

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 11, 2022

Findings Date: May 11, 2022

Project Analyst: Kim Meymandi

Co-Signer: Micheala Mitchell

Project ID #: O-12177-22

Facility: Ogden Park Home Training

FID #: 220065

County: New Hanover

Applicant(s): Cahita Dialysis, LLC

Project: Develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating two stations from Southeastern Dialysis Center-Wilmington

### 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

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

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP)

- Offer a new institutional health service for which there are any policies in the 2022 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- (2) Repealed effective July 1, 1987.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 dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington. Southeastern Dialysis Center-Wilmington will be certified for 30 stations upon completion of this project.

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

<b>Ogden Park Home Training</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
0	Total existing certified stations in the SMFP in effect on the day the review will begin	
+2	Stations to be added as part of this project (develop new 10-station facility)	O-12177-22
2	Total stations upon completion of proposed project and previously approved projects	

The following table shows the current and projected number of dialysis stations at Southeastern Dialysis Center-Wilmington upon completion of this project.

<b>Southeastern Dialysis Center-Wilmington</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
32	Total existing certified stations in the SMFP in effect on the day the review will begin	
-2	Stations to be deleted as part of this project (develop new facility by relocating 2 stations)	O-12177-22
30	Total stations upon completion of proposed project and previously approved projects	

Source: 2022 SMFP

**Patient Origin**

On page 115, the 2022 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 Ogden Park Home Training and Southeastern Dialysis Center-Wilmington are located in New Hanover County. Thus, the service area for this application is New Hanover County. Facilities may serve residents of counties not included in their service area.

This proposal is to develop Ogden Park Home Training, a new two-station dialysis facility in New Hanover County; therefore, historical patient data does not exist. In Section C, pages 24 and 26, the applicant provides the historical (CY2021) patient origin for SEDC-Wilmington and New Hanover Dialysis, as summarized in the following tables.

SEDC-Wilmington						
	In-Center		Home Hemodialysis		Peritoneal Dialysis	
County	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
New Hanover	79	89.80%	0	0.00%	38	60.32%
Bladen	1	1.10%	0	0.00%	1	1.59%
Brunswick	2	2.30%	0	0.00%	15	23.81%
Columbus	2	2.30%	0	0.00%	2	3.17%
Pender	4	4.50%	0	0.00%	7	11.11%
<b>Total</b>	<b>88</b>	<b>100.00%</b>	<b>0</b>	<b>0.00%</b>	<b>63</b>	<b>100.00%</b>

New Hanover Dialysis						
	In-Center		Home Hemodialysis		Peritoneal Dialysis	
County	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
New Hanover	42	93.30%	3	27.27%	0	0.00%
Bladen	0	0.00%	1	9.09%	0	0.00%
Brunswick	1	2.20%	2	18.18%	0	0.00%
Columbus	0	0.00%	2	18.18%	0	0.00%
Pender	2	4.40%	1	9.09%	0	0.00%
Sampson	0	0.00%	1	9.09%	0	0.00%
South Carolina	0	0.00%	1	9.09%	0	0.00%
<b>Total</b>	<b>45</b>	<b>100.0%</b>	<b>11</b>	<b>100.0%</b>	<b>0</b>	<b>0.00%</b>

In Section C.3, page 24, the applicant provides the projected in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for Ogden Park Home Training for the second full operating year following project completion (CY2025), as summarized in the following table.

Ogden Park Home Training						
	In-Center		Home Hemodialysis		Peritoneal Dialysis	
County	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
New Hanover	0.0	0.0%	5.6	100.0%	27.8	100.0%
<b>Total</b>	<b>0.0</b>	<b>0.0%</b>	<b>5.6</b>	<b>100.0%</b>	<b>27.8</b>	<b>0.0%</b>

In Section C.3, pages 24-26, the applicant provides the assumptions and methodology used to project Ogden Park Home Training’s patient origin. The applicant states that projected patient origin is based on:

- Data from December 31, 2020 showing DaVita was serving all New Hanover County home dialysis patients.
- Historical growth of the New Hanover County home dialysis patient population at the applicant’s existing two home dialysis programs in New Hanover County.
- The assumption that the applicant will continue to serve and train the New Hanover County home dialysis patients.

