

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 13, 2025

Findings Date: January 13, 2025

Project Analyst: Yolanda W. Jackson

Co-Signer: Micheala Mitchell

Project ID #: J-12554-24

Facility: Southpoint Dialysis

FID #: 090117

County: Durham

Applicant(s): DVA Renal Healthcare, Inc.

Project: Relocate entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more than 24 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.

NA

DVA Renal Healthcare, Inc. (hereinafter referred to as “the applicant”), proposes to relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis (Hope Valley) for a total of no more than 24 in-center (IC) stations at Southpoint Dialysis (Southpoint) upon project completion.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2024 SMFP
- acquire any medical equipment for which there is a need determination in the 2024 SMFP
- offer a new institutional health service for which there are any policies in the 2024 SMFP

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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 relocate the Southpoint Dialysis facility to the current Hope Valley Dialysis site and relocate no more than eight stations from Hope Valley Dialysis for a total of no more 24 in-center stations upon project completion. This project would consolidate Hope Valley and Southpoint. The applicant proposes to relinquish the remainder of Hope Valley's stations and close Hope Valley.

The following table found in Section A, page 15, shows the projected number of in-center stations at Southpoint Dialysis upon project completion.

Southpoint Dialysis	
# of Stations	Description
16	Total # of existing certified dialysis stations as reported in Table 9A in the Proposed 2025 SMFP
8	# of dialysis stations to be added as part of this project (relocate eight dialysis stations from Hope Valley Dialysis)
24	Total # of dialysis stations upon project completion

Source: Section A, page 15.

Patient Origin

On page 113, the Proposed 2024 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.*” Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrates historical and projected patient origin for in-center (IC) patients.

Southpoint Dialysis				
County	Historical 01/01/2023 to 12/31/2023		Second Full FY of Operation following Project Completion 01/01/2028 to 12/31/2028	
	IC Patients	% of Total	IC Patients	% of Total
Durham	49	77.8%	64	83.1%
Chatham	3	4.8%	3	3.9%
Edgecombe	1	1.6%	1	1.3%
Orange	4	6.3%	4	5.2%
Wake	4	6.3%	5	6.5%
Virginia	1	1.6%	0	0.0%
Other States	1	1.6%	0	0.0%
Total	63	100.0%	77	100.0%

Source: Section C, pages 21-22.

Hope Valley Dialysis		
County	Historical 01/01/2023 to 12/31/2023	
	IC Patients	% of Total
Durham	15	83.3%
Wake	1	5.6%
Georgia	1	5.6%
Other States	1	5.6%
Total	18	100.0%

Source: Section C, page 22.

In Section C, pages 22-24, and in Section Q following Form C Utilization, the applicant provides the assumptions and methodology used to project its patient origin. On page, 24, the applicant states:

“The patient population will remain flat, given the growth rate at each facility and within the county. The projections assume no growth rate for the patients at either Southpoint or Hope Valley during the period of growth, so as to be conservative.”

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

- The applicant’s projections for Southpoint patient utilization are based on the facility’s North Carolina patient population as of December 31, 2023, and excludes the two patients from other states.
- The applicant projects that patient population will remain flat based on the growth rate at each facility and within the county.
- The applicant projects that all of the Southpoint patients who reside in North Carolina counties will continue dialyzing at the relocated Southpoint facility upon project certification.
- The applicant projects that all the Hope Valley patients residing in NC counties will transfer their care to the relocated Southpoint facility upon project certification.

Analysis of Need

In Section C, pages 25-26, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 26, the applicant states:

“The relocation of stations from Hope Valley to Southpoint would help alleviate the facility’s high utilization rate and accommodate the combined census of the two facilities.”

