

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 2, 2023

Findings Date: June 2, 2023

Project Analyst: Cynthia Bradford

Co-Signer: Lisa Pittman

Project ID #: A-12313-23

Facility: Balsam Home Training

FID #: 230039

County: Jackson

Applicant: Wildrye Dialysis, LLC.

Project: Develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

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

Wildrye Dialysis, LLC (hereinafter referred to as “the applicant” or Wildrye), proposes to develop a new dialysis facility, Balsam Home Training (Balsam HT) in Sylva, NC dedicated to home hemodialysis (HH) and peritoneal dialysis (PD) training and support by relocating two existing stations from Sylva Dialysis. The facility will not provide in-center (IC) dialysis. Davita, Inc. is the parent company of Wildrye Dialysis.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2023 State Medical Facilities Plan (SMFP)
- Offer a new institutional health service for which there are any Policies in the 2023 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- (2) Repealed effective July 1, 1987.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 develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

The following table shows the projected number of stations at Balsam Home Training upon project completion.

Balsam Home Training		
Stations	Description	Project ID #
0	Total existing certified stations in the SMFP in effect on the day the review will begin	
2	Stations to be transferred/added as part of this project	
2	Total stations upon completion of proposed project	

Patient Origin

On page 113, the 2023 SMFP defines the service area for dialysis stations as, “... *the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Both Balsam HT and Sylva Dialysis are located in Jackson County. Thus, the service area for this application is Jackson County. Facilities may serve residents of counties not included in their service area.

The applicant proposes to develop a new dialysis facility in Sylva, NC dedicated to HH and PD training and support by relocating two existing stations from Sylva Dialysis; therefore, historical patient data does not exist. In Section C, page 23, the applicant provides the historical (CY2022) patient origin for Sylva Dialysis, as summarized in the following table.

Sylva Dialysis						
Last FY 01/01/2022 to 12/31/2022						
	In-Center		Home Hemodialysis		Peritoneal Dialysis	
County	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Jackson	14	66.70%			11	39.29%
Forsyth	1	4.80%			0	0.00%
Haywood	0	0.00%			6	21.43%
Macon	1	4.80%			2	7.14%
Swain	2	9.50%			9	32.14%
Transylvania	1	4.80%			0	0.00%
Virginia	1	4.80%			0	0.00%
Other States	1	4.80%			0	0.00%
Total	21	100.00%	0	0.00%	28	100.00%

In Section C.3, page 23, the applicant provides the projected in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for Balsam Home Training for the second full operating year following project completion (CY2026), as summarized in the following table.

Balsam HT						
Projected Patient Origin Second FY						
01/01/2026 to 12/31/2026						
	In-Center		Home Hemodialysis		Peritoneal Dialysis	
County	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Jackson	0		3.29	100.0%	11.69	100.0%
Total	0		3.29	100.0%	11.69	100.0%

In Section C.3, pages 23-25, the applicant provides the assumptions and methodology used to project Balsam Home Training’s patient origin. The applicant states that projected patient origin is based on:

- Data from December 31, 2022, shows DaVita was serving all Jackson County home dialysis patients.
- Historical growth of the Jackson County home dialysis patient population at the applicant’s existing home dialysis program in Jackson County.
- The assumption that when Balsam HT opens on January 1, 2025, one half of DaVita’s Jackson County PD patients will be on the waiting list for admission to Balsam HT.
- The assumption that the applicant will continue to serve and train the Jackson County home dialysis patients.

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

- The applicant projects growth of the Jackson County HH and PD patient census using 9.5% which is almost half of the 5YAACR as calculated using data from Davita's home program in Jackson County.
- The applicant clearly explains how and why growth is projected in the Jackson County HH and PD patient population.
- The applicant does not project any growth in patients residing outside of Jackson County.

Analysis of Need

In Section C.4, pages 26-28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- Physicians are referring more patients to home dialysis and more patients are choosing to dialyze at home providing greater flexibility and increased time for other activities.
- Developments in the technology to perform remote monitoring has improved clinical outcomes and provided savings in travel time and expense.
- Relocating 2 stations from Sylva Dialysis would provide sufficient capacity to accommodate the number of HHD patients projected to be trained at Balsam Blvd HT and would not negatively impact the patients at Sylva Dialysis, which has been experiencing a decline in census.
- The statewide home patient population has grown at a higher rate than the overall ESRD patient population.

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

- There was an increase in the number and percentage of patients utilizing both types of home dialysis modalities, between December 2017 and December 2021.
- The applicant provides a 2019 Executive Order in Exhibit C.4 proclaiming support for in-home dialysis.

