

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 25, 2020

Findings Date: June 25, 2020

Project Analyst: Mike McKillip

Co-Signer: Gloria C. Hale

Project ID #: J-11847-20

Facility: Downtown Raleigh Dialysis

FID #: 190643

County: Wake

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility by relocating no more than 10 stations from Wake Forest Dialysis Center and develop a home training and support program

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC, (hereinafter referred to as “the applicant” or DaVita, which is the parent company’s name), proposes to develop a new 10-station dialysis facility, Downtown Raleigh Dialysis, by relocating 10 stations from Wake Forest Dialysis Center, pursuant to Policy ESRD-2, and will develop a home training and support program.

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 169, the county need methodology shows there is no county need determination for additional dialysis stations in Wake County. The applicant is proposing to develop a new facility; therefore, the facility need methodology does not apply to this proposal. Therefore, neither of the two need determination methodologies in the 2020 SMFP apply to this proposal.

Policies

There are two policies in the 2020 SMFP that are applicable to this review, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities and Policy ESRD-2: Relocation of Dialysis Stations.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities on page 31 of the 2020 SMFP states:

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

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

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

The proposed capital expenditure for this project is greater than \$2 million, but less than \$5 million; therefore, Policy GEN-4 is applicable to this review. In Section B.6, page 16-17, and Exhibit B-4, the applicant provides a written commitment to providing

energy efficient lighting, building materials, HVAC equipment and water conservation equipment in its construction design. Therefore, the application is consistent with Policy GEN-4.

Policy ESRD-2: Relocation of Dialysis Stations, on page 20 of the 2020 SMFP, states:

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

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

The applicant proposes to relocate existing dialysis stations within Wake County, pursuant to Policy ESRD-2. Therefore, the application is consistent with Policy ESRD-2.

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 the application is conforming to this criterion based on the following:

- Neither the county nor facility need methodology is applicable to this review.
- The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.
- The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 because the proposal does not change the dialysis station inventory in Wake County.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new 10-station dialysis facility, Downtown Raleigh Dialysis, by relocating 10 stations from Wake Forest Dialysis Center, pursuant to Policy ESRD-2. Wake Forest Dialysis Center will be certified for 11 stations upon completion of this project.

The following table, summarized from data on page 7 of the application, shows the projected number of stations at Downtown Raleigh Dialysis upon project completion.

Downtown Raleigh Dialysis		
Stations	Description	Project ID #
0	Total existing certified stations in the SMFP in effect on the day the review will begin	
+10	Stations to be added as part of this project (develop new 10-station facility)	J-11847-20
10	Total stations upon completion of proposed project and previously approved projects	

The following table, summarized from information on page 9 of the application, shows the current and projected number of dialysis stations at Wake Forest Dialysis Center upon completion of this project.

Wake Forest Dialysis Center		
Stations	Description	Project ID #
21	Total existing certified stations in the SMFP in effect on the day the review will begin	
-10	Stations to be deleted as part of this project (develop new 10-station facility by relocating 10 stations)	J-11847-20
11	Total stations upon completion of proposed project and previously approved projects	

Patient Origin

On page 113, the 2020 SMFP defines the service area 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.*” Both facilities referred to in this application are 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.

This proposal is to develop Downtown Raleigh Dialysis, a new 10-station dialysis facility in Wake County; therefore, there is no historical utilization data.

In Section C.3, page 20, the applicant provides the projected in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for Downtown Raleigh Dialysis for the second full operating year following project completion, January 1, 2023 – December 31, 2023 (CY2023), as summarized in the following table:

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Wake	31	100.0%	0.0	0.0%	3	100.0%
Total	31	100.0%	0.0	0.0%	3	100.0%

In Section C.3, pages 20-22, the applicant provides the assumptions, methodology, and support documentation used to project Downtown Raleigh Dialysis’s patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 22-23, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below:

- With 1,388 total patients (2020 SMFP, Table 9C), Wake County has the second largest ESRD population in the state (page 22).
- The applicant surveyed patients that currently use its existing Wake and Durham County facilities and determined that many of these patients live in or near the central part of Wake County, inside Interstate 540. The applicant identified 31 in-center patients and one PD patient who are interested in transferring their care to the proposed facility, located near the central part of Wake County, and who stated in signed letters that the new facility will be more convenient for them. See Exhibit C-3.

