

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 22, 2021

Findings Date: January 22, 2021

Project Analyst: Misty L. Piekaar-McWilliams

Team Leader: Fatimah Wilson

Project ID #: Q-11972-20

Facility: Roanoke-Chowan Dialysis

FID #: 170240

County: Hertford

Applicant(s): Renal Treatment Centers-Mid-Atlantic, Inc.

Project: Add no more than 5 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 dialysis stations

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Renal Treatment Centers-Mid-Atlantic, Inc. (the applicant) operates a 10-station dialysis facility, Roanoke-Chowan Dialysis (RCD), in Murfreesboro, Hertford County. In this application, the applicant proposes to add no more than five (5) in-center (IC) dialysis stations to Roanoke-Chowan Dialysis pursuant to Condition 1 of the facility need methodology for a total of no more than 15 dialysis stations upon project completion.

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis

stations. According to Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations for Hertford 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 2020 SMFP if the facility is a “new” facility or a “small” facility (or both) as defined in the 2020 SMFP, and if the facility’s current reported utilization is at least 75%, 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 11, the applicant states the following:

Facility Need Methodology Condition 1	Response
Number of months the facility had been certified as of the data cut-off date in the SMFP	9
Number of stations in the facility as of the data cut-off date in the SMFP	10
According to Table 9B in the 2020 SMFP, the facility is designated as new, small, or new and small	Yes
Number of stations proposed in this application	5
Number of in-center patients per station as of the current reporting date	3.3
Current Reporting Date (no more than 90 days before the application is submitted)	8/31/2020
Previous Reporting Date (six months prior to the Current Reporting Date)	2/28/2020

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of 15 additional dialysis stations are needed at this facility, as illustrated in the following table.

ROANOKE-CHOWAN DIALYSIS FACILITY NEED METHODOLOGY	
# of In-center Patients as of the Current Reporting Date*	33
# of In-Center Patients as of the Previous Reporting Date**	21
Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	12
Divide Line 3 by Line 2 (6-month Growth Rate)	0.57
Multiply Line 4 by 2 (Annual Growth Rate)	1.14
Multiply Line 5 by Line 1 (New Patients)	37.71
Add Line 6 to Line 1 (Total Patients)	70.71
Divide Line 7 by 2.8 (Total # of Stations Needed)	25.26
# of Stations as of the Application Deadline^	10.00
Subtract Line 9 from Line 8 (Additional Stations Needed)	15.26

*Current Reporting Date should be no more than 90 days before the date the CON application was submitted.

**Previous Reporting Date is six months prior to the Current Reporting Date.

^Includes all stations that were 1) certified; 2) CON approved but not yet certified; and 3) proposed to be added in applications still under review as of the application deadline.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Roanoke-Chowan Dialysis is 15 dialysis stations, based on rounding allowed in Condition 1.b.(vii). However, whereas the applicant lists 21 in-center patients on page 11 of the application for their previous reporting date of February 28, 2020, the applicant lists 22 in-center patients on their December 31, 2019 End Stage Renal Disease (ESRD) data collection form and for their ending historical patient origin value for calendar year 2019 on page 19 of the application indicating the applicant would have needed 23.6 dialysis stations as of December 31, 2019. Condition 1a.(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 five (5) new dialysis stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP applicable to this review. Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 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.5(a) and (d), pages 13-14 and 15-16, Section N.2(b), page 49; Section O, pages 51-52; 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.5(b), page 15; Section B.5(d), pages 15-16, Section C.7, page 23; Section L, pages 44-47; Section N.2(c), page 49; 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.5(c), page 15, Section B.5(d), page 16; Section N.2(a), page 49; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value 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 2020 SMFP.
- The applicant adequately demonstrates how RCD'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 because the proposal demonstrates how it will promote safety, quality and access to dialysis services as stated above.

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

The applicant proposes to add no more than five (5) dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 dialysis stations upon project completion.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “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.” Thus, the service area for this facility is Hertford County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin for IC patients at Roanoke-Chowan Dialysis. RCD does not provide home hemodialysis (HD) and peritoneal dialysis (PD) services.