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

- The applicant projects growth of the New Hanover County HH and PD patient census using the Five-Year Average Annual Change Rate (AACR) of 7.86%, as calculated using data from the applicant’s two home programs in New Hanover County.
- The applicant clearly explains how and why growth is projected in the New Hanover County HH and PD patient population.
- The applicant does not project any growth in patients residing outside of New Hanover County.

**Analysis of Need**

In Section C.4, pages 25 and 27-29, 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.
- The physical plants of DaVita’s current PD and HH home training programs located at SEDC Wilmington and New Hanover Dialysis do not allow for expansion.
- 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, pages 24-27 and Section Q, pages 91-93 the applicant provides the calculations used to project the New Hanover County patient utilization at the proposed Ogden Park Home Training facility, as illustrated in the following table.

	<b>HHD Projections</b>	<b>PD Projections</b>
The applicant begins with the New Hanover County DaVita home patients as of 12/31/21	HHD Patients at New Hanover Dialysis=11	PD Patients at SEDC-Wilmington=63
The applicant projects the New Hanover home patient census forward one year to December 31, 2022 using the home patients at DaVita facilities in New Hanover County Five-Year AACR (7.68%) and adding one patient shifting to home dialysis modalities.	$3 \times 1.0768 = 3.24$ $3.24 + 1 = 4.24$	$38 \times 1.0768 = 40.99$ $40.99 + 1 = 41.99$
The applicant adds the home patients from outside of New Hanover County. This is the ending census for the first full interim year.	$4.24 + 8 = 12.24$	$41.99 + 25 = 66.99$
The applicant projects the New Hanover home patient census forward one year to December 31, 2023, using the home patients at DaVita facilities in New Hanover County Five-Year AACR (7.68%) and adding one patient shifting to home dialysis modalities.	$4.24 \times 1.0768 = 4.57$ $4.57 + 1 = 5.57$	$41.99 \times 1.0768 = 45.29$ $45.29 + 1 = 46.29$
The applicant adds the home patients from outside of New Hanover County. This is the ending census for the second full interim year.	$5.57 + 8 = 13.57$	$46.29 + 25 = 71.29$
The applicant projects one half of DaVita's New Hanover County home patients will be on the Ogden Park Home Training waiting list as of 12/31/2023.	$5.57 \times 0.5 = 2.785$	$46.29 \times 0.5 = 23.145$
The applicant projects that Ogden Park Home Training will be certified on 1/1/2023 and will begin offering services to the patients on the waiting list.	3	23
The applicant projects the New Hanover County patients at Ogden Park Home Training forward one year to 12/31/2024 using the home patients at DaVita facilities in New Hanover County Five-Year AACR (7.68%) and adds one IC patient converting to home dialysis. This is the ending census for OY1(2024).	$3 \times 1.0768 = 3.24$ $3.24 + 1 = 4.24$	$23 \times 1.0768 = 24.81$ $24.81 + 1 = 25.81$
The applicant projects the New Hanover County patients at Ogden Park Home Training forward one year to 12/31/2025 using the home patients at DaVita facilities in New Hanover County Five-Year AACR (7.68%) and adds one IC patient converting to home dialysis. This is the ending census for OY1(2025).	$4.24 \times 1.0768 = 4.57$ $4.57 + 1 = 5.57$	$25.81 \times 1.0768 = 26.84$ $26.84 + 1 = 27.84$

In Section C pages 24-30 and Section Q, Form C, 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 23% over the past five years and has a five-year average annual change rate of 5.33%. To illustrate the growth, the applicant provides data from the 2017 and 2018 July Semiannual Dialysis reports and the 2020, 2021 and 2022 SMFPs as shown in the table below.

	<b>NC All Modalities</b>	<b>% Change</b>	<b>NC ICHD Patients</b>	<b>% Change</b>	<b>NC Home Patients</b>	<b>% Change</b>
<b>12/31/2016</b>	17650		15448		2202	
<b>12/31/2017</b>	18303	3.70%	16032	3.78%	2271	3.13%
<b>12/31/2018</b>	19021	3.92%	16601	3.55%	2420	6.56%
<b>12/31/2019</b>	19622	3.16%	17012	2.48%	2610	7.85%
<b>12/31/2020</b>	19547	-0.38%	16838	-1.02%	2709	3.79%
<b>5-year AACR</b>		2.60%		2.20%		5.33%

Source: Page 25 of application

- The applicant states the home patient population in DaVita’s two facilities located in New Hanover County increased by 30% over the past five years and has a five-year average annual change rate of 7.86% as illustrated in the table below.

