

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 8, 2021

Findings Date: October 8, 2021

Project Analyst: Mike McKillip

Co-Signer: Gloria C. Hale

Project ID #: J-12096-21

Facility: Oak City Dialysis

FID #: 160068

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon project completion

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

The applicant, Total Renal Care of North Carolina, LLC (Oak City Dialysis), proposes to add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon completion of the project.

Need Determination

Chapter 9 of the 2021 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 9B, page 136, 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 1 of the facility need methodology in the 2021 SMFP if the facility is a

“new,” “small,” or “new and small” facility as defined in the 2021 SMFP, and if the facility’s current reported utilization is at least 75 percent, or 3.0 patients per station in a given week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. If applying pursuant to Condition 1, the facility may only apply once during the calendar year.

In Section B, page 19, the applicant reports the following:

Facility Need Methodology Condition 1 (New and Small Facilities Only)	Response
Number of months the facility had been certified as of the data cut-off date in the SMFP	16
Number of stations in the facility as of the data cut-off date in the SMFP	10
According to Table 9A in the & SMFP, the facility is designated as new, small, or new and small	New and small
Number of stations proposed in this application	10
Number of in-center patients per station as of the current reporting date	3.8
Current Reporting Date (no more than 90 days before the application is submitted)	5/31/2021
Previous Reporting Date (six months prior to the Current Reporting Date)	11/30/2020

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of 11 additional stations are needed at this facility, as illustrated in the following table.

1	# of In-center Patients as of the Current Reporting Date *	38
2	# of In-Center Patients as of the Previous Reporting Date **	30
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	8
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.3
5	Multiply Line 4 by 2 (Annual Growth Rate)	0.5
6	Multiply Line 5 by Line 1 (New Patients)	20.3
7	Add Line 6 to Line 1 (Total Patients)	58.3
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	20.8
9	# of Stations as of the Application Deadline [^]	10.0
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	10.8

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 11, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “*The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.*”

The applicant proposes to add 10 new stations; therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2021 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 29 of the 2021 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.”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 20-21; Section N, page 76; Section O, pages 79-81; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 21-22; Section C, pages 30-31; Section L, pages 68-72; Section N, page 76, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 22; Section N, page 76; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. 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 based on the following:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates how the facility's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on how it describes the facility's policies and programs, which promote the concepts of quality, equitable access and maximum value for resources expended.

(2) Repealed effective January 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, Oak City Dialysis, proposes to add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon completion of the project.

Patient Origin

On page 113, the 2021 SMFP defines the service area for the county need methodology 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-Graham counties and Avery-Mitchell-Yancey counties."* Oak City Dialysis is located in Wake County. Thus, the service area for this application is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant provides the following historical in-center (IC) patient origin for Oak City Dialysis, as summarized below.

County	Historical Oak City Dialysis Patient Origin (1/1/2020-12/31/2020)	
	Patients	% of Total
Wake	25	78.1%
Duplin	1	3.1%
Edgecombe	1	3.1%
Franklin	1	3.1%
Johnston	1	3.1%
Other States	3	9.4%
Total	32	100.0%

Source: Section C.2, page 25.

The following table illustrates the projected in-center patient origin at Oak City Dialysis in the second full fiscal year of operation (CY2024). The facility does not presently serve home training patients and does not propose to develop those services as part of this project.

County	Projected Patient Origin In-Center Patients 01/01/2024-12/31/2024	
	Patients	% of Total
Wake	60.8256	91.0%
Franklin	1	1.5%
Johnston	2	3.0%
Other States	2	3.0%
Pasquotank	1	1.5%
Total	66.8256	100.0%

Source: Section C.3, page 26.

In Section C, pages 26-27, the applicant provides the assumptions and methodology used to project its patient origin and its projected utilization. On page 26, the applicant states:

“Projections for patient utilization begin with the patient population at Oak City Dialysis as of May 31, 2021.”

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant begins with the May 31, 2021 patient census.
- The applicant uses a 20 percent annual rate of increase to project patient growth for the Wake County patient population, which is one-third of the annual rate of increase experienced by the applicant in CY2020.
- The applicant adds the 6 in-center patients residing in other counties.