The information is reasonable and adequately supported for the following reasons:

- The applicant demonstrates the need to develop a new dialysis facility to better serve DaVita dialysis patients in central Wake County by relocating existing dialysis stations consistent with Policy ESRD-2.
- The Wake Forest Dialysis Center is operating at 98.86% utilization per the 2020 SMFP.
- The applicant provides supporting documentation in Exhibit C-4.

Projected Utilization

In-Center Projected Utilization

In Section C.3, pages 20-22, the applicant describes its need methodology and assumptions for projected utilization for the proposed facility summarized as follows:

- The applicant states that 31 existing DaVita patients have signed letters expressing an interest in transferring their care to the proposed facility, including 14 patients served at Wake Forest Dialysis Center and 13 patients served at Oak City Dialysis in Wake County, and 4 patients serviced at Research Triangle Park Dialysis in Durham County. The applicant’s projected beginning census on January 1, 2022 is composed of 29 patients from DaVita facilities that are residents of Wake County who have signed those letter or are newly diagnosed with End Stage Renal Disease that are projected to transfer their care to the new facility upon certification.
- The applicant uses the 2020 SMFP Wake County Five-Year Annual Average Change Rate (AACR) of 3.6% for Wake County patient utilization growth.

The table below summarizes the beginning in-center patient census on January 1, 2022 and its growth through the ending patient census on December 31, 2023.

The applicant begins with 29 Wake County in-center patients as of January 1, 2022.	29
The applicant projects the Wake County in-center patients forward one year to December 31, 2022 using the Wake County Five-Year AACR. This is the projected ending census for Operating Year 1.	$29 \times 1.036 = 30.044$
The applicant projects the Wake County in-center patients forward one year to December 31, 2023 using the Wake County Five-Year AACR. This is the projected ending census for Operating Year 2.	$30.044 \times 1.036 = 31.12558$

As the table above shows, the applicant projects 30 in-center patients by the end of the first operating year, OY1 (CY2022), for a utilization rate of 3.0 patients per station per week or 75% (30 patients / 10 stations = 3.0 patients per station / 4 = 0.75). By the end of OY2 (CY2023), the applicant projects 31 in-center patients for a utilization rate of 77.5% (31 / 10 = 3.1 / 4 = .775). The projected utilization of 3.0 patients per station per week for CY2022 satisfies the 2.8 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant bases the beginning in-center patient census on existing DaVita patients who have expressed a desire to transfer their care to the proposed facility.
- The applicant projects the growth of the Wake County patient census using the Wake County Five-Year AACR of 3.6 percent, as reported in the 2020 SMFP.

Peritoneal Dialysis (PD) Projected Utilization

On page 22, the applicant provides the following table showing its projections of peritoneal dialysis (PD) patients through the first two operating years of the project.

PD Patient Projections	Start Date	# of Patients Start of Year	# of Patients End of Year	Average # of Patients in Year
Operating Year 1	1/1/2022	1	2	1.5
Operating Year 2	1/1/2023	2	3	2.5

Source: Table on page 22 of the application.

On page 22, the applicant describes its assumptions as follows:

“One PD patient who currently receive [sic] their support at Durham West Dialysis, a DaVita-operated facility in Durham County and who lives in Wake County, has signed a letter indicating that the new facility will be more convenient for them and they would consider transfer to Downtown Raleigh Dialysis. These letters can be found at Exhibit C-3. ... It is assumed that the patient who signed a letter of support for Downtown Raleigh Dialysis will transfer their care upon certification of the new facility. ... The period of the growth begins January 1, 2022 and is calculated forward to December 31, 2023. It is reasonable to assume that the Downtown Raleigh Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth.”

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant bases the beginning PD patient census on an existing DaVita patient who expressed an interest in transferring their care to the proposed facility.
- The Wake Forest Dialysis Center had a growth of four PD patients from June 30, 2019 to December 31, 2019 based on the ESRD Data Collection Forms for the facility, indicating sufficient growth in PD patients at a DaVita facility in Wake County.

