

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 30, 2022

Findings Date: June 30, 2022

Project Analyst: Gregory F. Yakaboski

Co-Signer: Lisa Pittman

Project ID #: Q-12198-22

Facility: Robersonville Dialysis

FID #: 170330

County: Martin

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than three in-center dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 13 in-center 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

The applicant, Total Renal Care of North Carolina, LLC (TRC), proposes to add no more than three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 13 in-center stations at Robersonville Dialysis upon completion of the project.

DaVita, Inc. (DaVita) is the ultimate parent company of TRC.

Robersonville Dialysis provides in-center (IC) dialysis however, the facility does not currently offer either a peritoneal dialysis (PD) program or a home hemodialysis (HH) program and does not propose to develop those services as part of this project.

Need Determination

Chapter 9 of the 2022 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 Martin County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 1 of the facility need methodology in the 2022 SMFP if the facility is a “new,” “small,” or “new and small” facility as defined in the 2022 SMFP, and if the facility’s current reported utilization is at least 75 percent, or 3.0 patients per station in a given week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. If applying pursuant to Condition 1, the facility may only apply once during the calendar year.

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

Facility Need Methodology Condition 1 (New and Small Facilities Only)	Response
Number of months the facility had been certified as of the data cut-off date in the SMFP	26
Number of stations in the facility as of the data cut-off date in the SMFP	10
According to Table 9A in the 2022 SMFP, the facility is designated as new, small, or new and small	small
Number of stations proposed in this application	3
Number of in-center patients per station as of the current reporting date	3.2
Current Reporting Date (no more than 90 days before the application is submitted)	12/31/2021
Previous Reporting Date (six months prior to the Current Reporting Date)	6/60/2021

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

1	# of In-center Patients as of the Current Reporting Date *	32
2	# of In-Center Patients as of the Previous Reporting Date **	29
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	3
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.1
5	Multiply Line 4 by 2 (Annual Growth Rate)	0.2
6	Multiply Line 5 by Line 1 (New Patients)	6.6
7	Add Line 6 to Line 1 (Total Patients)	38.6
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	13.8
9	# of Stations as of the Application Deadline [^]	10.0
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	3.8

Note: The number of in-center patients (29) reported in row 2 is based internal data of the applicant as of 6/31/2021 which was six months before the current reporting date of 12/31/2021. The project analyst notes that if the number of in-center patients (27) from the previous reporting period of 12/31/2020 was used in the table above, which would have looked back 12 months from the current reporting period, the number of additional stations needed in row 10 would have been greater than the 3.8 stations based on the six month data.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “*The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.*” The applicant proposes to add three new stations; therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2022 SMFP applicable to this review: Policy GEN-3: *Basic Principles*.

Policy GEN-3: *Basic Principles*, on page 30 of the 2022 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in

meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

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

Promote Equitable Access

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

Maximize Healthcare Value

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

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2022 SMFP.
- The applicant adequately demonstrates how the facility’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.

- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on how it describes the facility’s policies and programs, which promote the concepts of quality, equitable access and maximum value for resources expended.

(2) Repealed effective 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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 13 in-center stations at Robersonville Dialysis upon completion of the project.

Patient Origin

On page 115, the 2022 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.*” Robersonville Dialysis is in Martin County. Thus, the service area for this application is Martin County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	Historical- Last Full FY (CY2021)		Second Full FY of Operation following Project Completion (CY2025)	
	Patients	% of Total	Patients	% of Total
Martin	28	87.50%	34.68	89.75%
Beaufort	1	3.10%	1	2.60%
Halifax	1	3.10%	1	2.60%
Pitt	2	6.30%	2	5.20%
Total	32	100.0%	38.68	100.00%

Source: Tables on pages 25 and 26 of the application.

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

“Projections for patient utilization begin with the patient population at Robersonville Dialysis as of December 31, 2021.”

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

- The applicant begins with the December 31, 2021 patient census.
- The applicant uses a 5.5 percent annual rate of increase to project patient growth for the Martin County patient population, which is slightly less than half of the 11.2% annual growth rate experienced by the facility from 12/31/2019 to 12/31/2022 and less than a third of the 18.5% annual growth rate experienced by Robersonville Dialysis in CY2021.
- The applicant adds the 4 in-center patients residing in other counties for future projections, with no growth.
- The proposed new stations are projected to be certified as of January 1, 2024.
- Operating Year (OY) 1 is CY2024. OY2 is CY2025.

