

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 20, 2021

Findings Date: September 20, 2021

Project Analyst: Tanya M. Saporito

Co-signer: Fatimah Wilson

Project ID #: N-12097-21

Facility: Fayetteville Road Dialysis

FID #: 160286

County: Hoke

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

Project: Add no more than 11 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon project completion

REVIEW CRITERIA

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

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

C

Total Renal Care of North Carolina, LLC hereinafter referred to as “the applicant” or “TRC”, proposes to add no more than eleven dialysis stations to Fayetteville Road Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion. Pursuant to certificate of need Project ID #N-11885-20, the facility was certified on September 27, 2020 for nine additional stations, bringing the total number of dialysis stations to 19. Following completion of this project, the facility would be certified for 30 dialysis stations.

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 133, the county need methodology shows there is not a county need determination for additional dialysis stations in Hoke County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2021 SMFP, if the utilization rate for the facility as reported in the 2021 SMFP is at least 75.00% or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9A, page 124, the utilization rate reported for Fayetteville Road Dialysis is 105.0% or 4.2 patients per station per week, based on 42 in-center dialysis patients and 10 certified dialysis stations (42 patients / 10 stations = 4.2; 4.2 / 4 = 1.05).

As shown in Table 9D, page 139 in the 2021 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Fayetteville Road Dialysis is up to 11 additional dialysis stations. Thus, the applicant is eligible to apply to add up to 11 dialysis stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

In this application the applicant proposes to add no more than 11 new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to 11 stations; therefore, the application is consistent with Condition 2 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 would promote safety and quality in Section B, pages 20-21; Section N, page 78; Section O, pages 81-83; 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 in the delivery of dialysis services.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 21-22; Section C, page 32; Section L, pages 73-74; Section N, page 78; 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 78; 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 that promote the concepts of quality, equitable access and maximum value for resources.

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

The applicant proposes to add no more than 11 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion. The facility provides both in-center (IC) and peritoneal dialysis (PD) services.

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 area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.” Fayetteville Road Dialysis is located in Hoke County. Thus, the service area for this application is Hoke County. Facilities may serve residents of counties not included in their service area.

In Section C, page 25, the applicant provides the historical in-center (IC) and peritoneal dialysis (PD) patient origin for Fayetteville Road Dialysis for the last full fiscal year (FY), calendar year (CY) 2020, as summarized below:

COUNTY	HISTORICAL IN-CTR. PATIENTS (CY 2020)		HISTORICAL PD PATIENTS (CY 2020)	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Hoke	38	65.50%	10	41.67%
Cumberland	19	32.80%	9	37.50%
Harnett	0	0.00%	2	8.33%
Moore	1	1.70%	0	0.00%
Robeson	0	0.00%	2	8.33%
Other States	0	0.00%	1	0.00%
Total	58	100.0%	24	100.00%

Source: Section C.2, page 25.

In Section C, page 26, the applicant provides the projected in-center (IC) and peritoneal dialysis (PD) patient origin for Fayetteville Road Dialysis for the second full fiscal year (FY) of operation, calendar year (CY) 2024, as summarized below:

COUNTY	PROJECTED IN-CTR. PATIENTS (CY 2024)		PROJECTED PD PATIENTS (CY 2024)	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Hoke	78.7968	79.80%	14	50.00%
Cumberland	19	19.20%	9	32.14%
Harnett	0	0.00%	2	7.14%
Moore	1	1.00%	0	0.00%
Robeson	0	0.00%	2	7.14%
Other States	0	0.00%	1	3.57%
Total	98.7968	100.0%	28	100.00%

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. On page 26, the applicant states it begins future projections with the patient population at Fayetteville Road Dialysis as of December 31, 2020.

The applicant’s assumptions are reasonable and adequately supported because they are based on the existing patient census at Fayetteville Road Dialysis and the applicant’s historical experience.

Analysis of Need

In Section C, page 28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“There is a facility need determination of 11 stations for Fayetteville Road Dialysis, which had 19 existing stations as reported in Tables 9D and 9A of the 2021 SMFP. ... The addition of stations serves to increase capacity and proactively address the issues of growth and access at the facility. Dialysis patients spend a significant amount of time in their facilities preparing for and receiving treatment – three times a week for in-center patients. The additional stations provide opportunities to open appointment times on the more desirable first shift.”

