

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 21, 2022

Findings Date: June 21, 2022

Project Analyst: Kim Meymandi

Co-Signer: Gloria C. Hale

Project ID #: K-12199-22

Facility: Vance County Dialysis

FID #: 944655

County: Vance

Applicant(s): DVA Renal Healthcare, Inc.

Project: Add no more than five in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 47 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

DVA Renal Healthcare, Inc. (hereinafter referred to as “the applicant” or “DaVita”) proposes to add no more than five in-center dialysis stations to the existing Vance County Dialysis facility pursuant to Condition 2 of the facility need methodology for a total of no more than 47 stations upon project completion.

Need Determination (Condition 2)

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 9B, page 138, the county need methodology shows there is not a county need determination for additional dialysis stations in Vance County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2022 SMFP, if the utilization rate for the dialysis center as reported in the 2022 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Vance County Dialysis in Table 9A, page 132 of the 2022 SMFP is 93.57% or 3.74 patients per station per week, based on 131 in-center dialysis patients and 35 certified dialysis stations as of December 31, 2020 [131 patients / 35 stations = 3.74; 3.74 / 4 = 93.57%).

As shown in Table 9D on page 141 of the 2022 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Vance County Dialysis is up to ten additional stations; thus, the applicant is eligible to apply to add up to ten stations during the 2022 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than five new stations to Vance County Dialysis, which is consistent with the 2022 SMFP calculated facility need determination for up to ten dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2022 SMFP which is applicable to this review. *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.”

In Section B, pages 20-22, the applicant explains why it believes its application is consistent with Policy GEN-3. On page 22, the applicant states:

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

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

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

The applicant further discusses the promotion of safety and quality in Section N.2, page 76; and Section O, pages 79-81, and referenced exhibits.

The applicant further discusses the promotion of equitable access in Section C.6, pages 32-33; Section L, pages 68-72; and Section N.2, page 76; and referenced exhibits.

The applicant further discusses maximizing healthcare value for resources expended in Section N.2, page 76.

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 that the application is consistent with Policy GEN-3 based on how the facility’s projected volumes incorporate the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need.

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 47 stations upon project completion.

The following table, summarized from page 15 of the application, shows the current and projected number of dialysis stations at Vance County Dialysis upon project completion.

Vance County Dialysis

# of Stations	Description	Project ID #
42	Total # of existing certified stations as reported in Table 9A of the 2021 SMFP	
5	# of stations to be added as part of this project	K-12199-22
	# of stations to be deleted as part of this project	
	# of stations previously approved to be added but not yet certified	
	# of stations previously approved to be deleted	
	# of stations proposed to be added in an application still under review	
	# of stations proposed to be deleted in an application still under review	
47	Total # of stations upon completion of all facility projects	

As outlined in the table above, in this application, the applicant proposes to add five dialysis stations for a total of 47 stations upon the completion of this 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.” The facility referred to in this application is located in Vance County. Thus, the service area for this facility consists of Vance County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 25, the applicant provides the patient origin for in-center (IC) dialysis patients at Vance County Dialysis for the last full fiscal year (CY2021), as summarized in the table below. The facility does not provide home hemodialysis or peritoneal dialysis.

Vance County Dialysis Historical Patient Origin - CY2021

COUNTY	PATIENTS	% of Total
Vance	101	85.6%
Franklin	3	2.5%
Granville	5	4.2%
Warren	8	6.8%
Virginia	1	0.9%
Total	118	100.0%

Totals may not sum due to rounding

The following table summarizes projected patient origin for the second full operating year (CY2024) following project completion, as provided in Section C.3, page 26.

Vance County Dialysis Projected Patient Origin - CY2024

COUNTY	PATIENTS	% of Total
Vance	120.91	87.7%
Franklin	3.00	2.2%
Granville	5.00	3.6%
Warren	8.00	5.8%
Virginia	1.00	0.7%
Total	137.91	100.0%

Totals may not sum due to rounding

In Section C, pages 26-27, the applicant provides the assumptions and methodology it used to project IC patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin at Vance County Dialysis based on its existing population.
- The applicant increases the number of projected future patients originating from Vance County based on the Five-Year Average Annual Change Rate (AACR) of Vance County.
- The applicant assumes no growth in the patient population residing outside of Vance County.