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

- According to the Proposed 2025 SMFP, Hope Valley Dialysis had a utilization rate of 45.00% as of December 31, 2023.
- According to the Proposed 2025 SMFP, Southpoint Dialysis had a utilization rate of 98.44% as of December 31, 2023.
- The applicant states that Southpoint Dialysis and Hope Valley Dialysis are less than two miles apart.
- The applicant states that it is not possible to expand the footprint of the Southpoint facility at its current site.
- The applicant states that the Hope Valley Dialysis footprint can accommodate up to 24 in-center dialysis stations.
- The applicant states that the transferring Hope Valley Dialysis patients will have continuity of care as they will remain under the care of the same clinical and support staff they were accustomed to and receive the same high-quality care.

Projected Utilization

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

Form C Utilization	Last Full FY CY 2023	Interim Full FY CY 2024	Interim Full FY CY 2025	Interim Full FY CY 2026	1st Full FY CY 2027	2nd Full FY CY 2028
# of IC Patients at the Beginning of the Year	62.00	61.00	61.00	61.00	77.00	77.00
# of IC Patients at the End of the Year	63.00	61.00	61.00	61.00	77.00	77.00
Average # of Patients During the Year	62.50	61.00	61.00	61.00	77.00	77.00
# of Treatments / Patient /Year	149.09	148.20	148.20	148.20	148.20	148.20
Total # of Treatments	9,318.00	9,040.20	9,040.20	9,040.20	11,411.40	11,411.40

In Section Q, immediately following Form C Utilization, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant excludes out-of-state residents at each facility during the growth period.

- The applicant projects no growth rate at either Southpoint or Hope Valley during the period of growth.
- The applicant states that all the Southpoint patients who reside in North Carolina counties will continue to dialyze at the relocated Southpoint facility upon project certification.
- The applicant states that all Hope Valley patients residing in North Carolina counties will continue to dialyze in the same building and transfer their care to the relocated Southpoint upon project certification.

Southpoint Dialysis In-Center Projected Utilization		
	IC Stations	IC Patients
The applicant starts with the station count and NC patient census as of 12/31/2023.	16	61
The patient census is projected forward a year to 12/31/2024.		$61 \times 1.0 = 61$
The patient census is projected forward a year to 12/31/2025.		$61 \times 1.0 = 61$
The patient census is projected forward a year to 12/31/2026.		$61 \times 1.0 = 61$
The applicant projects that the project will be certified on 01/01/2027.		
Eight stations are projected to transfer from Hope Valley to Southpoint. This is the station count at the beginning of FY1.	$16 + 8 = 24$	
Sixteen (16) Hope Valley patients are projected to transfer to Southpoint. This is the patient census at the beginning of FY1.		$61 + 16 = 77$
The patient census is projected forward a year to 12/31/2027.		$77 \times 1.0 = 77$
The patient census is projected forward a year to 12/31/2028.		$77 \times 1.0 = 77$

The applicant projects to serve 77 patients on 24 stations, which is 3.2 patients per station per week ($77 \text{ patients} / 24 \text{ stations} = 3.208$), and 80.2% utilization rate ($3.208 / 4 = .8021$ or 80.2%) by the end of FY1 at Southpoint Dialysis. This meets the minimum of 2.8 in-center patients per station per week as of the end of the first fiscal year of operation following certification of the additional stations as required by 10A NCAC 14C .2203(b).

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

- The applicant begins the projections with the existing patients and stations as of December 31, 2023.
- The applicant does not include out-of-state residents.
- The applicant projects that the patient population will remain flat based on the growth rate at each facility and within Durham County.

Access to Medically Underserved Groups

In Section C, page 28, the applicant states:

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

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

Southpoint 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.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	79.4%
Racial and ethnic minorities	74.6%
Women	44.4%
Persons with disabilities	100.0%
Persons 65 and older	50.8%
Medicare beneficiaries	77.8%
Medicaid recipients	1.6%

Source: Section C, Page28.

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 provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.
- The applicant states the percentages of patients for each group listed above are based on recent facility experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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.

C

The applicant proposes to relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more than 24 in-center stations upon project completion.