Analysis of Need

In Section C, page 27, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“As the table above [on page 27] indicates, the facility has grown significantly since its certification in June of 2019. The following in-center patient projections apply a growth rate of 20.0% for the in-center patients living in Wake County, so as to be conservative. The period of the growth begins January 1, 2021 and is calculated forward to December 31, 2024. No growth calculations were performed for the patients living outside of Wake County.”

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

- The applicant applies a growth rate that is one-third the rate experienced in CY2020.
- Then applicant shows that the facility will need the additional stations to accommodate the existing and projected patient population.

Projected Utilization

In Section Q, the applicant provides the projected utilization, as illustrated in the following table.

Form C Utilization	Last Full FY CY2020	Interim OY 1/1/21- 12/31/21	Interim OY 1/1/22- 12/31/22	First Full OY 1/1/23- 12/31/23	Second Full OY 1/1/24- 12/31/24
# of Patients at the Beginning of the Year	20.00	32.00	41.73	48.88	57.46
# of Patients at the End of the Year	32.00	41.73	48.88	57.46	67.75
Average # of Patients during the Year	26.00	36.87	45.31	53.17	62.60
# of Treatments / Patient / Year	131.77	148.20	148.20	148.20	148.20
Total # of Treatments	3,426.00	5,463.64	6,714.45	7,879.50	9,277.56

In Section C, pages 27-28 and Section Q, pages 87-88, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- The first full FY is Operating Year 1, the period from January 1-December 31, 2023.
- The second full FY is Operating Year 2, the period from January 1-December 31, 2024.
- Projections begin with the facility census as of May 31, 2021.
- The applicant grows the Wake County patient census by 20%.
- The applicant assumes the facility will continue to serve 6 in-center patients residing in surrounding counties, but does not project any growth in that patient population.

The applicant provides a table in Section C, page 27, illustrating the application of its assumptions and methodology.

Oak City Dialysis In-Center Patients	
The applicant begins with the Oak City Dialysis patient population as of May 31, 2021.	38
The applicant projects the Wake County patient population forward seven months to December 31, 2021, using 7/12 of the applicant's assumed 20% annual rate of increase.	$32 \times 1.117 = 35.73333$
Add the 6 patients from other counties. This is the projected ending census for CY2021.	$35.73 + 6 = 41.73$
Project the Wake County patient population forward one year to December 31, 2022, using the applicant's assumed 20% annual rate of increase.	$35.73 \times 1.2 = 42.88$
Add the 6 patients from other counties. This is the projected ending census for CY2022.	$42.88 + 6 = 48.88$
Project the Wake County patient population forward one year to December 31, 2023, using the applicant's assumed 20% annual rate of increase.	$42.88 \times 1.2 = 51.456$
Add the 6 patients from other counties. This is the projected ending census for CY2023.	$51.46 + 6 = 57.46$
Project the Wake County patient population forward one year to December 31, 2024, using the applicant's assumed 20% annual rate of increase.	$51.456 \times 1.2 = 61.7472$
Add the 6 patients from other counties. This is the projected ending census for CY2024.	$61.75 + 6 = 67.75$

Totals may not sum due to rounding

As shown in the table above, the applicant projects Oak City Dialysis will serve 57 in-center patients by the end of the first full fiscal year of operation, for a utilization rate of 2.85 patients per station per week or 71.3% ($57 \text{ patients} / 20 \text{ stations} = 2.85 \text{ patients per station per week} / 4 = 0.713$). By the end of OY2 (December 31, 2024), following the applicant's methodology and assumptions, the facility will have 68 in-center patients dialyzing at the center for a utilization rate of 85% ($68 / 20 = 3.4 / 4 = 0.85$). The projected utilization exceeds the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on the ending census as of May 31, 2021, the most recent historical patient census.
- The applicant applies a growth rate that is one-third the rate experienced in CY2020.
- The projected utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Access to Medically Underserved Groups

In Section C.6, pages 30-31, the applicant discusses access to the facility's services, stating:

“By policy, the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.