Projected Utilization

In Section C.3, page 25 and Section Q, pages 87-88 the applicant provides the calculations used to project the Davita Jackson County patient utilization at the proposed Balsam Home Training facility, as illustrated in the following table:

	HHD Projections	PD Projections
The applicant begins with the DaVita home patients as of 12/31/21	HHD Patients at New Sylva Dialysis=0	PD Patients at Sylva Dialysis = 11
The home patient census of Jackson County residents is projected forward a year to 12/31/2022. It is increased by 9.5% and in-center patient conversions to home are added to the census.	0	11 x 1.095 = 12.045 12.045 + 1 = 13.045
The home patients from outside Jackson County are added. This is the ending census for the first full interim year	0	13.05 + 17 = 30.05
The home patient census of Jackson County residents is projected forward a year to 12/31/2023. It is increased by 9.5% and in-center patient conversions to home are added to the census.	0	13.05 x 1.095 = 14.284 14.28 + 1 = 15.28
The home patients from outside Jackson County are added. This is the ending census for the second full interim year	0	15.28 + 17 = 32.28
One half of DaVita's Jackson County PD patients are projected to be on the waiting list for Balsam HT on 12/31/2024	0	15.28 x 0.5 = 7.642
Balsam HT is projected to be certified on 1/1/2025 and begins with DaVita's Jackson County home patients projected to be on the waiting list.	2	8
The Balsam HT patient population is projected forward a year to 12/31/2025. It is increased by 9.5% and in-center patient conversions to home are added to the census. This is the ending census as of the end of the 1 st full FY.	2 x 1.095 = 2.19 2.19 + 1 = 3.19	8 x 1.095 = 8.76 8.76 + 1 = 9.76
The Balsam HT patient population is projected forward a year to 12/31/2026. It is increased by 9.5% and in-center patient conversions to home are added to the census. This is the ending census as of the end of the 2 nd full FY	3.19 x 1.095 = 3.49305 3.49 + 1 = 4.49	9.76 x 1.095 = 10.6872 10.69 + 1 = 11.69

In Section C pages 23-25 and Section Q, Page 87-88, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant states the home dialysis program in North Carolina is growing more rapidly than the overall ESRD patient population. The applicant states the statewide home patient population has increased by 25% over the past five years and has a five-year average annual change rate of 5.48%. To illustrate the growth, the applicant provides data from the 2018 July Semiannual Dialysis report and the 2020, 2021, 2022, and 2023 SMFPs as shown in the table below.

	NC All Modalities	% Change	NC ICHD Patients	% Change	NC Home Patients	% Change
12/31/2017	18303		16032		2271	
12/31/2018	19021	3.92%	16601	3.55%	2420	6.56%
12/31/2019	19622	3.16%	17012	2.48%	2610	7.85%
12/31/2020	19547	(0.38%)	16838	(1.02%)	2709	3.79%
12/31/2021	19495	(1.92%)	16685	(0.91%)	2810	3.73%
5-year AACR		1.61%		1.02%		5.48%

Source: Page 24 of application

- The applicant states the home patient population in DaVita’s facility located in Jackson County increased by 75% over the past five years and has a five-year average annual change rate of 19.44% as illustrated in the table below.

	HHD & PD Patients at DaVita Facilities in Jackson County	% Change
12/31/2018	4	
12/31/2019	6	50.00%
12/31/2020	9	50.00%
12/31/2021	9	0.00%
12/31/2022	7	(22.22%)
5-year AACR		19.44%

Source: Page 24 of application

- The applicant assumes that the Jackson County HHD/PD patient population receiving training and support at the Balsam Home Training program will grow by the five-year AACR 19.44% and assumes no growth for patients living outside of Jackson County.
- The applicant assumes two IC patients from Jackson County will transfer to home dialysis each year.
- The applicant assumes patients in each of the home training programs at Balsam Home Training will grow at a rate of 19.44% during the period of growth.

On page 28, the applicant provides the following table showing its projections of HH patients through the first two operating years of the project.

	# of HH Patients Trained
1 st Full FY (CY 2025)	12
2 nd Full FY (CY 2026)	15

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

- The applicant begins projections with the existing Jackson County patients receiving home dialysis training and support at DaVita facilities located in Jackson County.
- In the past five years statewide home patient population has increased by 6.5% and home patient population in DaVita’s facility located in Jackson County has increased by 19.44%.

Access to Medically Underserved Groups

In Section C.6, page 30, 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.

.....

Balsam HT 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. “

On page 30, the applicant provides the estimated percentage for each medically underserved group it will serve during FY2, as shown in the following table.