Roanoke-Chowan Dialysis Historical & Projected Patient Origin

COUNTY	LAST FULL OPERATING YEAR (OY) CY 2019		SECOND FULL OY CY 2023	
	# IC Pts.	% OF TOTAL	# IC Pts.	% OF TOTAL
Hertford	17	77.3%	40	80.0%
Northampton	4	18.2%	5	10.0%
Gates	1	4.5%	2	4.0%
Halifax	0	0.0%	1	2.0%
Chowan	0	0.0%	1	2.0%
Bertie	0	0.0%	1	2.0%
Total	22	100.0%	50	100.0%

Source: Application pages 19-20

In Section C, pages 20-21 and Section Q, Form C, the applicant provides the assumptions and methodology used to project IC patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects IC patient origin using their historical IC patient population as of August 31, 2020.
- Despite a growth rate of 57.1% in the first full year of operation (CY 2019) and 50% in the first eight (8) months of 2020, the applicant projects growth at 18% which is less than one-half the growth rates of the dialysis facility in CY 2019 or the first eight (8) months of 2020.

Analysis of Need

In Section B, page 11 and Section C, page 20, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant discusses the need for additional in-center dialysis stations based on RCD’s patient growth rate over the last year in Section C, pages 20-21, as follows:

- The applicant states as reported in the facility's December 2019 ESRD Data Collection form that the dialysis facility had 22 in-center patients as of December 31, 2019. This is a utilization rate of 55.0% based on 10 stations [$22 / 10 = 2.2$; $2.2 / 4 = 0.55$].
- The applicant states that as of August 31, 2020, RCD had 33 in-center patients, which is a utilization rate of 82.5% based on 10 stations [$33 / 10 = 3.3$; $3.3 / 4 = 0.825$] which is an increase rate of 27.5% from December 31, 2019, to August 31, 2020. Of the 33 in-center patients, the applicant states 23 were residents of Hertford County.
- The applicant notes that the Five Year Average Annual Change Rate (AACR) in Hertford County as reported in Table 9C in the 2020 SMFP is only 3.0%; however, the applicant states RCD's growth in 2019, its first full year of operation, was 57.1%, and was 50.0% in the first eight (8) months of 2020. Therefore, the applicant states it is reasonable to project a growth rate of at least 18% for the facility.
- The applicant assumes the patients from counties other than Hertford will continue to dialyze at RCD but does not assume any growth in patients from these counties.
- Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022, and OY2 is CY 2023, January 1-December 31, 2023.

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

- The utilization rate from December 31, 2019, to August 31, 2020, increased by 28.25% which is greater than Hertford County's Five Year ACCR and the applicant's projected growth rate of 18%.
- The applicant states the dialysis facility has a growth rate of 57.1% in the first full year of operation (CY 2019) and 50% in the first eight (8) months of 2020, in which it can be assumed the facility will continue to increase in utilization of dialysis stations.

Projected Utilization – In-center Patients

In Section C.3, page 21, the applicant provides a table to illustrate its methodology used to project in-center utilization, as shown below:

	# IC Stations	IC Patients
The applicant begins with the 33 patients dialyzing on 10 stations at the facility as of September 1, 2020.	10	33
Project the facility's Hertford County patient census forward 4 months to December 31, 2020, using a conservative growth rate of 18.0%		$23 \times 1.06 = 24.38$
Add 10 patients from outside Hertford County. This is the ending census as of December 31, 2020.		$24.38 + 10 = 34.38$
Project Hertford County patient population forward one year to December 31, 2021, using a 18% growth rate.		$24.38 \times 1.18 = 28.77$
Add 10 patients from outside Hertford County. This is the ending census as of December 31, 2021.		$28.77 + 10 = 38.77$
Projected certification date for this project is 1/1/2022. The station count as of this date is 15.	$10 + 5 = 15$	
Project Hertford County patient population forward one year to December 31, 2022, using a 18.0% growth rate.		$28.77 \times 1.18 = 33.95$
Add 10 patients from outside Hertford County. This is the ending census as of December 31, 2022 / Operating Year 1 (OY1).		$33.95 + 10 = 43.95$
Project Hertford County patient population forward one year to December 31, 2023, using a 18.0% growth rate.		$33.95 \times 1.18 = 40.06$
Add 10 patients from outside Hertford County. This is the ending census as of December 31, 2023 / Operating Year 2 (OY2).		$40.06 + 10 = 50.06$