Analysis of Need

In Section C.4, page 28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- Application of the facility need methodology shows that the facility is eligible to apply for up to ten dialysis stations. Section Q Form C, Utilization Assumptions and Methodology, provides information as to why the population projected to utilize the proposed services needs the proposed services.
- Vance County Dialysis' projected patient population for the first full operating year (OY) (01/01/2024 to 12/31/2024) is projected to grow to 133 in-center patients with a utilization rate of 70.7%, or 2.83 patients per station per week.
- The OY projections for patient population is based upon the 4.6% Vance County Five Year Average Annual Change Rate (AACR) as indicated in Table 9B, page 138, of the 2022 SMFP.
- The applicant does not project growth for patients who reside outside of Vance County.

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

- According to the 2022 SMFP, as of December 31, 2020, Vance County Dialysis was operating at a rate of 3.74 patients per station per week, or 93.57 percent of capacity.
- The applicant adequately demonstrates the need to add five dialysis stations pursuant to the facility need methodology based on its existing and future patient population.

Projected Utilization

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

Form C Utilization	Last Full FY 01/01/2021- 12/31/2021	Interim Year 01/01/2022- 12/31/2022	Interim Year 01/01/2023- 12/31/2023	First Full FY 01/01/2024- 12/31/2024	Second Full FY 01/01/2025- 12/31/2025
In-Center Patients					
# of Patients at the Beginning of the Year	113.00	118.00	122.65	127.51	132.59
# of Patients at the End of the Year	118.00	122.65	127.51	132.59	137.91
Average # of Patients during the Year	115.50	120.32	125.08	130.05	135.25
# of In-center Treatments / Patient / Year	153.06	148.20	148.20	148.20	148.20
Total # of In-center Treatments	17,678.00	17,831.87	18,536.24	19,273.02	20,043.68

In-Center Projected Utilization

In Section C.3, pages 26-27, and in Form C Utilization subsection of Section Q, the applicant provides the methodology used to project the patient census for OY1 and OY2, as summarized in the table below.

Vance County Dialysis Projected Utilization		
	IC Stations	IC Patients
The applicant begins with the 118 patients dialyzing on 42 stations at the facility as of 12/31/2021.	42	118
The applicant projects Vance County patient census forward one year to December 31, 2022 using the 4.6% five-year AACR growth rate for Vance County.		$101 \times 1.046 = 105.6460$
The applicant adds 17 patients from counties other than Vance County for a year-end census as of December 31, 2022.		$105.65 + 17 = 122.65$
The applicant projects the Vance County patient census forward one year to December 31, 2023 using the 4.6% five-year AACR growth rate for Vance County.		$105.65 \times 1.046 = 110.5057$
The applicant adds 17 patients from counties other than Vance County for a year-end census as of December 31, 2023.		$110.51 + 17 = 127.51$
The project is projected to be certified on 1/1/2024. This is the station count at the beginning of OY1.	$42 + 5 = 47$	
The applicant projects the Vance County patient census forward a year to December 31, 2024 using the 4.6% five-year AACR growth rate for Vance County.		$110.51 \times 1.046 = 115.589$
The applicant adds 17 patients from counties other than Vance County for a year-end census as of December 31, 2024. This is the projected ending census for Operating Year 1 (OY1) .		$115.59 + 17 = 132.59$
The applicant projects the Vance County patient census forward one year to December 31, 2025 using the 4.6% five-year AACR growth rate for Vance County.		$115.59 \times 1.046 = 120.9061$
The applicant adds 17 patients from counties other than Vance County for a year-end census as of December 31, 2025. This is the projected ending census for Operating Year 2 (OY2) .		$120.91 + 17 = 137.91$

At the end of OY1 (CY2024) Vance County Dialysis is projected to serve 132.59 in-center patients on 47 stations; and at the end of OY2 (CY2025) the facility is projected to serve 137.91 in-center patients on 47 stations.

The projected utilization rates for the first two operating years are as follows:

- OY1: 2.8 patients per station per week, or 70.5% utilization [$132.59 \text{ patients} / 47 \text{ dialysis stations} = 2.8$; $2.8 / 4 = 0.705$].