Analysis of Need

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

“As the table above [on page 27] indicates, the facility has grown significantly since its certification in July of 2019. The following in-center patient projections apply a growth rate of 5.5% for the in-center patients living in Martin County, so as to be conservative. The period of the growth begins January 1, 2022 and is calculated forward to December 31, 2025. No growth calculations were performed for the patients living outside of Martin County.”

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

- The applicant uses a 5.5 percent annual rate of increase to project patient growth for the Martin County patient population, which is slightly less than half of the 11.2% annual growth rate experienced by the facility from 12/31/2019 to 12/31/2022 and less than a third of the 18.5% annual growth rate experienced by Robersonville Dialysis in CY2021.
- The applicant adds the 4 in-center patients residing in other counties for future projections, with no growth.
- Then applicant shows that the facility will need the additional stations to accommodate the existing and projected patient population.

Projected Utilization

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

Form C Utilization	Last Full FY CY2021	Interim OY 1/1/22- 12/31/22	Interim OY 1/1/23- 12/31/23	First Full OY 1/1/24- 12/31/24	Second Full OY 1/1/25- 12/31/25
# of Patients at the Beginning of the Year	27.00	32.00	33.54	35.16	36.88
# of Patients at the End of the Year	32.00	33.54	35.16	36.88	38.69
Average # of Patients during the Year	29.50	32.77	34.35	36.02	37.78
# of Treatments / Patient / Year	149.69	148.20	148.20	148.20	148.20
Total # of Treatments	4,416.00	4,856.51	5,091.02	5,338.42	5,599.43

In Section C, pages 26-27 and Section Q, pages 87-88, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- The first full FY is Operating Year 1, the period from January 1-December 31, 2024.
- The second full FY is Operating Year 2, the period from January 1-December 31, 2025.
- Projections begin with the facility census as of December 31, 2021.
- The applicant grows the Martin County patient census by 5.5%.
- The applicant assumes the facility will continue to serve 4 in-center patients residing in surrounding counties but does not project any growth in that patient population.

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

Robersonville Dialysis In-Center Patients	
Start with the 28 Martin County patients dialyzing on the existing 10 in-center stations at Robersonville Dialysis as of December 31, 2021.	28
The applicant projects the Martin County patient population forward one year to December 31, 2022, using the applicant’s projected 5.5% annual rate of increase.	$28 \times 1.055 = 29.54$
Project the Martin County patient population forward one year to December 31, 2023, using the applicant’s projected 5.5% annual rate of increase.	$29.54 \times 1.055 = 31.16$
Project the Martin County patient population forward one year to December 31, 2024, using the applicant’s projected 5.5% annual rate of increase.	$31.16 \times 1.055 = 32.88$
Add the 4 patients from other counties. This is the projected ending census for Operating Year One (CY2024)	$32.88 + 4 = \mathbf{36.88}$
Project the Martin County patient population forward one year to December 31, 2025, using the applicant’s projected 5.5% annual rate of increase.	$32.88 \times 1.055 = 34.69$
Add the 4 patients from other counties. This is the projected ending census for Operating Year Two (CY2025) .	$34.69 + 4 = \mathbf{38.69}$

Totals may not sum due to rounding

As shown in the table above, the applicant projects Robersonville Dialysis will serve 37 in-center patients by the end of the first full fiscal year of operation, for a utilization rate of 2.846 patients per station per week or 71.15% ($37 \text{ patients} / 13 \text{ stations} = 2.846 \text{ patients per station per week} / 4 = 0.7115$ or 71.15%). By the end of OY2 (December 31, 2025), following the applicant’s methodology and assumptions, the facility will have 39 in-center patients dialyzing at the center for a utilization rate of 75% ($39 / 13 = 3.0 / 4 = 0.75$ or 75.0%). The projected utilization exceeds the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on the ending census as of December 31, 2021, the most recent historical patient census.
- The applicant uses a 5.5 percent annual rate of increase to project patient growth for the Martin County patient population, which is slightly less than half of the 11.2% annual growth rate experienced by the facility from 12/31/2019 to 12/31/2022 and less than a third of the 18.5% annual growth rate experienced by Robersonville Dialysis in CY2021.
- The applicant adds the 4 in-center patients residing in other counties for future projections, with no growth.
- The projected utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Access to Medically Underserved Groups