The applicant projects to serve 44 in-center patients in OY 1 and 50 in-center patients in OY 2. Thus, the applicant projects that RCD will have a utilization rate of 73.25% or 2.93 patients per station per week ($44 \text{ patients} / 15 \text{ dialysis stations} = 2.93$; $2.93 / 4 = 0.7325$ or 73.25%) in OY 1. The projected utilization of 2.9 patients per station per week at the end of OY1 meets 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 based on the following:

- The applicant projects future utilization based on historical utilization.
- The applicant utilized a projected annual growth rate of 18.0 percent for Hertford County patients which is less than one-half the growth rate experienced by the dialysis facility during CY 2019 or the first eight (8) months of 2020.
- The applicant assumes the patient residing outside of Hertford County will continue to dialyze at RCD and is added to the projections without any future growth through the first two 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.7, page 23, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex,

age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

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.

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

In Section C.7, page 28, the applicant projects the following estimated percentage of total patients for each group during the second year of operation following completion of the project, as summarized in the following table.

**Roanoke-Chowan Dialysis
Projected Estimated Percentage of Total Patients for Each Group**

	Estimated Percentage of Patients by Group
Female	40.9%
Male	59.1%
Unknown	0.0%
64 and Younger	59.1%
65 and Older	40.9%
American Indian	0.0%
Asian	0.0%
Black of African-American	95.5%
Native Hawaiian or Pacific Islander	0.0%
White or Caucasian	4.5%
Other Race	0.0%
Declined / Unavailable	0.0%
Medicare	72.7%
Medicaid	18.2%
Handicapped*	N/A

*Data not captured

Source: Estimated percentages based upon percentages reported in Section L, Questions 1 and 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 projects estimated percentage of total patients for each group using CY2019 patient population data.

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 projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately supports its assumptions.

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

NA

The applicant does not propose a reduction, elimination or relocation of 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 1 of the facility need methodology for a total of no more than 15 dialysis stations upon project completion.

In Section E, page 29, 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 because of the growth rate at the facility.
- *Relocate stations from another DaVita facility* – The applicant states that there is only one (1) other DaVita facility in Hertford County: Ahoskie Dialysis. Ahoskie Dialysis was operating at a 107.8% utilization rate as reported in their December 2019 ESRD Data Collection form. Given the utilization rate at Ahoskie Dialysis, relocating stations from Ahoskie Dialysis would negatively impact those patients.

On page 29, the applicant states that the proposal to add five (5) dialysis stations to Roanoke-Chowan Dialysis pursuant to Condition 1 of the facility need determination is the most effective alternative to meet the needs of the dialysis patients served at the facility because it helps meet the growing demand for dialysis services at RCD.

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
- 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. Therefore, the application is approved subject to the following conditions:

- 1. Renal Treatment Centers-Mid-Atlantic, Inc. (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 the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than five additional in-center dialysis stations pursuant to Condition 1 of the facility need methodology at Roanoke-Chowan Dialysis for a total of no more than 15 in-center stations upon project completion.**
 - 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on June 1, 2021. The second progress report shall be due on October 1, 2021 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 1 of the facility need methodology for a total of no more than 15 dialysis stations upon project completion.

Capital and Working Capital Costs

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

Roanoke-Chowan Dialysis Capital Cost

ITEM	COST
Medical Equipment	\$89,100
Non-Medical Equipment	\$7,869
Furniture	\$8,400
Total	\$105,369

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 employs a corporate model and regional database to ensure project costs are reasonable.
- The applicant receives input from their operations team and real estate team to ensure costs are adequate.

In Section F.3, pages 31-33, 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 30, 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	\$	\$
Accumulated reserves or OE *	\$105,369	\$105,369
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$105,369	\$105,369

* OE = Owner's Equity

In Section F, page 31, the applicant states that there are no working capital needs for the project.

Exhibit F contains the Consolidated Financial Statements for years ending December 31, 2019, that show DaVita, Inc., parent company to Renal Treatment Centers – Mid-Atlantic, Inc.

currently has over \$1 billion in cash and cash equivalents and over \$17 billion in total assets. Exhibit F.2 provides a letter dated October 5, 2020 and signed by DaVita's Chief Accounting Officer that commits the capital to the project.

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

- The applicant submitted documentation from their parent company showing sufficient funds in their accumulated reserves or owner's equity for the working capital needs of the project.
- The applicant submitted a letter from their Chief Accountant Officer committing the required working capital to the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two 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.