- OY 2: 2.9 patients per station per week, or 73.4% utilization [137.91 patients / 47 dialysis stations = 2.9; $2.9 / 4 = 0.734$].

The projected utilization of 2.8 patients per station per week at the end of OY1 equals the minimum standard of 2.8 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

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

- Vance County Dialysis was operating at 93.57% capacity as of December 31, 2020, as reported in the 2022 SMFP which exceeds the required minimum utilization of 75%.
- The applicant projects growth in the Vance County patient population using the Vance County Five Year AACR of 4.6% as published in the 2022 SMFP.
- The applicant does not project growth for patients residing outside of Vance County.
- Projected IC utilization at the end of OY1 equals the minimum of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, pages 30-31, the applicant states:

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

We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. ...

Vance County 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 during CY 2025, as shown in the following table.

Medically Underserved Groups	% of Total Patients
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Low Income persons	83.1%
Racial and ethnic minorities	55.0%
Women	36.2%
Persons with disabilities	100.0%
Persons 65 and older	37.1%
Medicare beneficiaries	63.6%
Medicaid recipients	18.6%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant currently serves the needs of medically underserved groups that utilize ESRD services and proposes to continue to do so.
- The applicant has policies in place to prevent discrimination.

Conclusion

The Agency reviewed the:

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

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

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

NA

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

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

CA

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 47 stations upon project completion.

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

- *Maintain the status quo* - The applicant states that maintaining the status quo is not an effective alternative due to the high utilization rate at the facility.
- *Relocate stations from another DaVita facility* – The applicant states that they currently have two operational facilities in Vance County; Kerr Lake Dialysis and Vance County Dialysis. Kerr Lake Dialysis is operating at less than 75% capacity and relocating any stations from this facility would negatively impact the facility and patients served.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. DVA Renal Care, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2022 SMFP, the certificate holder shall develop no more than five additional in-center dialysis station for a total of no more than 47 in-center stations at Vance County 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 January 1, 2023.**
- 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 in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 47 stations upon project completion.

Capital and Working Capital Costs

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

ITEM	COST
Medical Equipment	\$70,000
Non-Medical Equipment	\$19,892
Furniture	\$7,500
Total	\$97,392

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 44, 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 43, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DVA Renal Healthcare, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$97,392	\$97,392
Bonds	\$ 0	\$ 0
Other (Specify)	\$ 0	\$0
Total Financing	\$97,392	\$97,392

* OE = Owner's Equity

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

- Exhibit F contains the Consolidated Financial Statements for the year ending December 31, 2021 that shows DaVita, Inc., parent company to DVA Renal Healthcare, Inc. currently has \$462 million in cash and cash equivalents and \$17 billion in total assets.

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 operating years of the project, as summarized in the table below.

Vance County Dialysis Projected Revenue and Operating Expenses

	OY 1 CY 2024	OY 2 CY 2025
Total In-Center Treatments	19,273	20,044
Total Gross Revenue (charges)	\$6,558,706	\$6,820,967
Total Net Revenue	\$5,902,981	\$6,139,023
Average Net Revenue per Treatment	\$306	\$306
Total Operating Expenses (costs)	\$3,655,559	\$3,764,023
Average Operating Expense per Treatment	\$190	\$188
Net Income / Profit	\$2,247,422	\$2,375,000

*Values may not sum due to rounding

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

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 47 stations upon project completion.

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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Vance County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 132, of the 2022 SMFP, there are two existing or approved dialysis facilities in Vance 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:

Vance County Dialysis Facilities

Dialysis Facility	Certified Stations as of 12/31/2020	# of IC Patients as of 12/31/2020	Percent Utilization as of 12/31/2020	Patients Per Station Per Week as of 12/31/2020
Kerr Lake Dialysis (DaVita)	17	46	67.65%	2.71
Vance County Dialysis (DaVita)	35	131	93.57%	3.74
Total	52	177		

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

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

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

- There is a facility need determination in the 2022 SMFP at Vance County Dialysis for ten dialysis stations. The applicant proposes to add five stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Vance 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 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 in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 47 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 Vance County Dialysis, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 2/28/2022	OY1 (1/1/2024 to 12/31/2024)	OY2 (1/1/2025 to 12/31/2025)
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	5.25	6.00	6.00
Technicians (PCT)	15.75	17.75	17.75
Dietician	1.00	1.00	1.00

Social Worker	1.00	1.00	1.00
Admin/Business Office	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
TOTAL	25.50	28.25	28.25

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 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 applicant projects an increase in the FTE staffing positions necessary to accommodate the proposed increase in healthcare services at Vance County Dialysis.
- The increased costs are accounted for in the budgeted Operating Costs.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than five in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 47 stations upon project completion.

