

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 28, 2021

Findings Date: May 28, 2021

Project Analyst: Misty L. Piekaar-McWilliams

Team Leader: Fatimah Wilson

Project ID #: F-12047-21

Facility: Spencer Dialysis

FID #: 160495

County: Rowan

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

Project: Add no more than five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 19 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 or DaVita, the parent company (hereinafter referred to as “the applicant”) proposes to add no more than five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 19 in-center dialysis stations upon project completion.

Need Determination (Condition 2)

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 9C, the county need methodology shows there is not a county need determination for additional dialysis stations in Rowan 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 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 82.50 percent or 3.3 patients per station per week, based on 33 in-center dialysis patients and 10 certified dialysis stations (33 patients / 10 stations = 3.3; $3.3 / 4 = 82.50\%$).

As shown in Table 9D, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to six (6) additional stations; thus, the applicant is eligible to apply to add up to six (6) dialysis stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than five (5) new dialysis stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to six (6) 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 that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, 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.”

In Section B, pages 18-21, the applicant explains why it believes its application is consistent with Policy GEN-3. On pages 20-21, the applicant states:

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

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

- *maximizing healthcare value.*

As discussed in Sections B-3(a), (b), & (c), established policy and procedure will continue to guide this commitment.”

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 18-19; Section N, pages 63-64; Section O, pages 65-67; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B, page 20; Section L, pages 56-60; Section N, pages 63-64; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B, page 20; Section F, pages 36-37 (including applicable forms in Section Q); Section K, pages 52-53; and Section N, pages 63-64. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

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 reasons:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:

- The applicant adequately documents how the project will promote safety and quality in the delivery of end stage renal disease (ESRD) services in Rowan County.
 - The applicant adequately documents how the project will promote equitable access to ESRD services in Rowan County.
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended in Rowan 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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 19 stations upon project completion.

Project ID #F-11889-20 proposed to add no more than four (4) dialysis stations pursuant to facility need for a total of no more than 14 stations upon project completion. Project ID #F-11889-20 was complete on April 14, 2021, bringing the total number of stations at the facility to 14.

Patient Origin

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Spencer Dialysis is located in Rowan County. Thus, the service area for this facility is Rowan County. Facilities may serve residents of counties not included in their service area.

In Section C, page 22, the applicant provides the patient origin for in-center (IC) dialysis patients at Spencer Dialysis for the last full operating year (CY2020), as summarized in the table below.

Spencer Dialysis Patient Origin - CY2020

COUNTY	# IC PATIENTS	% IC Total
Rowan	28	71.8%
Davidson	9	23.1%
Mecklenburg	1	2.6%
Stanly	1	2.6%
Total	39	100.0%

Totals may not sum due to rounding

The following table summarizes projected patient origin for the second full operating year (CY2024) following project completion, as provided in Section C, page 23.

Spencer Dialysis Patient Origin - CY2024*

COUNTY	# IC PATIENTS	% IC Total
Rowan	48.9722	81.7%
Davidson	9	15.0%
Mecklenburg	1	1.7%
Stanly	1	1.7%
Total	59.9722	100.0%

Totals may not sum due to rounding

*The analyst notes the application reads 1/1/2024 to 1/1/2024 for the second full fiscal year; the analyst believes the application should read 1/1/2024 to 12/31/2024.

In Section C, pages 23-24, the applicant provides the assumptions and methodology it used to project IC patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the historical patient origin of Spencer Dialysis.

Analysis of Need

In Section C.4, page 25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 25, the applicant states:

"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 incenter patients. The additional stations provide opportunities to open appointment times on the more desirable first shift."

In Section C, pages 23-24, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it begins projections with the IC patient census at Spencer Dialysis as of December 31, 2020. On page 23, the applicant states that on December 31, 2020, its IC patient census was comprised of 28 Rowan County patients and 11 patients from other North Carolina counties.
- The applicant states that whereas the Rowan County Five Year Average Annual Change Rate (AACR) published in Table 9B of the 2021 SMFP is 3.4%, this facility, Spencer Dialysis, has experienced significantly higher growth in its first two (2) full years of operation at 73.7% in its first full year of operation and 18.2% in its second full year of operation; therefore, using a 15% growth rate is reasonable given this facility's historic growth rate.
- The applicant states the period of growth begins January 1, 2021 and is calculated forward to December 31, 2024.
- The applicant assumes the December 31, 2020 patients from outside Rowan County will continue to dialyze at Spencer Dialysis but does not assume any growth in patients from those counties and adds them to the calculations when appropriate.
- The applicant states services will be offered as of January 1, 2023. Therefore, operating year (OY) 1 is calendar year (CY) 2023, January 1, 2023 - December 31, 2023 and OY2 is CY2024, January 1, 2024 - December 31, 2024.