In Section D, pages 33-35, the applicant explains why it believes the needs of the population presently utilizing the services relocated will be adequately met following completion of the project. On page 33, the applicant states:

“The needs of all the current and projected patients will continue to be met at the relocated facility. All of the patients presently served at the current site are expected to continue receiving their dialysis services at the new location which is in close proximity to the present site.

The relocation of Southpoint will have no effect on the ability of low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care. Southpoint, by policy, will continue to make dialysis services available to all residents in its service area without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.

Southpoint will continue to 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, handicapped persons, elderly and other underserved persons.”

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

- The applicant states that all of the patients presently served at Hope Valley are expected to continue receiving their dialysis services at Southpoint which is in close proximity to Hope Valley.
- The applicant states that Southpoint will continue to provide services to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons.

Access to Medically Underserved Groups

In Section D, page 35, the applicant states:

“The closure of Hope Valley will not have any effect on the ability of any patient to obtain dialysis services. By policy, the proposed services will be made available to all residents in the service area without qualifications. Hope Valley will continue to

serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis. We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

Southpoint 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 underserved persons.”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services will be adequately met following completion of the project because:

- Hope Valley will close, and patients will transfer to Southpoint which will continue to 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.
- Southpoint will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons and other underserved persons.

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 needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (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.

The applicant proposes to relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more than 24 in-center stations upon project completion.

The applicant states in Section E, page 38, that there are no alternative methods to meet the need for the proposal and DaVita has made the operational decision to consolidate Southpoint and Hope Valley, with Hope Valley closing by the end of 2026. The applicant states that the following considerations, led to DaVita's decision to propose closing Hope Valley and consolidating operations:

- The applicant states that the Durham County total patient census has declined since the pandemic and the Proposed 2025 SMFP reports an Average Annual Change Rate (AACR) for the past five years for Durham County is (-1.5%).
- The applicant states that the census at both Southpoint and Hope Valley has declined during the pandemic and has remained relatively flat since the pandemic.
- While Hope Valley has remained underutilized, Southpoint's utilization rate has been high.
- It is not possible to expand the footprint of the Southpoint facility at its current site.
- Southpoint and Hope Valley are less than two miles apart.
- The Hope Valley footprint can accommodate up to 24 in-center dialysis stations.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. DVA Renal Healthcare, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall relocate no more than eight in-center stations from Hope Valley Dialysis to Southpoint Dialysis for a total of no more than 24 in-center dialysis stations upon project completion.**

- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify eight in-center stations at Hope Valley Dialysis and relinquish two in-center stations at Hope Valley Dialysis for a total of 0 in-center stations at Hope Valley Dialysis.**
 - 4. 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 June 1, 2025.**
 - 5. 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 relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more 24 in-center 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.

Site Preparation	\$18,500
Medical Equipment	\$124,020
Non Medical Equipment	\$57,300
Furniture	\$49,920
Interest during Construction	\$7,992
Total	\$257,732

In Section Q, immediately following Form F.1a, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states that the project manager for North Carolina partnered with their finance department to develop the capital cost for this project.
- The applicant states that they use a corporate model and regional database along with inputs from operations and the regional Real Estate team to ensure project costs are reasonable.
- The applicant states that the inputs from operations and the regional Real Estate team include the furniture, fixtures and equipment needed to accommodate the proposed expansion.

In Section F, page 42, the applicant projects that there will be no start-up costs or initial operating expenses because the revenues exceed operating costs at this existing facility.

Availability of Funds

In Section F, pages 41, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. DaVita, Inc. is the parent company and 100% owner of DVA Renal Healthcare, Inc. Exhibit F.2c contains a letter from the Chief Accounting Officer of DaVita, Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F.2 contains the Consolidated Balance Sheets for DaVita, Inc. and shows more than \$380 million in cash and cash equivalents and total assets in excess of 16.8 billion as of December 31, 2023.