Access

In Section C.7, page 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 handicap. We will serve patients regardless of ethnic or socioeconomic situation.... Downtown Raleigh 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.”

In Section L.3, page 51, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Downtown Raleigh Dialysis
 Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.0	0.0%	0.0	0.0%
Insurance*	2.5	8.0%	0.0	0.0%	0.4	13.3%
Medicare*	25.2	81.0%	0.0	0.0%	2.4	80.0%
Medicaid*	2.5	8.0%	0.0	0.0%	0.0	0.0%
Other (VA)	0.9	3.0%	0.0	0.0%	0.2	6.7%
Total	31.0	100.0%	0.0	0.0%	3.0	100.0%

Totals may not sum due to rounding
 *Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.

- The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new 10-station dialysis facility, Downtown Raleigh Dialysis, by relocating 10 stations from Wake Forest Dialysis Center, pursuant to Policy ESRD-2. Wake Forest Dialysis Center will be certified for 11 stations upon completion of this project.

In Section D.2, pages 28-29, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 29, the applicant provides a table which shows projected Wake Forest Dialysis Center utilization assuming the relocation of 10 stations and 14 in-center patients to the proposed facility, Downtown Raleigh Dialysis, which is summarized below:

The applicant begins with 80 total in-center patients at Wake Forest Dialysis Center as of January 1, 2020.	80
The applicant projects the Wake County in-center patients forward one year to December 31, 2020 using the Wake County Five-Year AACR.	$48 \times 1.036 = 49.7280$
The applicant adds 32 patients from outside of Wake County to the facility's census, for a total year-end census as of December 31, 2020.	$49.7 + 32 = 81.728$
The applicant projects the Wake County in-center patients forward one year to December 31, 2021 using the Wake County Five-Year AACR.	$49.728 \times 1.036 = 51.51821$
The applicant adds 32 patients from outside of Wake County to the facility's census, for a total year-end census as of December 31, 2021.	$51.51281 + 32 = 83.518$
The applicant projects that 14 Wake Forest Dialysis Center patients will transfer to the proposed new facility upon certification on January 1, 2022.	$51.51281 - 14 = 37.5182$
The applicant adds 32 patients from outside of Wake County to the facility's census, for a total in-center census as of January 1, 2022.	$38 + 32 = 70$
The applicant projects the Wake County in-center patients forward one year to December 31, 2022 using the Wake County Five-Year AACR.	$37.5182 \times 1.036 = 38.868$
The applicant adds 32 patients from outside of Wake County to the facility's census. This is the projected ending census for Operating Year 1.	$38.868 + 32 = 70.868$
The applicant projects the Wake County in-center patients forward one year to December 31, 2023 using the Wake County Five-Year AACR.	$38.868 \times 1.036 = 40.26814$
The applicant adds 32 patients from outside of Wake County to the facility's census. This is the projected ending census for Operating Year 2.	$40.26814 + 32 = 72.268$

As shown in the table above, Wake Forest Dialysis Center is projected to have a utilization rate of 6.45 patients per station per week or 161% ($71 \text{ patients} / 11 \text{ stations} = 6.45 / 4 = 1.61$) at that time. The applicant states that the population presently served at Wake Forest Dialysis Center will continue to have their needs adequately met by the remaining and proposed addition of dialysis stations. On page 29, the applicant states:

“Given this projected growth of the in-center patient population, additional Certificate of Need applications will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility's patients will continue to be met. The 2020 SMFP indicates that Wake Forest Dialysis Center has a need determination of 12 stations.”

In Section D.3, page 30, the applicant states:

“The relocation of stations from Wake Forest Dialysis Center will have no effect on the ability of low income persons, racial and ethnic minorities, women, disabled persons, and other under-served group and the elderly to obtain needed health care.

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

Wake Forest Dialysis Center will continue to assist 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 underserved persons.”

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 needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 develop a new 10-station dialysis facility, Downtown Raleigh Dialysis, by relocating 10 stations from Wake Forest Dialysis Center, pursuant to Policy ESRD-2.