Projected Utilization

In-Center Projected Utilization

In Section C, page 24, and in Form C Utilization subsection of Section Q, the applicant provides the methodology used to project the patient census for OY1 and OY2, as summarized in the table below.

Spencer Dialysis Projected Utilization		
	IC Stations	IC Patients
The applicant begins with the 39 patients dialyzing on 14 stations at the facility as of 1/1/2021.	14	39
The applicant projects Rowan County patient census forward a year to December 31, 2021 and increased by 15%.		$28 \times 1.15 = 32.20$
The applicant adds 11 patients residing in counties other than Rowan County for a year-end census as of December 31, 2021.		$32.20 + 11 = 43.20$
The applicant projects the Rowan County patient census forward one year to December 31, 2022 and increased by 15%.		$32.20 \times 1.15 = 37.03$
The applicant adds 11 patients residing in counties other than Rowan County for a year-end census as of December 31, 2022.		$37.03 + 11 = 48.03$
The project is projected to be certified on 1/1/2023. This is the station count at the beginning of OY1.	$14 + 5 = 19$	
The applicant projects the Rowan County patient census forward a year to December 31, 2023 and increased by 15%.		$37.03 \times 1.15 = 42.58$
The applicant adds 11 patients residing in counties other than Rowan County for a year-end census as of December 31, 2023. This is the projected ending census for Operating Year 1 (OY1) .		$42.58 + 11 = 53.58$
The applicant projects the Rowan County patient census forward one year to December 31, 2024 and increased by 15%.		$42.58 \times 1.15 = 48.97$
The applicant adds 11 patients residing in counties other than Rowan County for a year-end census as of December 31, 2024. This is the projected ending census for Operating Year 2 (OY2) .		$48.97 + 11 = 59.97$

The applicant projects to serve 54 in-center patients in OY1 and 60 in-center patients in OY2. Thus, the applicant projects that Spencer Dialysis will have a utilization rate of 71.1% or 2.842 patients per station per week ($54 \text{ patients} / 19 \text{ stations} = 2.842 / 4 = 0.711$ or 71.1%) in OY1 and 75.8% or 3.032 patients per station per week ($60 \text{ patients} / 19 \text{ stations} = 3.158 / 4 = 0.789$ or 78.9%) in OY2. The projected utilization of 2.842 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

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

- The applicant begins the projections with the existing Rowan County patient census at Spencer Dialysis as of December 31, 2020.
- The applicant projects IC utilization using a growth rate for the dialysis facility that is less than the growth rate for the facility during its first two (2) full years of operation.
- The applicant assumes the patients residing outside of Rowan County will continue to dialyze at Spencer Dialysis and are added to the projections without any future growth through the first two (2) operating years of the project.
- The projected utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 28, 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 such as those with disabilities, patients attending school or patients who work. ...

Spencer 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 28, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table. The applicant states it assumes the estimated percentage for the medically underserved groups listed in the following table will be the same as its patient population in CY2020 and projected patient population payor mix in CY2024.

Medically Underserved Groups	% of Total Patients
Low income persons	74.4%
Racial and ethnic minorities	67.8%
Women	38.2%
Persons with disabilities	100.0%
Persons 65 and older	32.4%
Medicare beneficiaries	61.5%
Medicaid recipients	10.3%

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 currently serves the needs of medically underserved groups that utilize ESRD services.
- The applicant has implemented policies to prevent discrimination.

Conclusion

The Agency reviewed the:

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

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

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

CA

The applicant proposes to add no more than five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 19 stations upon project completion.

In Section E, page 35, 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 that maintaining the status quo is not an effective alternative due to the growth rate at the facility.
- *Relocate stations from another DaVita facility* – The applicant states that of the three (3) DaVita facilities in Rowan County, all three (3) operate at greater than 75% capacity. By relocating a station to Spencer Dialysis from another DaVita facility located in Rowan County, the applicant states the transfer of a dialysis station to Spencer Dialysis would negatively impact the transferring facility’s operations and the patients presently served by that facility.

On page 35, the applicant states that its proposal is the most effective alternative because adding five (5) stations will help meet the need for services at Spencer Dialysis.

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

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 five (5) additional in-center dialysis stations for a total of no more than 19 in-center stations at Spencer Dialysis upon completion of this project.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress**

Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at:

<https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.