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

- The applicant provided a letter from an appropriate company official committing the amount of the projected capital cost to the proposed project.
- The Consolidated Balance Sheets demonstrate the availability of adequate cash and assets to fund the proposed project.

Financial Feasibility

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

	1st Full Fiscal Year CY 2027	2nd Full Fiscal Year CY 2028
Total # of Treatments	11,411	11,411
Total Gross Revenue	\$4,982,978	\$4,982,978
Total Net Revenue	\$4,576,266	\$4,576,266
Total Net Revenue Per Treatment	\$401	\$401
Total Operating Expenses (Costs)	\$2,819,620	\$2,858,821
Average Operating Expense (Costs) Per Treatment	\$247	\$251
Net Income	\$1,756,646	\$1,717,445

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 91-99. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected revenues for the first two full fiscal years will exceed the applicant’s projected operating expenses for the first two full fiscal years.
- 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 because 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 relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more than 24 in-center stations upon project completion.

On page 113, the Proposed 2025 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.” Southpoint Dialysis is located in Durham County.

Thus, the service area for this facility consists of Durham County. Facilities may serve residents of counties not included in their service area.

Durham County				
	Certified Stations as of 12/31/2023	In-Center Patients as of 12/31/2023	Utilization by % as of 12/31/2023	Patients per Station as of 12/31/2023
Bull City Dialysis	20	56	70.00%	2.80
Downtown Durham Dialysis	10	20	50.00%	2.00
Durham Dialysis	29	85	73.28%	2.93
Durham Regional Dialysis	10	30	75.00%	3.00
Durham West Dialysis	27	67	62.04%	2.48
FMC Dialysis Services of Briggs Avenue	29	84	72.41%	2.90
FMC Dialysis Services West Pettigrew	24	48	50.00%	2.00
Freedom Lake Dialysis Center	26	50	48.08%	1.92
Fresenius Kidney Care Eno River	19	52	68.42%	2.74
Fresenius Medical Care South Durham Dialysis	20	60	75.00%	3.00
Hope Valley Dialysis	10	18	45.00%	1.80
Research Triangle Park Dialysis	10	22	55.00%	2.20
Southpoint Dialysis	16	63	98.44%	3.94
Total	250	655		

Source: Table 9A, Chapter 9, 2024 SMFP.

In Section G, page 49, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. The applicant states:

“This application does not propose to increase the number of stations in Durham County. In fact, the proposed project includes the relocation and elimination of stations in the service area. The relocation of stations to Southpoint is necessary and a critical aspect of the facility closure discussed in Section C of this proposal, and it will not result in the duplication of existing services. Transferring stations will make it possible to accommodate the consolidation of DaVita patients from Southpoint and Hope Valley seamlessly, ensuring that there is no impact on the safety or efficiency of the delivery of services nor on the quality of care that the current and projected patients at Southpoint will continue to receive.”

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

- The applicant does not propose to increase the number of certified dialysis stations in Durham County.
- The applicant adequately demonstrates that the proposed relocation of the existing certified dialysis stations is needed in Durham County.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more 24 in-center stations upon project completion.

On Form H in Section Q, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Southpoint Dialysis		
	Current FTE Staff	Projected FTE Staff
	As of 8/31/2024	2nd Full FY CY 2028
Administrator	1.00	1.00
Registered Nurse (RNs)	2.00	3.00
Technicians (PCT)	6.00	9.00
Dietician	0.50	1.00
Social Worker	0.50	1.00
Admin/Business Office	1.00	1.00
Other (Biomedical Tech)	0.50	0.50
TOTAL	11.50	16.50

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 51-52, 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 states, in Form H Assumptions, that the number of FTE positions is a function of the number of stations available and/or the patient census to ensure safety and quality care and maximize cost effectiveness.
- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more than 24 in-center stations upon project completion.