In Section E.2, pages 31-32, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because the two existing DaVita facilities in Wake County are highly utilized and have experienced significant growth.
- *Expand an existing DaVita facility in Wake County* – The applicant states that Oak City Dialysis became operational in June 2019 and is not eligible for an expansion under the need determination methodology in the 2020 SMFP, and that Wake Forest Dialysis Center does not have capacity to expand, nor is it located in proximity to the central part of Wake County, so expanding either of those two facilities is not the most effective alternative.
- *Locate the facility in another part of Wake County* – The applicant states that, based on an evaluation of patient needs as reflected in the letters from existing patients in Exhibit C-3, developing a new facility in a location in central Wake County 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 for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC shall develop a new kidney disease treatment center to be known as Downtown Raleigh Dialysis by relocating no more than 10 in-center and home hemodialysis stations from Wake Forest Dialysis Center.**
- 3. Upon completion of this project, Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 10 stations at Wake Forest Dialysis Center for a total of no more than 11 in-center and home hemodialysis stations upon completion of the project.**

4. **Total Renal Care of North Carolina, LLC shall install plumbing and electrical wiring through the walls for no more than 10 in-center and home hemodialysis stations.**
 5. **Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility, Downtown Raleigh Dialysis, by relocating 10 stations from Wake Forest Dialysis Center, pursuant to Policy ESRD-2.

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.

Projected Capital Costs	
	Total Costs
Site Costs	\$153,340
Construction Costs	\$1,105,475
Architect/Engineering Fees	\$108,750
Medical Equipment	\$152,400
Nonmedical Equipment	\$318,925
Furniture	151,085
Interest during construction	\$63,679
Total Capital Costs	\$2,053,655

The applicant provides the assumptions used to project the capital cost in Section Q.

In Section F, page 34-35, the applicant states it projects \$154,942 in start-up costs and \$585,052 initial operating expenses, for total working capital required of \$739,994.

Availability of Funds

In Section F, pages 33 and 35, the applicant states that the capital and working capital cost, respectively, will be funded by DaVita, Inc., as shown in the tables below.

Sources of Capital Financing

Type	DaVita, Inc.
Loans	
Accumulated reserves or OE *	\$2,053,655
Bonds	
Other (Specify)	
Total Financing	\$2,053,655

* OE = Owner's Equity

Sources of Working Capital Financing

Type	DaVita, Inc.
Loans	
Accumulated reserves or OE *	\$739,994
Bonds	
Other (Specify)	
Total Financing	\$739,994

* OE = Owner's Equity

In Exhibit F-2, the applicant provides a letter dated January 15, 2020, from the Chief Accounting Officer, documenting its commitment to fund the capital and working capital costs of the project. Exhibit F-2 also contains Form 10K for DaVita, Inc. for fiscal year ended December 31, 2018, showing that applicant had \$323 million in cash and cash equivalents and \$19.1 billion in total assets.

The applicant adequately demonstrates the availability of funds for the capital and working 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 this project. In Section Q, Forms F.2 and F.4, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

Downtown Raleigh Dialysis Revenue and Expenses		
	CY2022	CY2023
Treatments	4,597	4,903
Gross Patient Revenue	\$1,541,202	\$1,652,399
Net Patient Revenue	\$1,458,355	\$1,564,044
Average Net Revenue per Treatment	\$317	\$319
Total Operating Expenses	\$1,170,104	\$1,214,085
Average Operating Expense per Treatment	\$255	\$248
Net Income	\$288,251	\$349,959

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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 and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new 10-station dialysis facility, Downtown Raleigh Dialysis, by relocating 10 stations from Wake Forest Dialysis Center, pursuant to Policy ESRD-2. Wake Forest Dialysis Center will be certified for 11 stations upon completion of this project.

