 SMFP, Table 9B, pages 163-164.

\*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.

In Section G, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County:

*“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 will not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant proposes to increase the number of dialysis stations in Wake County based on Condition 2 of the facility need determination in the 2020 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Wake County.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- Information which was 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 described 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

On Form H in Section Q, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

<b>WFDC Current and Projected Staffing</b>		
	<b>Current 12/31/19</b>	<b>Projected – OYs 1-2 (CYs 2022 &amp; 2023)</b>
Administrator	1.00	1.00
Registered Nurses	2.75	3.00
Home Training Nurse	0.50	0.50
Patient Care Technicians	8.00	8.50
Dietician	1.00	1.00
Social Worker	1.00	1.00
Admin/Business Office	1.00	1.00
Biomedical Tech	0.50	0.50
<b>TOTAL</b>	<b>15.75</b>	<b>16.50</b>

The assumptions and methodology used to project staffing are provided on Form H Staffing in Section Q, immediately following Form H. Adequate costs for the health manpower and management personnel proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 37-38, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2 and H-3.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents its existing and proposed staffing and proposes adequate funding for the proposed staffing increases.
- The applicant adequately documents that it has programs in place to recruit new employees and that it has existing training and education programs for its new and current employees.

**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.

C

### **Ancillary and Support Services**

In Section I, page 39, the applicant identifies the necessary ancillary and support services for the proposed services, explains how each ancillary and support service is or will be made available, and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides documentation of affiliation and coordination with the facilities identified as providing ancillary and support services.
- The applicant's statements about the ancillary and support services provided on-site are consistent with other information provided in the application.

### **Coordination**

In Section I, pages 39-40, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant states it has notified healthcare providers and social service agencies with which it has established relationships about the proposed project.
- The applicant provides documentation from the facility administrator that existing relationships with other healthcare providers will be maintained.

### **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 all the reasons described above.

- (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 applicant does not propose to construct any new space or renovate any existing space. 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 ... persons [with disabilities], 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, page 46, the applicant provides the historical payor mix during CY 2019 for its existing services at WFDC, as shown in the table below.

<b>WFDC – Historical Payor Mix (CY 2019)</b>				
	<b>In-Center Patients</b>		<b>PD Patients</b>	
<b>Payor Source</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Self Pay	0	0.0%	0	0.0%
Insurance*	8	10.0%	2	13.3%
Medicare*	66	82.5%	12	80.0%
Medicaid*	6	7.5%	0	0.0%
Other (VA)	0	0.0%	1	6.7%
<b>Total</b>	<b>80</b>	<b>100.0%</b>	<b>15</b>	<b>100.0%</b>

Table may not foot due to rounding.

\*Including any managed care plans

In Section L, page 45, the applicant provides the following comparison.

WFDC	% of Patients Served During CY 2019	% of the Population of Wake County
Female	43.9%	51.4%
Male	56.1%	48.6%
Unknown	0.0%	0.0%
64 and Younger	53.1%	88.0%
65 and Older	46.9%	12.0%
American Indian	1.0%	0.8%
Asian	2.0%	7.7%
Black or African-American	65.3%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	29.6%	67.9%
Other Race	2.0%	2.6%
Declined / Unavailable	0.0%	0.0%

Sources: TRC Internal Data, US Census Bureau

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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 ... persons [with disabilities] to programs receiving federal 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, the applicant states in Section L, page 46, that WFDC has no obligation to provide uncompensated care or community service under any federal regulations.

In Section L, page 46, the applicant states that during the last five years no patient civil rights access complaints have been filed against WFDC.

### **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.

- (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, page 47, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>WFDC – Projected Payor Mix (CY 2023)</b>				
	<b>In-Center Patients</b>		<b>PD Patients</b>	
<b>Payor Source</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Self Pay	0.0	0.0%	0.0	0.0%
Insurance*	7.2	10.0%	2.5	13.3%
Medicare*	59.6	82.5%	15.2	80.0%
Medicaid*	5.4	7.5%	0.0	0.0%
Other (VA)	0.0	0.0%	1.3	6.7%
<b>Total</b>	<b>72</b>	<b>100.0%</b>	<b>19</b>	<b>100.0%</b>

Table may not foot due to rounding.  
\*Including any managed care plans

As shown in the table above, during the applicant's second full fiscal year following project completion, the applicant projects to provide 82.5 percent and 80 percent of in-center and PD services, respectively, to Medicare patients and 7.5 percent and 0 percent of in-center and PD services, respectively, to Medicaid patients.