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. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

Oak City Dialysis 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 31, the applicant provides the estimated percentage for each medically underserved group it will serve during OY2, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	90.6%
Racial and ethnic minorities	90.5%
Women	38.1%
Persons with disabilities	100.0%
Persons 65 and older	33.3%
Medicare beneficiaries	75.0%
Medicaid recipients	9.4%

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:

- The applicant's corporate policy commits to provide services to all patients referred for ESRD services.
- The applicant's facilities have historically provided care to all in need of ESRD services, including underserved persons.

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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services 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 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, Oak City Dialysis, proposes to add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon completion of the project.

In Section E, page 41, 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 this is not an effective alternative due to growth rate and utilization of the facility.
- Relocate stations from another facility – The applicant states that this not an effective alternative because the existing DaVita facility is in Wake County, Wake Forest Dialysis, which is highly utilized.

Based on the explanations above, the applicant states that its proposal is the most effective alternative.

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 application is conforming or conditionally conforming to all statutory and regulatory review criteria.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.

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 (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop no more than ten in-center stations for a total of no more than 20 stations at Oak City Dialysis upon completion of the project.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on April 1, 2022. The second progress report shall be due on August 1, 2022 and so forth.**
- 4. 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, Oak City Dialysis, proposes to add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon completion of the project.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, the applicant projects the total capital cost for the project as summarized below.

	Total Costs
Medical Equipment	\$148,500
Nonmedical Equipment	\$13,115
Furniture	\$14,000
Total Capital Costs	\$175,615

In Section F.3, page 44, the applicant states it will not incur any working capital costs for this project.

In Section Q, page 92, 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 information on projected capital costs provided by the applicant in Form F.1a and on page 92 of the application.

Availability of Funds

In Section F, page 43, the applicant states that the capital costs will be funded as shown in the table below.

Type	Total Renal Care of North Carolina, LLC
Loans	
Accumulated reserves or OE *	\$175,615
Bonds	
Other (Specify)	
Total Financing	\$175,615

* OE = Owner's Equity

In Exhibit F.2, the applicant provides a letter from the Chief Accounting Officer for DaVita, Inc., the parent company for the applicant, documenting its commitment to fund the capital costs of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the documentation provided in Section F and Exhibit F.2, as described above.

Financial Feasibility

In Section Q, the applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in each of the first two full fiscal years of operation following completion of the proposed project, as shown in the table below.

Oak City Dialysis	1st Full FY 1/1/23-12/31/23	2nd Full FY 1/1/24-12/31/24
Total Billable Treatments	7,879	9,278
Total Gross Revenue (charges)	\$2,572,164	\$3,028,543
Total Net Revenue	\$2,409,180	\$2,836,641
Average Net Revenue per Treatment	\$306	\$306
Total Operating Expenses (costs)	\$2,199,044	\$2,343,109
Average Operating Expense per Treatment	\$279	\$253
Net Income	\$210,137	\$493,532

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

- Charges and expenses are based on historical facility operations projected forward.
- Payor percentages are based on historical facility operations.
- Employee FTEs and salaries are based on current staffing.
- 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.

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 the reasons described above.
- The applicant adequately demonstrates sufficient funds for the capital and operating needs of the proposal.

- The applicant adequately demonstrates 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, Oak City Dialysis, proposes to add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon completion of the project.

On page 113, the 2021 SMFP defines the service area for the county need methodology 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-Graham counties and Avery-Mitchell-Yancey counties.”* Oak City Dialysis is located in Wake County. Thus, the service area for this application is 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. Also, DaVita has been approved to develop an additional facility, Downtown Raleigh Dialysis, but the facility was not operational as of December 31, 2019. Fresenius Medical Care (FMC) and Bio-Medical Applications of North Carolina (BMA), currently operate 14 dialysis centers and have been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry, but the facilities were not yet operational on December 31, 2019. The following table shows the existing and approved dialysis facilities in Wake County, from Table 9A, pages 130-131 of the 2021 SMFP:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/19	In-Center Patients 12/31/19	Utilization Percent 12/31/19
BMA of Fuquay-Varina Kidney Center (BMA)	28	85	75.89%
BMA of Raleigh Dialysis (BMA)	50	193	96.50%
Cary Kidney Center (BMA)	24	79	82.29%
Downtown Raleigh Dialysis (DaVita)	0	0	0.00%
FMC Eastern Wake (BMA)	17	39	57.35%
FMC Morrisville (BMA)	10	32	80.00%
FMC New Hope Dialysis (BMA)	36	119	82.64%
FMC Northern Wake (BMA)	14	48	85.71%
Wake Dialysis Clinic (BMA)	47	204	108.51%
FKC Holly Springs (BMA)	0	0	0.00%
FMC Apex (BMA)	20	61	76.25%
FMC Central Raleigh (BMA)	19	46	60.53%
FMC Millbrook (BMA)	17	62	91.18%
FMC Rock Quarry (BMA)	0	0	0.00%
FMC White Oak (BMA)	15	53	88.33%
Oak City Dialysis (DaVita)	10	20	50.00%
Southwest Wake County Dialysis (BMA)	30	110	91.67%
Wake Forest Dialysis Center (DaVita)	21	80	95.24%
Zebulon Kidney Center (BMA)	30	99	82.50%