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

- The 2021 SMFP, Table 9D on page 139 shows a facility need determination for up to 11 dialysis stations at Fayetteville Road Dialysis.
- Then applicant demonstrates that the facility will need the additional stations to accommodate the existing and projected patient population.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the facility, as illustrated in the following table:

	LAST FULL FY CY 2020	INTERIM FY CY 2021	INTERIM FY CY 2022	1 ST FULL FY CY 2023	2 ND FULL FY CY 2024
# of IC Patients at the Beginning of the Year	42.00	58.00	65.60	74.72	85.66
# of Patients at the End of the Year	58.00	65.60	74.72	85.66	98.80
Average # of Patients during the Year	50.00	61.80	70.16	80.19	92.23
# of Treatments / Patient / Year	123.38	148.20	148.20	148.20	148.20
Total IC Patients	6,169.00	9,158.76	10,397.71	11,884.45	13,668.55
# of PD Patients at the Beginning of the Year	16.00	24.00	25.00	26.00	27.00
# of Patients at the End of the Year	24.00	25.00	26.00	27.00	28.00
Average # of Patients during the Year	20.00	14.50	25.50	26.50	27.50
# of Treatments / Patient / Year	151.85	148.20	148.20	148.20	148.20
Total PD Patients	3,037.00	3,630.90	3,779.10	3,927.30	4,075.50
Total IC and PD Treatments	9,206.00	12,789.66	14,176.81	15,811.75	17,744.05

In-Center Patient Utilization

In Section C, pages 27-28 and Section Q, pages 89-90, the applicant provides the assumptions and methodology used to project in-center patient utilization, as summarized below:

- The applicant begins patient census projections with the actual in-center facility census as of December 31, 2020 as reported to the Division of Health Service Regulation (DHSR) Healthcare Planning on the December 2020 ESRD Data Collection Form. That form reports 58 total IC patients: 38 Hoke County patients and 20 patients from outside Hoke County.
- The applicant states the first full FY is projected to be CY 2023 (January 1, 2023-December 31, 2023), and the second full FY is projected to be CY 2024 (January 1, 2024-December 31, 2024).
- The applicant states the Five Year Average Annual Change Rate (AACR) for Hoke County, reported in Table 9B of the 2021 SMFP is 10%; however, the actual growth of the facility since CY 2018 has been higher, as shown in the following table:

FY	IN-CTR. PATIENT CENSUS	ANNUAL CHANGE RATE
CY 2018	21	--
CY 2019	42	100.0%
CY 2020	58	38.1%
3 Year AACR		46.0%

- Based on the historical patient growth at the facility and the Five Year AACR in the 2021 SMFP, the applicant projects a 20% patient census growth at the facility through CY 2024.
- The applicant states PY 1 is CY 2023 and PY 2 is CY 2024.

The following table, from Section C page 27 and Section Q page 90 illustrates the application of the assumptions and methodology:

In-Center Patient Utilization, Fayetteville Road Dialysis

	# STATIONS	IC PATIENTS
Begin with 58 patients dialyzing on 19 stations as of January 1, 2021.	19	58
Project Hoke County patient population forward one year to December 31, 2021 using applicant's 20% growth rate.		$38 \times 1.20 = 45.60$
Add 20 patients from outside Hoke County. This is the facility census for the first full interim year.		$45.60 + 20 = 65.60$
Project Hoke County patient population forward one year to December 31, 2022 using applicant's 20% growth rate.*		$45.60 \times 1.20 = 54.720$
Add 20 patients from outside Hoke County. This is the facility census for the second full interim year.		$54.720 + 20 = 74.72$
Stations are projected to be certified by January 1, 2023. This is the beginning of the first full FY of the project.	$19 + 11 = 30$	
Project Hoke County patient population forward one year to December 31, 2023 using applicant's 20% growth rate.		$54.72 \times 1.20 = 65.6640$
Add 20 patients from outside Hoke County. This is the ending census for the first full FY.		$65.6640 + 20 = 85.66$
Project Hoke County patient population forward one year to December 31, 2023 using applicant's 20% growth rate.		$65.66 \times 1.20 = 78.7968$
Add 20 patients from outside Hoke County. This is the ending census for the second full FY.		$78.7968 + 20 = 98.80$

*The Project Analyst notes there is a typographical error in the table that does not affect the analysis.