On page 47, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant's projected payor mix is based on its historical payor mix.
- The applicant does not project any changes to its current services in this application which would make it unreasonable for the applicant to base its projections on its historical experience.

**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.

- (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, page 48, the applicant adequately describes the range of means by which patients will have access to 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.

- (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 49, 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 applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes because it provides written documentation of its offer to serve as a clinical learning site for nursing students attending Wake Technical Community College.

### **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 all the reasons described above.

- (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 12 dialysis stations to WFDC pursuant to Condition 2 of the facility need methodology for a total of 23 stations following completion of this project and Project I.D. #J-11847-20 (relocate 10 stations).

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates two dialysis centers in Wake County – Wake Forest Dialysis Center and Oak City Dialysis. However, Oak City Dialysis did not become operational until June 2019. There were 14 additional dialysis facilities, with two more facilities approved but which were not yet operational, as of December 31, 2018. The 18 existing and approved dialysis facilities in Wake County as of December 31, 2018 are shown in the table below.

<b>Wake County Existing/Approved Dialysis Facilities            Certified Stations and Utilization as of December 31, 2018</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
Wake Forest Dialysis Center	DaVita	Raleigh	22	98.86%
Oak City Dialysis*	DaVita	Raleigh	0	NA
BMA of Fuquay-Varina Kidney Center	BMA	Fuquay-Varina	28	84.82%
BMA of Raleigh Dialysis	BMA	Raleigh	50	90.50%
Cary Kidney Center	BMA	Cary	24	89.58%
FMC Eastern Wake	BMA	Rolesville	17	64.71%
FMC Morrisville	BMA	Cary	10	45.00%
FMC New Hope Dialysis	BMA	Raleigh	36	86.11%
FMC Northern Wake	BMA	Wake Forest	14	87.50%
FKC Holly Springs*	BMA	Holly Springs	0	NA
FMC Apex	BMA	Apex	20	82.50%
FMC Central Raleigh	BMA	Raleigh	19	67.11%
FMC Millbrook	BMA	Raleigh	17	76.47%
FMC Rock Quarry*	BMA	Raleigh	0	NA
FMC Wake Dialysis Clinic	BMA	Raleigh	50	98.50%
FMC White Oak	BMA	Garner	12	62.50%
Southwest Wake County Dialysis	BMA	Raleigh	30	95.00%
Zebulon Kidney Center	BMA	Zebulon	30	86.67%

Source: 2020 SMFP, Table 9B, pages 163-164.

\*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.

In Section N, page 50, 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 Center 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 DaVita.*

...

*..., DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients. The expansion of Wake Forest Dialysis Center will enhance accessibility to dialysis for current and projected 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. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”*



The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable (see Sections C, F, N, and Q of the application and any exhibits).
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past (see Sections B, C, N, and O of the application and any exhibits).
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix (see Sections C, L, and N of the application and any exhibits).

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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 based on all the reasons described 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

On Form A in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 110 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, pages 52-53, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident resulting in an Immediate Jeopardy violation occurred in one of these facilities. The applicant states that all the problems have been corrected and the facility is back in compliance. Supporting documentation is provided in Exhibit O-2. After reviewing and considering information provided by the applicant and

publicly available data and considering the quality of care provided at all 110 facilities, the applicant provides 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.

G.S. 131E-183 (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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

### **10 NCAC 14C .2203 PERFORMANCE STANDARDS**

(a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.*

-NA- WFDC is an existing facility. Therefore, this Rule is not applicable to this review.

(b) *An applicant proposing to increase the number of dialysis stations in:*

(1) *an existing dialysis facility; or*

(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

*shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*

-C- In Section C, page 21, and on Form C in Section Q, the applicant projects that WFDC will serve 71 patients on 23 stations, or a rate of 3.1 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
  
- C- In Section C, pages 20-22, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.