Source: 2021 SMFP, Table 9A.

In Section G, page 44, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states:

“Based on the facility need methodology in the 2021 SMFP under Condition 1, Oak City Dialysis qualifies to add up to 10 dialysis stations.

In Section B, Question 3 and Section C, Question 3 of this application, we demonstrate the need that Oak City Dialysis 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 based on the following:

- The applicant adequately demonstrates that Oak City Dialysis needs additional stations to serve its existing and projected patient population.

- The applicant adequately demonstrates that the proposed addition of ten stations is needed in addition to the existing and approved 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 based on 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

The applicant, Oak City Dialysis, proposes to add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon completion of the project.

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) positions for the Oak City Dialysis facility, as summarized in the following table:

POSITION	Current FTE Positions	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.00	1.00	1.00
Registered Nurse	1.25	2.50	2.50
Technicians	3.75	7.50	7.50
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Business Office	0.50	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
Total	8.00	13.50	13.50

Source: Section Q Form H

The assumptions and methodology used to project staffing are provided in Section Q, page 100. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H.3, pages 53-54, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The facility is an existing facility and the applicant bases its staffing on its historical experience providing dialysis services at the facility.
- The applicant has existing policies in regard to recruitment, training and continuing education.

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

The applicant, Oak City Dialysis, proposes to add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon completion of the project.

Ancillary and Support Services

In the table in Section I, page 56, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 56-59, the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at Oak City Dialysis.
- The applicant discusses how it provides each necessary ancillary and support service at Oak City Dialysis.

Coordination

In Section I, page 59, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant discusses its relationships with local health care providers.
- The applicant discusses its relationships with local social service providers.
- The applicant provides letters in Exhibit I.2 documenting the continuation of these working relationships.

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 January 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 states there is no construction or renovation associated with the proposed project. 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, page 68, the applicant provides the historical payor mix for in-center dialysis during CY2020 for Oak City Dialysis, as summarized in the table below.

Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	2	6.3%
Insurance *	3	9.4%
Medicare *	24	75.0%
Medicaid *	3	9.4%
Total	32	100.0%

*Including any managed care plans

In Section L, page 69, the applicant provides the following comparison for facility patients and the service area population.

Oak City Dialysis	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY, CY2020	Percentage of the Population of the Service Area
Female	38.1%	51.4%
Male	61.9%	48.6%
Unknown		
64 and Younger	66.7%	88.0%
65 and Older	33.3%	12.0%
American Indian	0.0%	0.8%
Asian	4.8%	7.7%
Black or African-American	81.0%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	9.5%	59.6%
Other Race	4.8%	2.6%
Declined / Unavailable	0.0%	

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 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;

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 70, the applicant states that Oak City Dialysis is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 70, the applicant states that during the last 18 months no patient civil rights equal access complaints have been filed against 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.

- (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.3(a), page 71, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY2024) following completion of the project, as summarized in the table below.

Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	4.18	6.3%
Insurance *	6.26	9.4%
Medicare *	50.12	75.0%
Medicaid *	6.26	9.4%
Total	66.83	100.0%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 6.3% of its services will be provided to Self-Pay patients, 75% to Medicare recipients and 9.4% to Medicaid recipients.