In Section C.6, page 31, the applicant discusses access to the facilities' services, stating:

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

We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

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

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

Medically Underserved Groups	Percentage of Total Patients
Low income persons	93.8%
Racial and ethnic minorities	96.9%
Women	50.0%
Persons with disabilities	100.0%
Persons 65 and older	53.1%
Medicare beneficiaries	87.5%
Medicaid recipients	6.3%

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... 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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 13 in-center stations at Robersonville Dialysis upon completion of the project.

In Section E.2, page 41, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- Maintain the status quo – The applicant states this is not an effective alternative due to growth rate and utilization of the facility.
- Relocate stations from another facility – The applicant states that while the one other dialysis facility in Martin County, Dialysis Care of Martin County, is currently operating at less than 75% utilization relocating stations from this facility is not an effective alternative because it would disrupt patient and teammate scheduling and thus

negatively impact the patients being served and the facilities operations. 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.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. Pursuant to Condition 1 of the facility need determination in the 2022 SMFP, the certificate holder shall develop no more than three additional in-center dialysis stations for a total of no more than 13 in-center stations at Robersonville 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. The first progress report shall be due on October 1, 2022.

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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 13 in-center stations at Robersonville Dialysis upon completion of the project.

Capital and Working Capital Costs

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

Site Costs	\$0
Construction Costs	\$0
Medical & Non-Medical Equipment and Furniture Costs	\$55,926
Total	\$55,926

In Section Q, pages 91-92, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant describes each item that makes up the projected capital cost.
- The applicant provided the individual and combined cost of each item that makes up the projected capital cost.
- The applicant relied on DaVita's historical experience in developing similar projects and worked with its Finance staff to develop the projected capital costs.

In Section F.3, page 44, the applicant states there are no projected start-up expenses or initial operating expenses because Robersonville Dialysis is an existing and operational facility.

Availability of Funds

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

Sources of Capital Financing

Type	Total Renal Care of North Carolina, LLC
Loans	
Cash and Cash Equivalents, Accumulated reserves or OE *	\$55,926
Bonds	
Other (Specify)	
Total Financing	\$55,926

* OE = Owner's Equity

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

Exhibit F.2 also contains pertinent sections of DaVita's FORM 10-K for the fiscal year ending December 31, 2021 showing cash and cash equivalents of \$461,900,000.

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

Financial Feasibility

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

	1 st Full Fiscal Year (CY2024)	2 nd Full Fiscal Year (CY2025)
Total Treatments	5,338	5,599
Total Gross Revenues (Charges)	\$1,681,602	\$1,763,820
Total Net Revenue	\$1,508,219	\$1,581,960
Average Net Revenue per Treatment	\$283	\$283
Total Operating Expenses (Costs)	\$1,435,722	\$1,480,642
Average Operating Expense per Treatment	\$269	\$264
Net Income	\$72,497	\$101,318

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 13 in-center stations at Robersonville Dialysis upon completion of the project.

On page 115, the 2022 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.”* Robersonville Dialysis is in Martin County. Thus, the service area for this application is Martin County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 127 of the 2022 SMFP, there are two existing or approved dialysis facilities in Martin County, both of which are owned and operated by DaVita. Information on these dialysis facilities, from Table 9A of the 2022 SMFP, is provided below:

Dialysis Facility	In-Center Patients (12-31-20)	# of Certified Stations (12-31-20)	Utilization (12-31-20)
Dialysis Care of Martin County	39	15	65.0%
Robersonville Dialysis*	27	10	67.5%

Source: 2022 SMFP, Table 9A.

*Designated as a small facility according to the facility need determination methodology.

In Section G, page 50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Martin County. The applicant states:

“Based on the facility need methodology in the 2022 SMFP under Condition 1, Robersonville Dialysis qualifies to add up to 4 dialysis stations.

In Section B, Question 3 and Section C, Question 3 of this application, we demonstrate the need that Robersonville Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Martin 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 Robersonville Dialysis needs additional stations to serve its existing and projected patient population.
- The applicant adequately demonstrates that the proposed addition of three stations is needed in addition to the existing and approved stations in Martin County.