As the table above shows, using conventional rounding, the applicant's methodology results in a projection of 86 in-center patients by the end of the first full FY (CY 2023), for a utilization rate of 2.87 patients per station per week or 71.7% ($86 \text{ patients} / 30 \text{ stations} = 2.87 \text{ patients per station per week}$; $2.87 / 4 = 0.7167$). By the end of OY 2 (CY 2024), following the applicant's methodology and assumptions, the facility will have 99 in-center patients dialyzing at the center for a utilization rate of 82.5% ($99 / 30 = 3.3$; $3.3 / 4 = 0.825$). The projected utilization of 2.87 patients per station per week in OY 1 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 for IC patients is reasonable and adequately supported based on the following:

- The applicant bases the beginning in-center patient census on the most recent historical patient census at the facility.
- The applicant projects growth based on the actual historical patient growth and the Five Year AACR reported in the 2021 SMFP for Hoke County.
- The applicant does not project growth of patients from outside Hoke County, but adds them to the facility census at the appropriate points in time.
- The projected utilization rate by the end of OY 1 exceeds the minimum standard of 2.8 patients per station per week

Peritoneal Dialysis Utilization

In Section C, page 28 and Section Q, page 90, the applicant provides the assumptions and methodology used to project PD patient utilization, as summarized below:

- The applicant begins patient census projections with the actual in-center facility census as of December 31, 2020 as reported to the Division of Health Service Regulation (DHSR) Healthcare Planning on the December 2020 ESRD Data Collection Form. That form reports 24 total PD patients: 10 Hoke County PD patients and 14 PD patients from outside Hoke County.
- The applicant states the first full FY is projected to be CY 2023 (January 1, 2023-December 31, 2023), and the second full FY is projected to be CY 2024 (January 1, 2024-December 31, 2024).
- The applicant states the period of growth for the PD patients begins January 1, 2021 and projects through the end of the first PY (CY 2024).
- The applicant projects the PD patient census to increase by one patient per year, as shown in the following table:

	START DATE	# PTS. BEGIN	# PTS. END	AVG. PTS. IN YEAR
Interim Period	1/1/2021	24	25	24.5
Interim Period	1/1/2022	25	26	25.5
PY 1	1/1/2023	26	27	26.5
PY 2	1/1/2024	27	28	27.5

- The applicant assumes one patient receives three treatments per week, 52 weeks per year, and assumes a 5% missed treatment rate [$3 \times 52 \times 0.95 = 148$].

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

- The applicant bases the beginning PD patient census on the most recent historical patient census at the facility.
- In 2020 the Fayetteville Road Dialysis home program trained 24 PD patients. The applicant conservatively bases the future need for services upon a growth rate of one PD patient per year.

Access to Medically Underserved Groups

In Section C.6, page 31, the applicant describes the provision of access to medically underserved groups. The applicant states:

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

Fayetteville Road 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 32, the applicant provides the estimated percentage for each medically underserved group it will serve during OY 2, as shown in the following table.

Fayetteville Road Dialysis

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	86.2%
Racial and ethnic minorities	82.5%
Women	51.3%
Persons with disabilities	100.0%
Persons 65 and older	41.3%
Medicare beneficiaries	77.6%
Medicaid recipients	6.9%

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, by policy, commits to provide services to all patients in need of ESRD services.
- Total Renal Care facilities have historically provided care to all in need of ESRD services, including all 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 dialysis 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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to add no more than 11 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

In Section E, page 42, 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 alternative was dismissed given the growth rate at the facility.
- Relocate stations from another DaVita (parent company to Total Renal Care of North Carolina, LLC) facility – the applicant states one of three existing DaVita facilities in Hoke County was operating at less than 75% capacity at the time the application was filed. Relocating stations from that facility (Lumbee River Dialysis) would negatively impact that facility's ability to effectively treat patients and operate efficiently; therefore, the applicant determined that this was not the most effective alternative.

Based on the explanations above, the applicant states that its proposal is the most effective alternative to meet the increased demand for dialysis stations at the facility.

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 credible 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. Pursuant to Condition 2 of the facility need determination in the 2021 SMFP, the certificate holder shall develop no more than 11 in-center stations for a total of no more than 30 stations upon project completion.**
- 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 third month. The first progress report shall be due on January 2, 2022. The second progress report shall be due on April 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 proposes to add no more than 11 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	COST
Site Preparation	\$61,588
Construction/Renovation Contract	\$725,211
Medical Equipment	\$303,160
Non-Medical Equipment	\$242,912
Miscellaneous Costs	\$289,563
Total	\$1,622,434

In Section Q, page 94, 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 applicant’s experience regarding what is required to add the additional dialysis stations, including water treatment system, patient TVs, and dialysis chairs.

In Section F, page 45, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project since it is a facility that is already operational.