- b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on February 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 five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 19 stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant provides a table to illustrate projected capital cost of the project, as shown in the table below:

ITEM	COST
Medical Equipment	\$74,250
Non-Medical Equipment	\$7,444
Furniture	\$7,000
Total	\$88,694

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states the costs are based on the input from the North Carolina project manager and the applicant's finance department.

- In Section F, page 37, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

Availability of Funds

In Section F, page 36, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DaVita	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$88,694	\$88,694
Bonds	\$ 0	\$ 0
Other (Specify)	\$ 0	\$0
Total Financing	\$88,694	\$88,694

* OE = Owner's Equity

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

- Exhibit F.2 contains the Consolidated Financial Statements for the year ending December 31, 2020, that shows DaVita, Inc., parent company to Total Renal Care of North Carolina, LLC currently has \$3.2 million in cash and cash equivalents and \$16 billion in total assets.

Financial Feasibility

The applicant provides pro forma financial statements for the first two (2) full operating years following completion of the project. In Section Q, Form F.2, the applicant projects that revenues will exceed operating expenses in the first two (2) operating years of the project, as summarized in the table below.

Spencer Dialysis Projected Revenue and Operating Expenses

	OY 1 CY 2023	OY 2 CY 2024
Total In-Center Treatments	7,530	8,415
Total Gross Revenue (charges)	\$2,443,076.78	\$2,730,197.71
Total Net Revenue*	\$2,581,031.88	\$2,884,365.90
Average Net Revenue per Treatment	\$342.78	\$342.76
Total Operating Expenses (costs)	\$2,003,285.86	\$2,127,276.97
Average Operating Expense per Treatment	\$266.04	\$252.80
Net Income / Profit	\$577,746.03	\$757,088.94

Source: Section Q, Form F.2

*Applicant included 2020 data including the consolidation of the components of "Adjustments to Revenue" in its total net revenue calculations.

Numbers 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 applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant's accounting department projected the financial feasibility of the proposed project and adjusted the reporting of some of its 2020 data into a single line item and reported it as Total Adjustments to Revenue in its calculations for Total Net Revenue.
- Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for the reasons stated above.

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for the reasons stated above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 19 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Spencer Dialysis is located in Rowan County. Thus, the service area for this facility is Rowan County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 129 of the 2021 SMFP, the applicant operates three (3) dialysis centers in Rowan County. Information from Table 9A of the 2021 SMFP is provided below:

Rowan County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/19	# IN-CTR PATIENTS	PATIENTS / STATION	PERCENT UTILIZATION
Dialysis Care of Kannapolis	30	98	3.26	81.67%
Dialysis Care of Rowan County	33	111	3.36	84.09%
Spencer Dialysis	10*	33	3.30	82.50%
Total	73	242		

Source: 2021 SMFP, Table 9A, page 129 and page 42 of the application.

*Spencer Dialysis is currently licensed for 14 dialysis stations (Project ID #F-11889-20).

In Section G, page 43, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Rowan County. The applicant states:

“While adding stations at this facility does increase the number of stations in Rowan County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

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

- There is a facility need determination in the 2021 SMFP for Spencer Dialysis for six (6) dialysis stations. The applicant proposes to add five (5) stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to add no more than five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 19 stations upon project completion.

In Section Q, Form H Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Spencer Dialysis, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 12/31/2020	OY1 (CY2023)	OY2 (CY2024)
Administrator	1.00	1.00	1.00
RNs	1.75	2.50	2.50
Technicians (PCT)	5.25	7.25	7.25
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Admin./Business Office	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
TOTAL	10.50	13.25	13.25

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 44-45, 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 applicant projects an increase in the FTE staffing positions necessary to accommodate the proposed increase in healthcare services at Spencer Dialysis.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.
- The applicant provides supporting documentation of their annual in-service training as well as courses offered by DaVita's School of Clinical Education continuing education program.

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 described above.

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

C

The applicant proposes to add no more than five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 19 stations upon project completion.

Ancillary and Support Services

In Section I, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 46-48, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.2. The

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

- The applicant specifically identifies the providers of the ancillary and support services.
- The applicant provides documentation identifying providers the dialysis facility has agreements in place with to offer ancillary and supporting services to its patients.

Coordination

In Section I, page 49, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has numerous years of experience serving the needs of dialysis patients.
- The applicant has established relationships and agreements with community health care providers and social service agencies and can provide appropriate referrals for necessary services and care related to their patients' conditions.

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

- (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 five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 19 stations upon project completion.

In Section K, page 52, the applicant states that the project does not involve the construction of new space or renovation of the current space. The facility floor plan is included in Exhibit K-2.