Medically Underserved Groups	Estimated Percentage of Total Patients during the 2nd Full FY
Low-income persons	76.19%
Racial and ethnic minorities	31.10%
Women	40.00%
Persons with disabilities	100.00%
Persons 65 and older	42.20%
Medicare beneficiaries	73.81%
Medicaid recipients	2.38%

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:

- DaVita related facilities have a history of providing services to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.
- The applicant’s estimated percentage for each underserved group is based upon the percentages for Sylva Dialysis, the facility from which stations are being relocated.

Conclusion

The Agency reviewed the:

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

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

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

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

C

The applicant proposes to develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

In Section D, pages 36-37, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project.

On page 37, the applicant provides a table which shows projected Sylva Dialysis relocation of two stations to the proposed facility, Balsam Home Training Program.

	ICHD Stations	ICHD Patients
Sylva Dialysis begins with 21 patients dialyzing on 16 stations at the facility as of 01/01/2022	16	21
The facility's patient census is projected forward a year to 12/31/2023 and is increased by 0%. This is the ending census as of the end of Interim Year 1.		21 x 1.0 = 21
The facility's patient census is projected forward a year to 12/31/2024 and is increased by 0%. This is the ending census as of the end of Interim Year 2		21 x 1.0 = 21
Balsam HT is projected to be certified on 01/01/2025. Two stations are projected to transfer to Balsam HT from Sylva Dialysis. Two in-center patients are projected to be on the waiting list for Balsam HT.	16 - 2 = 14	21 - 2 = 19
This is the station count and in-center census on 01/01/2025	14	19
The facility's patient census is projected forward a year to 12/31/2025 and is increased by 0%. This is the ending census as of the end of OY 1		19 x 1.0 = 19

As shown in the table above, Sylva Dialysis is projected to serve 19 in-center HD patients on 14 stations as of the date the stations are projected to be relocated. Thus, the applicant projects that Sylva Dialysis will have a utilization rate of 33.9% or 1.357 patients per station per week (19 patients / 14 stations = 1.357 / 4 = 0.339 or 33.9%).

On page 37, the applicant states:

“...the facility will have sufficient capacity to ensure that the needs of the facility's patients will continue to be met. Additional CON applications will be submitted based on facility needs as the facility approaches full capacity of stations.”

Access to Medically Underserved Groups

In Section D, page 37, the applicant states:

“Sylva Dialysis, by policy, will continue to make dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.

....

Sylva Dialysis will continue to assist 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 home dialysis training and support will be adequately met following completion of the project for the following reasons:

- The applicant provides a statement of its intent to continue serving medically underserved populations.
- DaVita related facilities have a history of providing services to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally 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.

CA

The applicant proposes to develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

In Section E.2, page 40, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because of the projected growth in the home dialysis patient population. Therefore, the applicant determined this is not the most effective alternative.
- *Add home training stations to an existing DaVita facility*- The applicant states that approximately 57% of all dialysis patients in Jackson County are home patients. The projected growth of home patients is expected to outpace growth of ICHD in Jackson County. Expanding the footprint at Sylva Dialysis would be cost prohibitive and less effective than developing a new facility to increase capacity to meet the need of the projected patients.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Wildrye Dialysis, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

- 2. The certificate holder shall develop a new kidney disease treatment center dedicated to home hemodialysis and peritoneal dialysis training and support to be known as Balsam Home Training by relocating no more than two in-center and home hemodialysis stations from Sylva Dialysis in Sylva, NC.**
 - 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify two stations at Sylva Dialysis for a total of no more than 14 in-center and home hemodialysis stations upon completion of the project.**
 - 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 October 1, 2023. The second progress report shall be due on April 1, 2024 and so forth.**
 - 5. The certificate holder shall install plumbing and electrical wiring through the walls for no more than 2 in-center and home hemodialysis stations.**
 - 6. 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 develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

Capital and Working Capital Costs

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

Capital Costs	
Site Preparation	\$30,187
Construction/Renovation Contract(s)	\$771,203
Architect / Engineering Fees	\$52,740
Medical Equipment	\$85,762
Non-Medical Equipment	\$29,205
Furniture	\$38,170
Interest during Construction	\$32,233
Total Capital Cost	\$1,039,499

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

- The applicant uses DaVita’s team of Project Managers partnered with Finance to develop the capital cost for the project.
- The Project Manager uses DaVita experience, a corporate model, and regional database with specific inputs for this project, being furniture, fixtures and equipment.

In Section F, page 44, the applicant states it projects \$118,143 in start-up costs and \$269,099 initial operating expenses, for total working capital required of \$387,242.