	OY 1 CY 2022	OY 2 CY 2023
Total Treatments	6,129	6,966
Total Gross Revenue (charges)	\$2,019,847	\$2,295,509
Total Net Revenue	\$1,929,625	\$2,192,975
Average Net Revenue per Treatment	\$330	\$330
Total Operating Expenses (costs)	\$1,904,884	\$2,047,133
Average Operating Expense per Treatment	\$310.80	\$293.87
Net Income	\$24,741	\$145,842

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 projects that revenues will exceed operating expenses in the first two (2) operating years of the project.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described 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 all the reasons described 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 1 of the facility need methodology for a total of no more than 15 dialysis stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* Thus, the service area for this facility is Hertford County. Facilities may serve residents of counties not included in their service area.

There are two (2) dialysis centers in Hertford County. The applicant operates both dialysis centers in Hertford County. Utilization of both dialysis centers is shown in the following table from Chapter 9, Table 9B, page 157 of the 2020 SMFP and page 35 of the application:

Hertford County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CENTER PTS.	% UTILIZATION	# PTS. / STATION PER WEEK
Roanoke-Chowan Dialysis	10	14	35.00%	1.400
Ahoskie Dialysis	26	65	62.50%	2.500
Total	36	79		

Source: 2020 SMFP, Table 9B and application, page 35.

In Section G.2, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Hertford County. The applicant states:

“While adding stations at this facility does increase the number of stations in Hertford 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:

- Based on the facility need methodology in the 2020 SMFP under Condition 1, RCD qualifies for 15 additional stations based on their previous reporting date of February 28, 2020 but qualified for as many as 23.6 dialysis stations on December 31, 2019 based on their December 31, 2019 ESRD data collection form. However, the applicant only applied to add up to five (5) proposed dialysis stations which is less than either their projected need of 15 or 23.6 dialysis stations.
- The applicant adequately demonstrates that the five (5) 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 1 of the facility need methodology for a total of no more than 15 dialysis 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 RCD, as summarized below.

Roanoke-Chowan Dialysis Current and Projected Staffing

POSITION	CURRENT # FTEs AS OF 12/31/19	PROJECTED # FTEs	
		OY 1 (CY 2022)	OY 2 (CY 2023)
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	1.25	2.00	2.00
Licensed Practical Nurses (LPNs)	0.00	0.00	0.00
Home Training Nurse	0.00	0.00	0.00
Patient Care Technician (PCTs)	3.75	5.75	5.75
Medical Records	0.00	0.00	0.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Housekeeping	0.00	0.00	0.00
Maintenance	0.00	0.00	0.00
Administration/Bus. Office	0.50	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
Total	8.00	11.25	11.25

Source: Section Q, Form H

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, page 36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibits H-1, H-2 and H-3 provide supporting documentation. In Exhibit H-4, the applicant provides a letter from the medical director indicating his intent to continue to serve as medical director for the proposed services and indicates his support for adding six (6) dialysis stations. In a request for clarification by the Agency, the applicant states, “*Yes, the application is requesting five dialysis stations. There is a typo on the medical director’s letter.*”

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

- The applicant bases their projections on experience operating multiple dialysis facilities in the health service area and through the State.
- The dialysis facility is an existing facility with a recruitment process already existing in the health service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Clarifying information requested by the Agency

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 decide 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 1 of the facility need methodology for a total of no more than 15 dialysis stations upon project completion.

Ancillary and Support Services

In Section I, page 38, the applicant identifies the necessary ancillary and support services for the proposed services as shown in the table below:

Roanoke-Chowan Dialysis	
ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	On site
Home Hemodialysis Training & Follow-Up Program	Albemarle Dialysis
Peritoneal dialysis training & follow-up program	Albemarle Dialysis
Isolation – Hepatitis B	On site
Psychological counseling	On site by RN
Nutritional counseling	On site by RD
Social Work services	On site by MSW
Laboratory services	DaVita Laboratory Services, Inc.
Acute dialysis in an acute care setting	Referral to Martin General Hospital
Emergency care	Referral to Martin General Hospital
Blood bank services	Referral to Martin General Hospital
Diagnostic and evaluation services	Referral to Martin General Hospital
X-ray services	Referral to Martin General Hospital
Pediatric nephrology	Referral to Martin General Hospital
Vascular surgery	Referral to Martin General Hospital
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	Vocational Rehabilitation of Williamston
Transportation	CPTA

On page 38, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant identifies the necessary ancillary and support services for dialysis patients located in or near Hertford County and how these will be made available.