Availability of Funds

In Section F, page 44, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

TYPE	TRC	TOTAL
Loans	\$0	\$0
Cash/Cash Equivalents/Accumulated reserves or OE *	\$1,622,434	\$1,622,434
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$1,622,434	\$1,622,434

* OE = Owner’s Equity

Exhibit F.2c contains a letter dated June 23, 2021 from the Chief Accounting Officer of DaVita, confirming the availability and authorizing the use of accumulated reserves for the capital needs of the project in the amount of \$1,622,434. In Exhibit F.2 the applicant provides a copy of the consolidated balance sheets for DaVita, Inc. which shows cash and cash equivalents in the amount of \$324,958,000 as of December 31, 2020.

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

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

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:

	INTERIM YEAR (CY 2021)	INTERIM YEAR (CY 2022)	1 ST FULL FY (CY 2023)	2 ND FULL FY (CY 2024)
Total Treatments*	12,790	14,177	15,812	17,744
Total Gross Revenues (Charges)	\$4,922,913	\$5,399,227	\$5,954,414	\$6,604,251
Total Net Revenue	\$4,841,592	\$5,309,085	\$5,853,877	\$6,491,428
Average Net Revenue per Treatment	\$387.55	\$374.49	\$370.22	\$365.84
Total Operating Expenses (Costs)	\$2,644,432	\$2,963,547	\$3,502,069	\$3,758,279
Average Operating Expense per Treatment	\$206.76	\$209.04	\$221.48	\$211.81
Net Income	\$2,197,160	\$2,345,538	\$2,351,808	\$2,733,149

Numbers may not sum due to rounding by Project Analyst

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 into the operating years.
- Payor percentages are based on historical facility operations.
- 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 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 proposes to add no more than 11 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

On page 113, the 2021 SMFP defines the service area for 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-Yancy counties.”* Fayetteville Road Dialysis is in Hoke County. Thus, the service area for this facility is Hoke County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A on page 124 of the 2021 SMFP, there are three existing or approved dialysis facilities in Hoke County, all of which are owned and operated by DaVita. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

HOKE COUNTY DIALYSIS FACILITIES CERTIFIED STATIONS AND UTILIZATION AS OF DECEMBER 31, 2019				
DIALYSIS FACILITY	OWNER	LOCATION	# OF CERTIFIED STATIONS	UTILIZATION
Dialysis Care of Hoke County	TRC	Raeford	24	91.67%
Fayetteville Road Dialysis	TRC	Raeford	10*	105.00%
Lumbee River Dialysis	TRC	Red Springs	15	60.00%

Source: 2021 SMFP, Table 9A, page 124.

*Nine additional stations were certified in September 2020.

In Section G, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Hoke County. The applicant states that this application is based upon the facility need determination in the 2021 SMFP for 11 stations at Fayetteville Road Dialysis. The applicant states:

“While adding stations does increase the number of stations in Hoke 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 Fayetteville Road Dialysis needs additional stations to serve its existing and projected patient population.
- The applicant adequately demonstrates that the proposed addition of the 11 dialysis stations is needed in addition to the existing and approved stations in Hoke 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 proposes to add no more than 11 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

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

POSITION	CURRENT FTE POSITIONS	FTE POSITIONS OY 1	FTE POSITIONS OY 2
Administrator	1.00	1.00	1.00
RN	2.50	3.75	3.75
Home Training Nurse	0.50	1.00	1.00
Patient Care Technician	7.25	11.25	11.25
Dietician	0.50	1.00	1.00
Social Worker	0.50	1.00	1.00
Administration	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
Total	13.75	20.50	20.50

Source: Section Q Form H.

The assumptions and methodology used to project staffing are provided in Section Q, page 102. 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 54-55, 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.

The applicant proposes to add no more than 11 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

Ancillary and Support Services

In Section I, page 57, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 57-60, 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 Fayetteville Road Dialysis.
- The applicant documents how it currently provides and will continue to provide each necessary ancillary and support service at Fayetteville Road Dialysis.

Coordination

In Section I, page 60, 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 documents its relationships with local health care providers.
- The applicant documents its relationships with local social service providers.

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.

- (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

The applicant proposes to add no more than 11 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

In Section K, page 65, the applicant states that the project involves constructing 2,847 square feet of new space in the facility. Line drawings are provided in Exhibit K.

On pages 65-66, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal because it is based on the applicant's experience in constructing and renovating when necessary over 100 dialysis facilities in North Carolina. The applicant explains how DaVita's development department is organized with project managers, architects, contractors and other professionals who collaborate to ensure that the cost, design and means of construction are the most reasonable alternative for the proposal.