Availability of Funds

In Section F, pages 42 and 45, the applicant states that the capital and working capital cost, respectively, will be funded by Wildrye Dialysis, LLC, as shown in the tables below.

Sources of Capital Cost Financing

Type	Wildrye Dialysis, LLC
Loans	\$0
Accumulated reserves or OE *	\$1,039,499
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$1,039,499

* OE = Owner’s Equity

Sources of Working Capital Financing

Type	Wildrye Dialysis, LLC
Loans	\$0
Accumulated reserves or OE *	\$387,242
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$387,242

* 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.2c contains a letter dated January 13, 2023, from Chief Accounting Officer for DaVita Kidney Care, parent company to Wildrye Dialysis, LLC authorizing the use of accumulated reserves for the capital and working capital needs of the project.
- The applicant documents that it has adequate cash and assets to fund the capital and working capital costs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Section Q, Forms F.2 and F.4, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

Balsam Home Training Projected Revenue and Operating Expenses		
	1st Full Fiscal Year CY2025	2nd Full Fiscal Year CY2026
Treatments	1,701	2,159
Gross Patient Revenue	\$866,258	\$1,084,443
Net Patient Revenue	\$832,957	\$1,042,175
Average Net Revenue per Treatment	\$490	\$483
Total Operating Expenses	\$538,198	\$600,344
Average Operating Expense per Treatment	\$316	\$278
Net Income	\$294,759	\$441,831

Totals may not sum due to rounding.

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

- The applicant bases charges and expenses on historical revenue and expenses for DaVita's North Carolina facilities.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

On page 113, the 2023 SMFP defines the service area for dialysis stations as, “... *the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Both Balsam Home Training and Sylva Dialysis are located in Jackson County. Thus, the service area for this application is Jackson County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 124 of the 2023 SMFP and the information provided by the applicant in Section G page 49, there is one existing dialysis facility in Jackson County which is owned and operated by DaVita. The facility provides training and support for peritoneal dialysis alongside their in-center programs. Information on these dialysis facilities, from Table 9A of the 2023 SMFP is summarized below.

Jackson County Dialysis Facilities						
Dialysis Facility	Owner	Certified Stations as of 12/31/2020	# of IC Patients as of 12/31/2021	Percent Utilization as of 12/31/2020	Patients per Station per Week as of 12/31/2020	Number of Additional Approved Stations
Sylva Dialysis	DaVita	16	23	35.94%	1.437	0
Total		16	23	35.94%		0

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 Jackson County. The applicant states:

“...The home patient population and the number of home training patients in Jackson County is projected to grow. The addition of a new facility in the county offering home training and support, as well as the relocation of stations to be dedicated to HHD training serves to meet the needs of the county's growing population of patients referred by the DaVita's admitting nephrologists. The proposed project, therefore, serves to increase capacity rather than duplicate any existing or approved services in the 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:

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Jackson County.
- The applicant adequately demonstrates that the proposed relocation of the two stations for the development of a new facility dedicated exclusively to the training and support of home dialysis patients is needed in addition to the operational facilities in Jackson 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 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.

The applicant proposes to develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

In Section Q, Form H, the applicant provides the projected staffing in full-time equivalent (FTE) positions for the first and second full operating years of the proposed services, as summarized in the following table.

Balsam Home Training		
POSITION	PROJECTED FTE POSITIONS FY2025	PROJECTED FTE POSITIONS FY2026
Administrator	1.00	1.00
Home Training Nurse	0.50	0.50
PCT	0.75	0.75
Dietitian	0.50	0.50
Social Worker	0.50	0.50
Administrative/Business Office	0.50	0.50
Biomedical Tech	0.25	0.25
Total	4.00	4.00

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, pages 52-53, 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 reasonably accounts for the FTE staffing positions necessary to accommodate the proposed healthcare services at Balsam Home Training.
- The 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 stated above.

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

C

The applicant proposes to develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

Ancillary and Support Services

In Section I, page 55, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 55-58, the applicant explains how each ancillary and support service is made available.

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

- The applicant currently provides dialysis services at another facility in Jackson County.
- The applicant discusses how it will provide each necessary ancillary and support service at Balsam Home Training.

Coordination

In Section I, page 58, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

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

- The applicant discusses its relationships with local health care providers.
- The applicant discusses its relationships with local social service providers.

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.

- (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 develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

In Section K, page 63, the applicant states that the project will involve renovation of 2,930 square feet of space to be leased in an existing building. The proposed floor plan is provided in Exhibit K.2.

On pages 65-66, and in Exhibit K-4, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. The site appears to be suitable for the proposed dialysis home training facility based on the applicant's representations and supporting documentation.