Ancillary and Support Services

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 54-56, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The facility is an existing facility already providing the necessary ancillary and support services.
- The applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

Coordination

In Section I, page 57, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

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

- The facility is an existing facility that has existing relationships with local health care and social service providers.
- The applicant provides a letter from the facility administrator attesting to the established relationships between the facility and other healthcare providers and social service agencies in Durham County.
- The applicant provides a letter from the medical director of the facility attesting to the relationship between the medical director's physician practice and the facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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.

C

The applicant proposes to relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more than 24 in-center stations upon project completion.

In Section K, page 61, the applicant states that the project will not consist of construction of new space nor renovation of existing space. In Section C, page 21, the applicant states that the project will move Southpoint's equipment into the current Hope Valley facility which can accommodate up to 24 in-center dialysis stations.

On pages 61-62, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal because the applicant uses a corporate model and database with inputs from operations to ensure costs are reasonable.

- On page 62, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services because the applicant states that the majority of the patients served by the facility are covered by Medicare and/or Medicaid and under the Prospective Payment Systems (PPS), facilities are paid a single case-mix-adjusted payment which includes composite rate services and ESRD-related drugs, laboratory services, and medical equipment and supplies. The applicant states that the applicant's capital expenditures for the proposed project are not costs that can be passed along to the public.
- On pages 62-63, the applicant identifies the applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

In Section L, pages 66-67, the applicant provides the historical payor mix during CY 2023 for its existing services, as shown in the tables below.

Southpoint Dialysis Historical Payor Mix CY 2023						
Payment Source	In-center		Hemodialysis		Peritoneal Dialysis	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	0	0.0%	0.0	0.0%	0.0	0.0%
Insurance*	11	17.5%	0.0	0.0%	0.0	0.0%
Medicare*	49	77.8%	0.0	0.0%	0.0	0.0%
Medicaid*	1	1.6%	0.0	0.0%	0.0	0.0%
Other-VA	2	3.2%	0.0	0.0%	0.0	0.0%
Total	63	100.0%	0.0	0.0%	0.0	0.0%

*Including any managed care plans

Source: Section L, page 66.

Hope Valley Dialysis Historical Payor Mix CY 2023						
Payment Source	In-center		Hemodialysis		Peritoneal Dialysis	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	0	0.0%	0.0	0.0%	0.0	0.0%
Insurance*	0	0.0%	0.0	0.0%	0.0	0.0%
Medicare*	18	100.0%	0.0	0.0%	0.0	0.0%
Medicaid*	0	0.0%	0.0	0.0%	0.0	0.0%
Other- VA	0	0.0%	0.0	0.0%	0.0	0.0%
Total	18	100.0%	0.0	0.0%	0.0	0.0%

*Including any managed care plans

Source: Section L, page 67.

In Section L, pages 67-68, the applicant provides the following comparisons.

Southpoint Dialysis	% of Total Patients Served ^	% of the Population of the Service Area *
Female	44.4%	52.0%
Male	55.6%	48.0%
Unknown	0.0%	0.0%
64 and Younger	49.2%	84.9%
65 and Older	50.8%	15.1%
American Indian	0.0%	1.2%
Asian	3.2%	6.1%
Black or African-American	60.3%	34.5%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	25.4%	55.2%
Other Race	11.1%	2.9%
Declined / Unavailable	-	-

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>.

Hope Valley Dialysis	% of Total Patients Served	% of the Population of the Service Area *
Female	44.4%	52.0%
Male	55.5%	48.0%
Unknown	0.0%	0.0%
64 and Younger	33.3%	84.9%
65 and Older	66.67%	15.1%
American Indian	0.0%	1.2%
Asian	5.3%	6.1%
Black or African-American	52.6%	34.5%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	36.8%	55.2%
Other Race	5.3%	2.9%
Declined / Unavailable	-	-

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>.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 68, the applicant states it has no such obligation.

The applicant further states, on page 68, that during the 18 months immediately preceding the application deadline, no patient civil rights access complaint has been filed against Southpoint Dialysis or Hope Valley Dialysis.