On pages 52-53, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states a project manager partners with the finance department to use a corporate model and regional database to ensure project costs are reasonable.
- The applicant's proposed project is using existing space to add additional dialysis stations and does not include the construction of new space or renovation of the current space.

On page 53, 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 based on the following:

- The applicant states costs and charges to the public for the proposed services are not expected to be unduly increased by the proposed project given that the majority of the patients receiving services from the applicant are covered by Medicare/Medicaid in which a single case-mix-adjusted payment rate is paid to the applicant for services.

On pages 53-54, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

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 56, the applicant provides the historical payor mix for Spencer Dialysis during the last full operating year (CY2020) for its existing services, as shown in the table below.

**Spencer Dialysis
 Historical Payor Mix CY 2020****

Payor Category	In-Center	
	# of Patients	% of Total
Self-pay	1	2.6%
Insurance*	3	7.7%
Medicare*	24	61.5%
Medicaid*	4	10.3%
Other (Incl. VA)	7	17.9%
Total	39	100.0%

*Including any managed care plans

**The project analyst observes that the application lists the last fiscal year from 1/1/2020-12/31/2021. The project analyst believes it should read 1/1/2020-12/31/2020; however, this does not have an effect on the applicant's analysis.

In Section L, page 57, the applicant provides the following comparison.

	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population in the Service Area *
Female	38.2%	50.6%
Male	61.8%	49.4%
Unknown	0.0%	0.0%
64 and Younger	67.6%	82.1%
65 and Older	32.4%	17.9%
American Indian	0.0%	0.6%
Asian	0.9%	1.2%
Black or African-American	64.7%	16.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	32.4%	79.4%
Other Race	2.9%	1.8%
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.

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in

comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 58, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 58, the applicant states that during the last 18 months immediately preceding the application deadline that no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 59, 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.

**Spencer Dialysis
Projected Payor Mix CY2024**

Payment Source	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	1.54	2.6%
Insurance*	4.61	7.7%
Medicare*	36.91	61.5%
Medicaid*	6.15	10.3%
Other (incl. VA)	10.76	17.9%
Total	59.97	100.0%

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 2.6% of in-center dialysis services will be provided to self-pay patients, 61.5% to Medicare patients, and 10.3% to Medicaid patients.

On page 59, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon patient payment that has been received by the existing facility in the last fiscal year. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Spencer Dialysis.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, pages 60, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L.5.

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 62, the applicant describes the extent to which health professional training programs in the area will 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 submits supporting documentation showing the facility has offered its location to Rowan-Cabarrus Community College as a clinical learning site for nursing students.

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 five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 19 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Spencer Dialysis is located in Rowan County. Thus, the service area for this facility is Rowan County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 129 of the 2021 SMFP, the applicant operates three (3) dialysis centers in Rowan County. Information from Table 9A of the 2021 SMFP is provided below:

Rowan County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/19	# IN-CTR PATIENTS	PATIENTS / STATION	PERCENT UTILIZATION
Dialysis Care of Kannapolis	30	98	3.26	81.67%
Dialysis Care of Rowan County	33	111	3.36	84.09%
Spencer Dialysis	10*	33	3.30	82.50%
Total	73	242		

Source: 2021 SMFP, Table 9A, page 129 and page 42 of the application.

*Spencer Dialysis is currently licensed for 14 dialysis stations (Project ID #F-11889-20).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 63, the applicant states:

“The expansion of Spencer Dialysis will have no effect on competition in Rowan County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.”

Regarding the impact of the proposal on cost effectiveness, quality, and access to medically underserved groups in Section N, pages 63-64, the applicant states:

“The expansion of Spencer Dialysis will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services... As discussed in Section B and Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients.”

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

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

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

Conclusion

The Agency reviewed the:

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

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

- (19) Repealed effective 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 Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 108 of this type of facility located in North Carolina.

In Section O, page 67, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care resulting in a finding of "*Immediate Jeopardy*" occurred in any of its facilities. 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 as 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- Spencer Dialysis is an existing facility. Therefore, this Rule is not applicable to this review.

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

(1) an existing dialysis facility; or

(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C, page 24, and Form C in Section Q, the applicant projects that Spencer Dialysis will serve 54 in-center patients on 19 stations, or a rate of 2.842 patients per station per week or 71.1% ($54 / 19 = 2.842 / 4 = 0.711$ or 71.1%), as of the end of the first operating year (CY2023) following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

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

- C- In Section C, pages 23-24, in Section Q, Form C, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.