On pages 63-65, the applicant adequately explains how the cost, design and means of construction represent a reasonable alternative for the proposal based on the following:

- The proposed project involves renovating an existing space as opposed to building new space which can result in a higher capital cost.
- The applicant relies on the extensive experience of DaVita's corporate Team Genesis service to develop the project at a reasonable cost while designing the facility with energy efficiency, water conservation and sustainability features.

On page 64, 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 developing the new facility is considered "*part of the growth of the company*" and those costs will be borne by the applicant and will not be passed along to the public.

On pages 64-65, the applicant identifies applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K-4.

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

The applicant proposes to develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

Balsam Home Training will be a new facility and therefore has no history. In Section L.1, page 69, the applicant provides the historical payor mix for FY2022 for Sylva Dialysis, as shown in the table below.

Sylva Historical Payor Mix CY 2022						
Payor Source	IC		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.00	0.0%	0.00	0.0%	0.00	0.0%
Insurance*	1.00	4.8%	0.00	0.0%	8.00	28.6%
Medicare*	17.00	81.0%	0.00	0.0%	20.00	71.4%
Medicaid*	1.00	4.8%	0.00	0.0%	0.00	0.0%
Misc. (including VA)	2.00	9.5%	0.00	0.0%	0.00	0.0%
Total	21.00	100.0%	0.00	0.0%	28.00	100.0%

*Including any managed care plans
 Note: Table may not foot due to rounding

In section L, page 70, the applicant provides the following comparison.

	Percentage of Total Sylva Patients Served during the Last Full FY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	40.0%	51.0%
Male	60.0%	49.0%
Unknown	0.0%	0.0%
64 and Younger	57.8%	79.5%
65 and Older	42.2%	20.5%
American Indian	26.7%	9.4%
Asian	0.0%	1.2%
Black or African-American	0.0%	2.4%
Native Hawaiian or Pacific Islander	0.0%	0.0%
White or Caucasian	68.9%	84.6%
Other Race	4.4%	2.30%
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>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

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

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

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

C

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

The facility is not an operational facility; therefore, there have been no civil rights access complaints filed against the facility within the last five years.

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 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.

Balsam Home Training Projected Payor Mix FY 2026						
	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
Payment Source	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.00	0.0%	0.00	0.0%
Insurance*	0.0	0.0%	0.51	11.4%	3.34	28.6%
Medicare*	0.0	0.0%	3.59	80.0%	8.35	71.4%
Medicaid*	0.0	0.0%	0.39	8.6%	0.00	0.0%
Other (VA)	0.0	0.0%	0.00	0.0%	0.00	0.0%
Total	0.0	0.0%	4.49	100.01%	11.69	100.0%

Totals may not sum due to rounding.
 *Including any managed care plans.

As shown in the table above, during the second full calendar year of operation, the applicant projects that 0.0% of HHD and 0.0% of PD services will be provided to self-pay patients; 80.0% of HHD and 71.4% of PD services to Medicare patients; and 8.6% of HHD, and 0.0% of PD services to Medicaid patients.

On page 71, the applicant provides the assumptions and methodology used to project payor mix during the second fiscal full years 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 historical payor mix of HHD and PD patients in existing home programs in Jackson County.

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

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 develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

In Section M, page 74, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the applicant's description of its efforts to reach out to training programs and the fact that the applicant provides a copy of the letter to Southwestern Community College offering the facility as a training site for nursing students.

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 develop a new home dialysis training facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two existing dialysis stations from Sylva Dialysis.

On page 113, the 2023 SMFP defines the service area for dialysis stations as, “... *the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Both Balsam Home Training and Sylva Dialysis are located in Jackson County. Thus, the service area for this application is Jackson County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 124 of the 2023 SMFP and the information provided by the applicant in Section G page 49, there is one existing dialysis facilities in Jackson County which is owned and operated by DaVita. The facility provides training and support for home peritoneal dialysis alongside their in-center programs. Information on these dialysis facilities, from Table 9A of the 2023 SMFP is summarized below.

Jackson County Dialysis Facilities						
Dialysis Facility	Owner	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	Number of Additional Approved Stations
Sylva Dialysis	DaVita	16	26	40.63%	1.625	0
Total		16	26	40.63%		0

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

“The proposed facility 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 or will be patients referred by DaVita’s admitting nephrologists.”

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 development of Balsam HT 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 all the reasons described above.

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

C

In Section Q Form O 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.

NA

The applicant proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for home hemodialysis and peritoneal dialysis patients. The applicant does not propose to include any certified in-center stations as a part of the proposed project. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving home hemodialysis and peritoneal dialysis patients.