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-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are 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. Bio-Medical Applications of North Carolina, Inc. (BMA) currently operates 14 dialysis centers and has 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, 2018. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table 9B, pages 163-164 of the 2020 SMFP:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	In-Center Patients 12/31/18	Utilization Percent 12/31/18
BMA of Fuquay-Varina Kidney Center (BMA)	28	95	84.82%
BMA of Raleigh Dialysis (BMA)	50	181	90.50%
Cary Kidney Center (BMA)	24	86	89.58%
FMC Eastern Wake (BMA)	17	44	64.71%
FMC Morrisville (BMA)	10	18	45.00%
FMC New Hope Dialysis (BMA)	36	124	86.11%
FMC Northern Wake (BMA)	14	49	87.50%
Wake Dialysis Clinic (BMA)	50	197	98.50%
FKC Holly Springs (BMA)	0	0	NA
FMC Apex (BMA)	20	66	82.50%
FMC Central Raleigh (BMA)	19	51	67.11%
FMC Millbrook (BMA)	17	52	76.47%
FMC Rock Quarry (BMA)	0	0	NA
FMC White Oak (BMA)	12	30	62.50%
Oak City Dialysis (DaVita)	0	0	NA
Southwest Wake County Dialysis (BMA)	30	114	95.00%
Wake Forest Dialysis Center (DaVita)	22	87	98.86%
Zebulon Kidney Center (BMA)	30	104	86.67%

Source: 2020 SMFP, Table 9B.

In Section G.2, pages 38-39, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wake County. The applicant states:

“As of December 31, 2018 there were 15 operational and four CON approved dialysis facilities in Wake County with a total of 379 certified stations. This certificate of need application does not propose to increase the number of stations in Wake County. Transferring ten stations from Wake Forest Dialysis Center will create a new facility at a different location to better serve patients identified in Section C-3, but it will not result in the duplication of existing services.”

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

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Wake County.
- The applicant adequately demonstrates that the proposed relocation of the 10 stations for the development of a new facility is needed in addition to the operational facilities in Wake County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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 the reasons stated above.

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

C

In Section Q, Form H, the applicant provides the projected staffing in full-time equivalent (FTE) positions for the first and second full operating years of the proposed services, as summarized in the following table.

POSITION	PROJECTED FTE POSITIONS CY2022	PROJECTED FTE POSITIONS CY2023
Administrator	1.00	1.00
Registered Nurse	1.25	1.25
Home Training Nurse	0.50	0.50
Technicians (PCT)	3.75	3.75
Dietitian	0.50	0.50
Social Worker	0.50	0.50
Administrative/Business Office	0.50	0.50
Biomedical Technician	0.50	0.50
Total	8.50	8.50

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, pages 40-41, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit H-3, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I.1, page 42, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 42, as summarized below.

**Downtown Raleigh Dialysis
 Ancillary and Support Services**

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

In Section I.2, page 43, the applicant describes its relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K.1, page 45, the applicant states that the project will involve new construction of 9,600 square feet. The proposed floor plan is provided in Exhibit K-1.

In Section K.3, page 45, the applicant adequately explains how the cost, design and means of construction represent a reasonable alternative for the proposal.

In Section K.3, page 46, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K.3, page 46, the applicant identifies applicable energy saving features that will be incorporated into the construction plans.

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The applicant proposes to develop Downtown Raleigh Dialysis, a new 10-station dialysis facility, by relocating 10 stations from Wake Forest Dialysis Center. Downtown Raleigh Dialysis will be a new facility and therefore has no history. In Section L.1, page 50, the applicant provides the Wake Forest Dialysis Center's historical payor mix for CY2019, as shown in the table below.

Payor Source	In-Center Patients	Peritoneal Dialysis Patients
Self Pay	0.0%	0.0%
Insurance	10.0%	13.3%
Medicare	82.5%	80.0%
Medicaid	7.5%	0.0%
VA	0.0%	6.7%
Total	100.0%	100.0%

Totals may not sum due to rounding

In Section L.1(a), page 49, the applicant provides comparison of the demographical information on Wake Forest Dialysis Center patients and the service area patients during the last full operating year, as summarized below.

	Percentage of Total Wake Forest Dialysis Center Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	42.1%	51.3%
Male	57.9%	48.7%
Unknown	0.0%	0.0%
64 and Younger	55.8%	88.4%
65 and Older	44.2%	11.6%
American Indian	0.0%	0.8%
Asian	2.5%	7.5%
Black or African-American	56.3%	21.0%
Native Hawaiian or Pacific Islander	1.3%	0.1%
White or Caucasian	36.3%	68.1%
Other Race	3.8%	2.5%
Declined / Unavailable	0.0%	0.0%

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2(a), page 50, the

applicant states that the facility is not obligated to provide uncompensated care or community service.