Ancillary and Support Services

In Section I, pages 56-59, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is and will continue to be made available and provides supporting documentation in Exhibit I.2. The

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

- The stated ancillary and support services are currently available.
- The applicant provides evidence that the ancillary and support services are currently being provided.

Coordination

In Section I, page 59, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

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

- The applicant provides a listing of established relationships with the existing health care system in Exhibit I.2.
- The applicant provides letters from the facility administrator and the facility medical director in Exhibit I.2. committing to the continuation of the established 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.

- (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 69, the applicant provides the historical payor mix for Vance County Dialysis during the last full operating year (CY2021) for its existing services, as shown in the table below.

**Vance County Dialysis
Historical Payor Mix CY 2021**

Payor Category	In-Center	
	# of Patients	% of Total
Self-pay	1.0	0.8%
Insurance*	12.0	10.2%
Medicare*	75.0	63.6%
Medicaid*	22.0	18.6%
Miscellaneous (Incl. VA)	8.0	6.8%
Total	118.0	100.0%

*Including any managed care plans

In Section L, page 69, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full OY	Percentage of the Population in the Service Area*
Female	36.2%	53.3%
Male	63.8%	46.7%
Unknown	0.0%	0.0%
64 and Younger	62.9%	80.9%
65 and Older	37.1%	19.1%
American Indian	0.0%	1.0%
Asian	0.0%	0.8%
Black or African-American	69.0%	51.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	22.4%	45.1%
Other Race	8.6%	1.6%
Declined / Unavailable	0.0%	0.0%

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

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 70, 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 70, the applicant states that during the 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 71, 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.

**Vance County Dialysis
Projected Payor Mix CY2025**

Payment Source	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	1.17	0.8%
Insurance*	14.02	10.2%
Medicare*	87.65	63.6%
Medicaid*	25.71	18.6%
Miscellaneous (incl. VA)	9.35	6.8%
Total	137.91	100.0%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 0.8% of in-center dialysis services will be provided to self-pay patients, 63.6% to Medicare patients, and 18.6% to Medicaid patients.

On page 71, 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 because the projected payor mix is based on the historical payor mix and treatment volumes of Vance County Dialysis.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.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

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

- The applicant offers the facility as a clinical learning site for students from Vance-Granville Community College.
- In Exhibit M.1, the applicant provides a copy of the letter sent to Vance-Granville Community College offering the site as a clinical training program.

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 in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 47 stations upon project completion.

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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Vance County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 132, of the 2022 SMFP, there are two existing or approved dialysis facilities in Vance 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:

Vance County Dialysis Facilities

Dialysis Facility	Certified Stations as of 12/31/2020	# of IC Patients as of 12/31/2020	Percent Utilization as of 12/31/2020	Patients Per Station Per Week as of 12/31/2020
Kerr Lake Dialysis (DaVita)	17	46	67.65%	2.71
Vance County Dialysis (DaVita)	35	131	93.57%	3.74
Total	52	177		

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

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

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

“The expansion of Vance County 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, N, O and Q of the application and any exhibits.

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

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

- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

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

C

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

In Section O.5, page 81, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of "*Immediate Jeopardy*" occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

10 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- Vance County Dialysis is an existing facility. Therefore, this Rule is not applicable to this review.

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

(1) an existing dialysis facility; or

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

-C- In Section Q, Form C, the applicant projects that Vance County Dialysis will serve 133 in-center patients on 47 stations, or a rate of 2.8 patients per station per week or 70.7% ($133 / 47 = 2.830/4 = 0.7074$ or 70.7%), as of the end of the first operating year (CY2024) following project completion. This equals the minimum performance standard of 2.8 patients per station per week.

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

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