	<b>HHD &amp; PD Patients at DaVita Facilities in New Hanover County</b>	<b>% Change</b>
12/31/2017	57	
12/31/2018	60	5.26%
12/31/2019	71	18.33%
12/31/2020	60	-15.49%
12/31/2021	74	23.33%
5-year AACR		7.86%

Source: Page 25 of application

- The applicant assumes that the New Hanover County Home patient population receiving training and support at the Ogden Park Home Training program will grow by the five-year AACR 7.68% and assumes no growth for patients living outside of New Hanover County.
- The applicant assumes one IC patient from New Hanover County will transfer to home dialysis each year.
- The applicant assumes patients in each of the home training programs at Ogden Park Home Training will grow at a rate of 25% during the period of growth.

On page 30, the applicant provides the following table showing its projections of HH and PD patients through the first two operating years of the project.

<b>Ogden Park Home Training Program</b>		
	<b>HH Patients Trained</b>	<b>PD Patients Trained</b>
1 <sup>st</sup> Full FY (CY 2024)	13	25
2 <sup>nd</sup> Full FY (CY 2025)	16.25	31.25

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

- The applicant begins projections with the existing New Hanover County patients receiving home dialysis training and support at DaVita facilities located in New Hanover County.
- In the past five years statewide home patient population has increased by 23% and home patient population in DaVita’s two facilities located in New Hanover County has increased by 30%.

**Access to Medically Underserved Groups**

In Section C.6, page 31, the applicant states:

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

.....

*Ogden park home training 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 32, the applicant provides the estimated percentage for each medically underserved group it will serve during OY2, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	45.7%
Racial and ethnic minorities	35.8%
Women	45.7%
Persons with disabilities	100.0%
Persons 65 and older	44.4%
Medicare beneficiaries	65.1%
Medicaid recipients	4.8%

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 SEDC-Wilmington, 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 dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington. Southeastern Dialysis Center-Wilmington will be certified for 30 stations upon completion of this project.

In Section D, pages 38-39, 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 39, the applicant provides a table which shows projected SEDC-Wilmington relocation of two stations to the proposed facility, Ogden Park Home Training Program.

SEDC-Wilmington		
	ICHD Stations	ICHD Patients
The applicant begins with total HD patients dialyzing at SEDC-Wilmington as of January 1, 2022.	32	88
The applicant projects the ICHD patient population forward one year to December 31, 2022 using a 0% growth rate.		88 x 1.0 = 88
The applicant projects the ICHD patient population forward one year to December 31, 2023 using a 0% growth rate.		88 x 1.0 = 88
Ogden Park Home Training is projected to be certified on 1/1/2024. Two existing station are projected to be relocated from SEDC-Wilmington.	32 – 2 = 30	88
The applicant projects the ICHD patient population forward one year to December 31, 2024 using a 0% growth rate. This is the ending census for OY1.		88 x 1.0 = 88
The applicant projects the ICHD patient population forward one year to December 31, 2025 using a 0% growth rate. This is the ending census for OY2.		88 x 1.0 = 88

As shown in the table above, SEDC-Wilmington is projected to serve 88 in-center HD patients on 30 stations as of the date the stations are projected to be relocated. Thus, the applicant projects that SEDC-Wilmington will have a utilization rate of 73.3% or 2.933 patients per station per week (88 patients / 30 stations = 2.933 / 4 = 0.7333 or 73.3%).

On page 39, the applicant states:

*“Given this projected growth of the in-center patient population, 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 39, the applicant states:

*“SEDC Wilmington 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.*

....

*SEDC-Wilmington 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.

The applicant proposes to develop a new dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington.

In Section E.2, page 43, 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 there are three DaVita operated facilities in New Hanover County. Adding home training services to Cape Fear Dialysis would require significant renovations and expansion of the existing footprint. Because Cape Fear Dialysis is an older facility the renovations would be costly and interrupt the day-to-day operations. It is not possible to add home training at SEDC-Wilmington or New Hanover Dialysis because it is not possible to expand the footprint at these facilities.