The facility is not an operational facility; therefore, there have been no civil rights access complaints filed against the facility within the last five years.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.3, page 51, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Downtown Raleigh Dialysis
 Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.0	0.0%	0.0	0.0%
Insurance*	2.5	8.0%	0.0	0.0%	0.4	13.3%
Medicare*	25.2	81.0%	0.0	0.0%	2.4	80.0%
Medicaid*	2.5	8.0%	0.0	0.0%	0.0	0.0%
Other (VA)	0.9	3.0%	0.0	0.0%	0.2	6.7%
Total	31.0	100.0%	0.0	0.0%	3.0	100.0%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, during the second full calendar year of operation, the applicant projects that 0% of the in-center dialysis patients will be private pay patients and 89% will have all or part of their services paid for by Medicare or Medicaid.

On page 51, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient payor mix is based on the historical payor mix for its other facilities in the service area.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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.5, page 52, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, page 53, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes, and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
 - (16) Repealed effective July 1, 1987.
 - (17) Repealed effective July 1, 1987.
 - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new 10-station dialysis facility, Downtown Raleigh Dialysis, by relocating 10 stations from Wake Forest Dialysis Center, pursuant to Policy ESRD-2. Wake Forest Dialysis Center will be certified for 11 stations upon completion of this project.

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-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are 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. Bio-Medical Applications of North Carolina, Inc. However, Oak City Dialysis did not become operational until June 2019. (BMA) currently operates 14 dialysis centers and has 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, 2018. See the following table that shows the existing and approved dialysis facilities in Wake County, from Table 9B, pages 163-164 of the 2020 SMFP:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	In-Center Patients 12/31/18	Utilization Percent 12/31/18
BMA of Fuquay-Varina Kidney Center (BMA)	28	95	84.82%
BMA of Raleigh Dialysis (BMA)	50	181	90.50%
Cary Kidney Center (BMA)	24	86	89.58%
FMC Eastern Wake (BMA)	17	44	64.71%
FMC Morrisville (BMA)	10	18	45.00%
FMC New Hope Dialysis (BMA)	36	124	86.11%
FMC Northern Wake (BMA)	14	49	87.50%
Wake Dialysis Clinic (BMA)	50	197	98.50%
FKC Holly Springs (BMA)	0	0	NA
FMC Apex (BMA)	20	66	82.50%
FMC Central Raleigh (BMA)	19	51	67.11%
FMC Millbrook (BMA)	17	52	76.47%
FMC Rock Quarry (BMA)	0	0	NA
FMC White Oak (BMA)	12	30	62.50%
Oak City Dialysis (DaVita)	0	0	NA
Southwest Wake County Dialysis (BMA)	30	114	95.00%
Wake Forest Dialysis Center (DaVita)	22	87	98.86%
Zebulon Kidney Center (BMA)	30	104	86.67%

Source: 2020 SMFP, Table 9B.

In Section N.1, page 54, 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 proposed facility will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed.

The bottom line is Downtown Raleigh Dialysis will enhance convenience to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services. 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 cost-effectiveness of the proposal (see Sections C, F and Q of the application and any exhibits).

- Quality services will be provided (see Section C and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections C, D, and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q, Form A, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by DaVita or a related entity.

In Section O.2, pages 56-57, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in one DaVita facility; Waynesville Dialysis Center. The applicant states that a plan of correction was prepared and accepted, and that Waynesville Dialysis Center is currently back in compliance. 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 July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center

teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

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

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.

-C- In Section C.3, pages 20-23, the applicant projects 30 in-center patients will be served by the proposed facility by the end of the first operating year, CY2022, for a utilization rate of 3.0 patients per station per week or 75% (30 patients / 10 stations = 3.0 patients per station / 4 = 0.75). The projected utilization of 3.0 patients per station per week exceeds the 2.8 in-center patients per station threshold required by 10A NCAC 14C .2203(a).

(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.

-NA- The applicant is proposing to establish a new ESRD facility.

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

-C- In Section C.3, pages 20-23, the applicant provides the assumptions and methodology used to project utilization of the facility.