Conclusion

The Agency reviewed the:

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

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

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

CA

The applicant proposes to add no more than three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 13 in-center stations at Robersonville Dialysis upon completion of the project.

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

POSITION	Current FTE Positions	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.00	1.00	1.00
Registered Nurse	1.25	1.75	1.75
Technicians	3.75	5.00	5.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Business Office	0.50	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
Total	8.00	10.25	10.25

Source: Section Q Form H

The assumptions and methodology used to project staffing are provided in Section Q, page 100. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H.2 and H.3, pages 53-54, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The facility is an existing facility and the applicant bases its staffing on its historical experience providing dialysis services at the facility.
- The applicant has existing policies regarding 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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 13 in-center stations at Robersonville Dialysis upon completion of the project.

Ancillary and Support Services

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

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

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

Coordination

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 68, the applicant provides the historical payor mix for in-center dialysis during CY2021 for Robersonville Dialysis, as summarized in the table below.

Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.0	0.0%
Insurance *	2.0	6.3%
Medicare *	28.0	87.5%
Medicaid *	2.0	6.3%
Total	32.0	100.0%

*Including any managed care plans

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

Robersonville Dialysis	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY, CY2021	Percentage of the Population of the Service Area
Female	50.0%	53.0%
Male	50.0%	47.0%
Unknown	0.0%	0.0%
64 and Younger	46.9%	76.1%
65 and Older	53.1%	23.9%
American Indian	0.0%	0.6%
Asian	0.0%	0.5%
Black or African-American	93.8%	42.1%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	3.1%	55.3%
Other Race	3.1%	1.3%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

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

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

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

C

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

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3(a), page 71, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY2025) following completion of the project, as summarized in the table below.

Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.00	0.0%
Insurance *	2.42	6.3%
Medicare *	33.85	87.5%
Medicaid *	2.42	6.3%
Total	38.69	100.0%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 87.5% to Medicare recipients and 6.3% to Medicaid recipients.

On page 71, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical (CY2021) payor mix percentages for the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, page 72, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 13 in-center stations at Robersonville Dialysis upon completion of the project.

In Section M, page 74, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 13 in-center stations at Robersonville Dialysis upon completion of the project.

On page 115, the 2022 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.*” Robersonville Dialysis is in Martin County. Thus, the service area for this application is Martin County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 127 of the 2022 SMFP, there are two existing or approved dialysis facilities in Martin County, both of which are owned and operated by DaVita. Information on these dialysis facilities, from Table 9A of the 2022 SMFP, is provided below:

Dialysis Facility	In-Center Patients (12-31-20)	# of Certified Stations (12-31-20)	Utilization (12-31-20)
Dialysis Care of Martin County	39	15	65.0%
Robersonville Dialysis*	27	10	67.5%

Source: 2022 SMFP, Table 9A.

*Designated as a small facility according to the facility need determination methodology.

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

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

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

“The expansion of Robersonville Dialysis will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services. As noted in Form H, with additional capacity, greater operational efficiency is possible which positively impacts cost-effectiveness. As discussed in Section B and Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients. As discussed in Section C, Question 6, and documented in Exhibit L.5, the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients.”

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant 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 publicly available during the review and used by the Agency

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

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

C

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 106 dialysis facilities owned, operated, or managed by a DaVita or a related entity located in North Carolina.

In Section O, page 81, the applicant states that, during the 18 months immediately preceding the submittal of the application, no DaVita facility was found to have had an incident related to quality of care that resulted in a finding of "*Immediate Jeopardy*". After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective 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 with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- The applicant is not proposing to establish a new ESRD 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 C, pages 26-27, the applicant projects Robersonville Dialysis will serve 37 in-center patients by the end of the first full fiscal year of operation, for a utilization rate of 2.846 patients per station per week or 71.15% ($37 \text{ patients} / 13 \text{ stations} = 2.846 \text{ patients per station per week} / 4 = 0.7115$ or 71.15%). The projected utilization of 2.846 patients per station per week exceeds the 2.8 in-center patients per station per week threshold required by 10A NCAC 14C .2203(a).

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

- C- In Section C, pages 26-27, and in Section Q, pages 87-88 the applicant provides the assumptions and methodology used to project utilization of the facility.