On page 71, the applicant provides the assumptions and methodology used 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 because it is based on the historical (CY2020) payor mix percentages 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 based on the reasons stated above.

- (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.5, page 72, 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

The applicant, Oak City Dialysis, proposes to add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon completion of the project.

In Section M, page 74, 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.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant currently provides applicable health professional training programs in the area with access to the facility.
- The applicant provides documentation of its willingness to provide applicable health professional training programs in the area with access to the facility.

Conclusion

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, Oak City Dialysis, proposes to add no more than 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 20 stations upon completion of the project.

On page 113, the 2021 SMFP defines the service area for the county need methodology 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-Graham counties and Avery-Mitchell-Yancey counties.”* Oak City Dialysis is located in Wake County. Thus, the service area for this application is 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. Also, DaVita has been approved to develop an additional facility, Downtown Raleigh Dialysis, but the facility was not operational as of December 31, 2019. Fresenius Medical Care (FMC) and Bio-Medical Applications of North Carolina (BMA), currently operate 14 dialysis centers and have been approved to develop two additional facilities in Wake County, FKC Holly Springs and FMC Rock Quarry, but the facilities were not yet operational on December 31, 2019. The following table shows the existing and approved dialysis facilities in Wake County, from Table 9A, pages 130-131 of the 2021 SMFP:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/19	In-Center Patients 12/31/19	Utilization Percent 12/31/19
BMA of Fuquay-Varina Kidney Center (BMA)	28	85	75.89%
BMA of Raleigh Dialysis (BMA)	50	193	96.50%
Cary Kidney Center (BMA)	24	79	82.29%
Downtown Raleigh Dialysis (DaVita)	0	0	0.00%
FMC Eastern Wake (BMA)	17	39	57.35%
FMC Morrisville (BMA)	10	32	80.00%
FMC New Hope Dialysis (BMA)	36	119	82.64%
FMC Northern Wake (BMA)	14	48	85.71%
Wake Dialysis Clinic (BMA)	47	204	108.51%
FKC Holly Springs (BMA)	0	0	0.00%
FMC Apex (BMA)	20	61	76.25%
FMC Central Raleigh (BMA)	19	46	60.53%
FMC Millbrook (BMA)	17	62	91.18%
FMC Rock Quarry (BMA)	0	0	0.00%
FMC White Oak (BMA)	15	53	88.33%
Oak City Dialysis (DaVita)	10	20	50.00%
Southwest Wake County Dialysis (BMA)	30	110	91.67%
Wake Forest Dialysis Center (DaVita)	21	80	95.24%
Zebulon Kidney Center (BMA)	30	99	82.50%

Source: 2021 SMFP, Table 9A.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states:

“The expansion of Oak City 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 DaVita.”

Regarding the impact of the proposal on cost effectiveness, quality and access by medically underserved groups, in Section N, page 76, the applicant states:

“The expansion of Oak City Dialysis 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. As noted in Form H, with additional capacity, greater operational efficiency is possible which positively impacts cost-effectiveness. As discussed in Section B and Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients.

As discussed in Section C, Question 6, and documented in Exhibit L.5, the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients.”

See also Sections B, C, F, L, O and Q of the application and any exhibits.

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 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.
- 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.
- 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.

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 the reasons stated above.

- (19) Repealed effective January 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 Q Form O, 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 108 dialysis facilities owned, operated, or managed by a DaVita or a related entity located in North Carolina.

In Section O, page 81, the applicant states that, during the 18 months immediately preceding the submittal of the application, no DaVita facility was found to have had an incident related to

quality of care that resulted in a finding of “*Immediate Jeopardy*”. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita 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 January 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 or conditionally conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10A 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- Oak City Dialysis is an existing facility.

(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 Q, Form C, the applicant projects that Oak City Dialysis will serve 57 in-center patients on 20 dialysis stations. The projected utilization of 2.85 ($57 / 20 = 2.85$) patients per station per week for OY1 satisfies the 2.8 in-center patients per station per week threshold for the first year following completion of the project, as required by this Rule.

- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- C- In Section C, pages 26-27, the applicant provides the assumptions and methodology it used to project in-center utilization at the facility.