Coordination

In Section I, pages 38-39, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant operates additional dialysis stations in North Carolina and has established ancillary and support services in the area.
- The applicant has existing relationships with local healthcare providers in the area including but not limited to Martin General Hospital and Vidant Medical Center.

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 nor 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 handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 45, the applicant provides the historical payor mix for RCD patients during CY 2019 for its existing services, as shown in the table below:

Roanoke-Chowan Dialysis Historical Payor Mix CY 2019

Payment Source	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	0.0	0.0%
Insurance*	2.0	9.1%
Medicare*	16.0	72.7%
Medicaid*	4.0	18.2%
Other (VA)	0.0	0.0%
Total	22.0	100.0%

*Including any managed care plans

In Section L.1(a), page 44, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA *
Female	40.9%	50.2%
Male	59.1%	49.8%
Unknown	0.0%	0.0%
64 and Younger	59.1%	79.6%
65 and Older	40.9%	20.4%
American Indian	0.0%	1.3%
Asian	0.0%	0.8%
Black or African-American	95.5%	61.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	4.5%	35.5%
Other Race	0.0%	1.4%
Declined / Unavailable	0.0%	0.0%

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

Conclusion

The Agency reviewed the:

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 45, 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 45, the applicant states that during the last five years 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.

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.

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

C

In Section L.3, page 46, 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.

**Roanoke-Chowan Dialysis
Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	0.0	0.0%
Insurance*	4.6	9.1%
Medicare*	36.4	72.7%
Medicaid*	9.1	18.2%
Other (VA)	0.0	0.0%
Total	50.1	100.0%

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 72.7% of services will be provided to Medicare patients and 18.2% to Medicaid patients.

On page 47, 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 recent facility history of actual treatment volumes. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant's projected payor mix is based on the historical payor mix of RCD.

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.

- (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 46-47, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 five (5) dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 15 dialysis stations upon project completion.

In Section M, page 48, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant submitted documentation expressing interest in partnering with Rowan-Chowan Community College (RCCC) to extend their services as a clinical training site at the dialysis facility to RCCC 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 1 of the facility need methodology for a total of no more than 15 dialysis stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Roanoke-Chowan Dialysis is located in Hertford County. Thus, the service area for this facility is Hertford County. Facilities may serve residents of counties not included in their service area.

There are two (2) dialysis centers in Hertford County. The applicant operates both dialysis centers in Hertford County. Utilization of both dialysis centers is shown in the following table from Chapter 9, Table 9B, page 157 of the 2020 SMFP and page 35 of the application:

Hertford County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CENTER PTS.	% UTILIZATION	# PTS. / STATION PER WEEK
Roanoke-Chowan Dialysis	10	14	35.00%	1.400
Ahoskie Dialysis	26	65	62.50%	2.500
Total	36	79		

Sources: 2020 SMFP, Table 9B and application, page 35.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 49, the applicant states:

“The expansion of Roanoke-Chowan Dialysis will have no effect on competition in Hertford 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, in Section N.2, page 49, the applicant states:

*“...By reducing the economic and physical burdens on our patients, this project will enhance the quality and **cost effectiveness** (emphasis added) of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”*

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

Regarding the impact of the proposal on quality, in Section N.2, page 49, the applicant states:

*“...By reducing the economic and physical burdens on our patients, this project will enhance the **quality** (emphasis added) 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.”*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N.2, page 49, the applicant states:

“...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 C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant 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 A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O.2, pages 52-53, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in one DaVita facility: Waynesville Dialysis Center. The applicant states that a plan of correction was prepared and accepted, and that Waynesville Dialysis Center is currently back in compliance. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as 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- The applicant is not proposing to establish a new kidney disease treatment center or dialysis 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.3, page 21, the applicant projects that RCD will serve 44 in-center patients on 15 dialysis stations, or a rate of 2.9 patients per station per week, as of the end of the first operating

year following project completion. This meets the minimum performance standard of 2.8 patients per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.3, pages 20-21, the applicant provides the assumptions and methodology it used to project IC patient utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.