On page 66, 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, because the cost of the proposal is budgeted by the corporation. Additionally, the applicant serves mostly Medicare and/or Medicaid recipients at this facility and those charges are set, such that no capital cost expenses can be passed to patients.

On pages 66-67, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 70 the applicant provides the historical payor mix for in-center dialysis during CY 2020, as summarized in the table below:

PAYOR CATEGORY	# IN-CENTER PTS	% OF TOTAL	# PD PTS.	% OF TOTAL
Self-Pay	1.0	1.7%	0.0	0.0%
Insurance*	4.0	6.9%	7.0	29.2%
Medicare*	45.0	77.6%	14.0	58.3%
Medicaid*	4.0	6.9%	1.0	4.2%
Other (VA)	4.0	6.9%	2.0	8.3%
Total	58.0	100.0%	24.0	100.00%

*Includes managed care plans
 Source: application page 70.

In Section L, page 71, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	51.3%	50.7%
Male	48.8%	49.3%
Unknown	--	--
64 and Younger	58.8%	89.4%
65 and Older	41.3%	10.6%
American Indian	6.3%	9.1%
Asian	1.3%	1.5%
Black or African-American	66.3%	35.5%
Native Hawaiian or Pacific Islander	0.0%	0.4%
White or Caucasian	8.8%	4.5%
Other Race	5.6%	13.5%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 72, the applicant states that Fayetteville Road 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 72, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility identified in Section A, Question 4.

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 73, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY 2024) following completion of the project, as summarized in the table below:

PAYOR CATEGORY	# IN-CENTER PTS	% OF TOTAL	# PD PTS.	% OF TOTAL
Self-Pay	1.70	1.7%	0.00	0.0%
Insurance*	6.81	6.9%	8.17	29.2%
Medicare*	76.65	77.6%	16.33	58.3%
Medicaid*	6.81	6.9%	1.17	4.2%
Other (VA)	6.81	6.9%	2.33	8.3%
Total	98.80	100.0%	28.00	100.00%

*Includes managed care plans

Source: application page 73.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.7% of IC dialysis services will be provided to self-pay patients, 76.65% to Medicare recipients and 6.81% to Medicaid recipients. The applicant projects that 58.3% of PD dialysis services will be provided to Medicare recipients and 4.2% to Medicaid recipients.

On page 73, 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 upon the sources of patient payment that have been received in the last full operating year by 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, page 74, 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 proposes to add no more than 11 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

In Section M, page 76, 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 documents its willingness to continue to provide applicable health professional training programs in the area with access to the facility for training.

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 proposes to add no more than 11 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

On page 113, the 2021 SMFP defines the service area for 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-Yancy counties.”* Fayetteville Road Dialysis is in Hoke County. Thus, the service area for this facility is Hoke County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A on page 124 of the 2021 SMFP, there are three existing or approved dialysis facilities in Hoke County, all of which are owned and operated by DaVita. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

HOKE COUNTY DIALYSIS FACILITIES CERTIFIED STATIONS AND UTILIZATION AS OF DECEMBER 31, 2019				
DIALYSIS FACILITY	OWNER	LOCATION	# OF CERTIFIED STATIONS	UTILIZATION
Dialysis Care of Hoke County	TRC	Raeford	24	91.67%
Fayetteville Road Dialysis	TRC	Raeford	10*	105.00%
Lumbee River Dialysis	TRC	Red Springs	15	60.00%

Source: 2021 SMFP, Table 9A, page 124.

*Nine additional stations were certified in September 2020.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 78, the applicant states:

“The expansion of Fayetteville Road Dialysis will have no effect on competition in Hoke County....”

The expansion of Fayetteville Road Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 78, the applicant states:

“...with additional capacity, greater operational efficiency is possible which positively impacts cost-effectiveness.”

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

Regarding the impact of the proposal on quality, in Section N, page 78, the applicant states:

“...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. ... 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.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 78, the applicant states:

“...the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability... .”

See also Sections B, C and L 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

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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 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 DaVita or a related entity in North Carolina.

In Section O, page 83, the applicant states that, during the 18 months immediately preceding the submittal of the application, no related facility in North Carolina 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 July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical

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

C

The 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- Fayetteville Road 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 and Section C, page 33 the applicant projects that Fayetteville Road Dialysis will serve 86 in-center patients on 30 dialysis stations. The projected utilization of 2.87 ($86 / 30 = 2.867$) patients per station per week for OY 1 satisfies 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). The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 26-28 and Section Q, pages 89-90, the applicant provides the assumptions and methodology it used to project in-center utilization at the facility. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.