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, page 69, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Southpoint Dialysis Projected Payor Mix CY 2028						
	In-center		Home Hemodialysis		Peritoneal Dialysis	
Payment Source	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.00	0.0%	0.00	0.0%	0.00	0.0%
Insurance*	13.44	17.5%	0.00	0.0%	0.00	0.0%
Medicare*	59.89	77.8%	0.00	0.0%	0.00	0.0%
Medicaid*	1.22	1.6%	0.00	0.0%	0.00	0.0%
Other - VA	2.44	3.2%	0.00	0.0%	0.00	0.0%
Total	77.00	100.0%	0.00	0.0%	0.00	0.0%

*Including any managed care plans

Note: Table may not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 77.8% of in-center services will be provided to Medicare patients and 1.6% to Medicaid patients.

On page 69, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the sources of patient payment that have been received in the last full fiscal year by the existing facility and no adjustment rate has been applied to this payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 70, the applicant describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L.5.

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 relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more 24 in-center stations upon project completion.

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides a letter expressing their intent to extend their services as a clinical training site for nursing students at a community college in the area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more 24 in-center stations upon project completion.

On page 113, the Proposed 2025 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.” Southpoint Dialysis is located in Durham County. Thus, the service area for this facility consists of Durham County. Facilities may serve residents of counties not included in their service area.

Durham County				
	Certified Stations as of 12/31/2023	In-Center Patients as of 12/31/2023	Utilization by % as of 12/31/2023	Patients per Station as of 12/31/2023
Bull City Dialysis	20	56	70.00%	2.80
Downtown Durham Dialysis	10	20	50.00%	2.00
Durham Dialysis	29	85	73.28%	2.93
Durham Regional Dialysis	10	30	75.00%	3.00
Durham West Dialysis	27	67	62.04%	2.48
FMC Dialysis Services of Briggs Avenue	29	84	72.41%	2.90
FMC Dialysis Services West Pettigrew	24	48	50.00%	2.00
Freedom Lake Dialysis Center	26	50	48.08%	1.92
Fresenius Kidney Care Eno River	19	52	68.42%	2.74
Fresenius Medical Care South Durham Dialysis	20	60	75.00%	3.00
Hope Valley Dialysis	10	18	45.00%	1.80
Research Triangle Park Dialysis	10	22	55.00%	2.20
Southpoint Dialysis	16	63	98.44%	3.94
Total	250	655		

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, the applicant states:

“The proposed project will have no effect on competition in Durham County. This project proposes the relocation and elimination of existing stations. The proposed project will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 74, the applicant states that greater operational efficiency is possible with additional capacity which positively impacts cost effectiveness.

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

Regarding the impact of the proposal on quality, in Section N, page 74, the applicant states that DaVita is committed to providing quality care to the ESRD population and works to make every reasonable effort to accommodate all of its patients.

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, page 74, the applicant states the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and works to make every reasonable effort to accommodate all of its patients.

See also Section L and C 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

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

The applicant proposes to relocate the entire facility and relocate no more than eight stations from Hope Valley Dialysis for a total of no more than 24 in-center stations upon project completion.

On Form O in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 108 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 108 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.

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.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

(a) *An applicant proposing to establish a new dialysis facility for in-center hemodialysis services 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 full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.*

-NA- The applicant does not propose to establish a new dialysis facility for in-center hemodialysis services.

(b) *An applicant proposing to increase the number of in-center 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 full fiscal year of operation following certification of the additional stations.

- C- In Section C, page 29, and on Form C in Section Q, the applicant projects that Southpoint Dialysis will serve 77 patients on 24 stations, or a rate of 3.2 in-center patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant's projections meet the requirement of 2.8 in-center patients per station per week.

- (c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*

- NA- The applicant does not propose to develop a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*

- NA- The applicant does not propose to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

- (e) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*

- C- Immediately following Form C in Section Q, pages 85-87, the applicant provides the assumptions and methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.