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. Cahita 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 Ogden Park Home Training by relocating no more than two in-center and home hemodialysis stations from Southeastern Dialysis Center Wilmington.**

- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify two stations at Southeastern Dialysis Center Wilmington for a total of no more than 30 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 June 1, 2022. The second progress report shall be due on October 1, 2022 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 dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington.

**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.

Site Costs	\$32,255
Construction Costs	\$708,139
Miscellaneous Costs	\$184,127
<b>Total</b>	<b>\$924,521</b>

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 the 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 47, the applicant states it projects \$97,899 in start-up costs and \$404,024 initial operating expenses, for total working capital required of \$501,923.

**Availability of Funds**

In Section F, pages 45 and 48, the applicant states that the capital and working capital cost, respectively, will be funded by Cahita Dialysis, LLC, as shown in the tables below.

**Sources of Capital Cost Financing**

Type	Cahita Dialysis, LLC
Loans	\$0
Accumulated reserves or OE *	\$924,521
Bonds	\$0
Other (Specify)	\$0
<b>Total Financing</b>	<b>\$924,521</b>

\* OE = Owner’s Equity

**Sources of Working Capital Financing**

Type	Cahita Dialysis, LLC
Loans	\$0
Accumulated reserves or OE *	\$501,923
Bonds	\$0
Other (Specify)	\$0
<b>Total Financing</b>	<b>\$501,923</b>

\* 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 17, 2022, from Chief Accounting Officer for DaVita Kidney Care, parent company to Cahita 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.

<b>Ogden Park Home Training Projected Revenue and Operating Expenses</b>		
	<b>1<sup>st</sup> Full Fiscal Year CY2024</b>	<b>2<sup>nd</sup> Full Fiscal Year CY2025</b>
Treatments	4,218	4,776
Gross Patient Revenue	\$1,992,787	\$2,251,967
Net Patient Revenue	\$1,942,166	\$2,194,658
Average Net Revenue per Treatment	\$460	\$460
Total Operating Expenses	\$808,047	\$879,990
Average Operating Expense per Treatment	\$192	\$184
Net Income	\$1,134,119	\$1,314,668

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 dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington.

On page 115, the 2022 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 Ogden Park Home Training and Southeastern Dialysis Center-Wilmington are located in New Hanover County. Thus, the service area for this application is New Hanover County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 129 of the 2022 SMFP and the information provided by the applicant in Section G page 52, there are three existing dialysis facilities in New Hanover County all of which are owned and operated by DaVita. Two of the three facilities provide training and support for home hemodialysis and peritoneal dialysis alongside their in-center programs. Information on these dialysis facilities, from Table 9A of the 2022 SMFP is summarized below.

**New Hanover 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
Cape Fear Dialysis	DaVita	32	94	73.44%	2.9375	0
New Hanover Dialysis	DaVita	18	60	83.33%	3.3333	0
SEDC-Wilmington	DaVita	32	98	76.56%	3.0625	0
<b>Total</b>		<b>82</b>	<b>252</b>	<b>77.78%</b>		<b>0</b>

In Section G, page 52, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in New Hanover County. The applicant states:

*“...The home patient population and the number of home training patients in New Hanover 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 New Hanover 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 New Hanover 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.

C

The applicant proposes to develop a new dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington.

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.



**Ogden Park Home Training**

<b>POSITION</b>	<b>PROJECTED FTE POSITIONS CY2024</b>	<b>PROJECTED FTE POSITIONS CY2025</b>
Administrator	0.30	0.30
Home Training Nurse	1.00	1.00
Dietitian	0.25	0.25
Social Worker	0.25	0.25
Administrative/Business Office	0.25	0.25
Biomedical Tech	0.25	0.25
<b>Total</b>	<b>2.30</b>	<b>2.30</b>

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 55-56, 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 Ogden Park 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 dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington.

**Ancillary and Support Services**

In Section I, page 58, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 58-61, 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 multiple facilities in New Hanover County.
- The applicant discusses how it will provide each necessary ancillary and support service at Ogden Park Home Training.

**Coordination**

In Section I, page 61, 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 dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington.

In Section K, page 66, the applicant states that the project will involve renovation of 3,250 square feet of space to be leased in an existing building. The proposed floor plan is provided in Exhibit K.2.

On page 66, the applicant identifies the proposed site and in Exhibit K-4 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 66-67, 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 67, 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 67-68, the applicant identifies applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K-4.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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 dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington.

Ogden Park Home Training will be a new facility and therefore has no history. In Section L.1, page 73, the applicant provides the historical payor mix for CY2021 for SEDC Wilmington, as shown in the table below.

<b>SEDC Wilmington Historical Payor Mix CY 2021</b>						
	<b>IC</b>		<b>HH</b>		<b>PD</b>	
<b>Payor Source</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	1.0	1.1%	0.0	0.0%	1.0	1.6%
Insurance*	2.0	2.3%	0.0	0.0%	14.0	22.2%
Medicare*	73.0	83.0%	0.0	0.0%	41.0	65.1%
Medicaid*	9.0	10.2%	0.0	0.0%	3.0	4.8%
Misc. (including VA)	3.0	3.4%	0.0	0.0%	4.0	6.3%
<b>Total</b>	<b>88.0</b>	<b>100.0%</b>	<b>0.0</b>	<b>0.0%</b>	<b>63.0</b>	<b>100.0%</b>

\*Including any managed care plans

**Note:** Table may not foot due to rounding

In section L, page 74, the applicant provides the following comparison.

	<b>Percentage of Total SEDC Wilmington Patients Served during the Last Full OY</b>	<b>Percentage of the Population of the Service Area Where the Stations are Located*</b>
Female	45.7%	52.4%
Male	54.3%	47.5%
Unknown	0.0%	0.0%
64 and Younger	55.6%	81.6%
65 and Older	44.4%	18.4%
American Indian	0.0%	0.6%
Asian	0.7%	1.6%
Black or African-American	34.4%	13.4%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	64.2%	82.2%
Other Race	0.7%	2.1%
Declined / Unavailable	0.0%	0.0%

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

## **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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 74, 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 75, 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.

**Ogden Park Home Training  
 Projected Payor Mix CY2025**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.00	0.0%	0.00	1.6%
Insurance*	0.0	0.0%	1.01	18.2%	5.06	22.2%
Medicare*	0.0	0.0%	4.56	81.8%	22.77	65.1%
Medicaid*	0.0	0.0%	0.00	0.0%	0.00	4.8%
Other (VA)	0.0	0.0%	0.00	0.0%	0.00	6.3%
<b>Total</b>	<b>0.0</b>	<b>0.0%</b>	<b>5.57</b>	<b>100.0%</b>	<b>27.84</b>	<b>100.0%</b>

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 1.6% of PD services will be provided to self-pay patients; 81.8% of HHD and 65.1% of PD services to Medicare patients; and 0.0% of HHD, and 4.8% of PD services to Medicaid patients.

On page 75, 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 New Hanover 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 76, 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 dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington.

In Section M, page 78, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant provides a copy of the training agreement with UNC Wilmington offering several DaVita facilities as training sites for nursing students.
- The applicant states that the training agreement with UNC Wilmington will be amended to include Ogden Park Home Training when the facility is certified.

### **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 dialysis facility in Wilmington dedicated to HH and PD training and support by relocating two existing stations from SEDC-Wilmington.

On page 115, the 2022 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 Ogden Park Home Training and Southeastern Dialysis Center-Wilmington are located in New Hanover County. Thus, the service area for this application is New Hanover County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 129 of the 2022 SMFP and the information provided by the applicant in Section G page 52, there are three existing dialysis facilities in New Hanover County all of which are owned and operated by DaVita. Two of the three facilities provide training and support for home hemodialysis and peritoneal dialysis alongside their in-center programs. Information on these dialysis facilities, from Table 9A of the 2022 SMFP is summarized below.

**New Hanover 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
Cape Fear Dialysis	DaVita	32	94	73.44%	2.9375	0
New Hanover Dialysis	DaVita	18	60	83.33%	3.3333	0
SEDC-Wilmington	DaVita	32	98	76.56%	3.0625	0
<b>Total</b>		<b>82</b>	<b>252</b>	<b>77.78%</b>		<b>0</b>

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 80, the applicant states:

*“The development of Ogden parks home training will have no effect on any dialysis facilities located in New Hanover County. DaVita operates the other three facilities in the county.”*

*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.”*

Regarding the impact of the proposal on cost effectiveness, quality, and access to medically underserved groups in Section N, page 80, the applicant states:

*“The development of Ogden Park Home Training Program 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 85, 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.