

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 19, 2022

Findings Date: December 19, 2022

Project Analyst: Donna Donihi

Co-Signer: Gloria C. Hale

Project ID #: L-12274-22

Facility: Wooten Boulevard Home Training

FID #: 220670

County: Wilson

Applicant(s): Dovehurst Dialysis, LLC

Project: Develop a new dialysis facility to be dedicated to home hemodialysis & peritoneal dialysis training and support by relocating 2 stations from Wilson 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

Dovehurst Dialysis, LLC (hereinafter referred to as “the applicant”) proposes to develop a new dialysis facility, Wooten Boulevard Home Training (Wooten Blvd. HT) in Wilson dedicated exclusively to home hemodialysis (HH) and peritoneal dialysis (PD) training and support by relocating two existing stations from Wilson Dialysis Center in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

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- (2) Repealed effective July 1, 1987.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 Wilson dedicated to HH and PD training and support by relocating two existing stations from Wilson Dialysis. Wilson Dialysis will be certified for 42 stations upon completion of this project.

The following table shows the projected number of stations for Wooten Boulevard Home Training upon project completion.

<b>Wooten Boulevard 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	L-12274-22
2	Total stations upon completion of the proposed project and previously approved projects	

The following table shows the current and projected number of dialysis stations at Wilson Dialysis upon completion of this project.

<b>Wilson Dialysis</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
39	Total existing certified stations 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)	L-12274-22
37	Total stations upon completion of the 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 Wooten Boulevard Home Training and Wilson Dialysis are in Wilson County. Thus, the service area for this application is Wilson County. Facilities may serve residents of counties not included in their service area.

This proposal is to develop Wooten Boulevard Home Training, a new two-station dialysis facility in Wilson; therefore, historical patient data does not exist. In Section C, page 23, the applicant provides the historical (CY2021) patient origin for Wilson Dialysis, as summarized in the following tables.

Wilson Dialysis						
County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Wilson	107	89.9%	7	50.00%	40	72.73%
Edgecombe	0	0.0%	2	14.29%	0	0.0%
Franklin	1	0.8%	0	0.00%	1	1.82%
Greene	2	1.7%	0	0.00%	2	3.64%
Johnston	6	5.0%	1	7.14%	2	3.64%
Nash	0	0.0%	2	14.29%	6	10.91%
Pitt	-	-	-	-	1	1.82%
Wake	-	-	-	-	1	1.82%
Wayne	-	-	2	14.29%	2	3.64%
Other States	3	2.5%	0	0.00%	-	0.00%
<b>Total</b>	<b>119</b>	<b>100.00%</b>	<b>14</b>	<b>100.00%</b>	<b>55</b>	<b>100.00%</b>

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

Wooten Blvd. Home Training				
County	Second Full FY 01/01/2026 to 12/31/2026			
	Home Hemodialysis		Peritoneal Dialysis	
	HH Patients	% of Total	PD Patients	% of Total
Wilson	13.7591	100.0%	46.2038	100.0%
<b>Total</b>	<b>13.7591</b>	<b>100.0%</b>	<b>46.2038</b>	<b>100.0%</b>

In Section C.4, page 24, the applicant provides the assumptions and methodology used to project Wooten Blvd. Home Training’s patient origin. The applicant states that the projected patient origin is based on:

- Historical growth of almost 25% of the home dialysis patient population in the last five years statewide.
- Historical five-year growth of almost 20% for DaVita facilities with home training in Wilson County ending December 31, 2021.

- The 5-Year average annual growth rate (AACR) for the home training patient population in the home program at DaVita's Wilson County dialysis facilities was 8.1%.
- The applicant assumes Wooten Blvd. Home Training will see an 8.1% AACR for Wilson County patients only and not patients outside the county.

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

- The applicant projects growth of Wooten Blvd. Home training HH and PD patient census using the Five-Year (AACR) of 8.1%, as calculated using data from the applicant's home program in its Wilson County Dialysis facilities.
- The applicant clearly explains how and why growth is projected in the Wilson County HH and PD patient population.
- The applicant does not project any growth in patients residing outside of Wilson County.

### **Analysis of Need**

In Section C.4, pages 24-25, 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.
- One-half of DaVita's Wilson County home patients will be on the waiting list for admission to Wooten Blvd. Home Training, the second DaVita-owned facility in the county offering home training services.
- 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 Wilson County patient utilization at the proposed Wooten Blvd. HT facility, as illustrated in the following table.

	<b>HHD Projections</b>	<b>PD Projections</b>
The applicant begins with the DaVita home patients as of 12/31/2021.	HHD Pt. Census at Wilson Dialysis = 7	PD Pt. Census at Wilson Dialysis = 40
The home patient census of Wilson County residents is projected forward a year to 12/31/2022. It is increased by 8.1% and in-center patient conversions to home are added to the census.	$7 \times 1.081 = 7.567$ $7.567 + 1 = 8.57$	$40 \times 1.081 = 43.24$ $43.24 + 2 = 45.24$
The home patients from outside Wilson County are added. This is the ending census for the first full interim year.	$8.57 + 7 = 15.57$	$45.24 + 15 = 60.24$
The home patient census of Wilson County residents is projected forward a year to 12/31/2023. It is increased by 8.1% and in-center patient conversions to home are added to the census.	$8.57 \times 1.081 = 9.261$ $9.261 + 1 = 10.26$	$45.24 \times 1.081 = 48.904$ $48.904 + 2 = 50.90$
The home patients from outside Wilson County are added. This is the ending census for the second full interim year.	$10.26 + 7 = 17.26$	$50.90 + 15 = 65.90$
The home patient census of Wilson County residents is projected forward a year to 12/31/2024. It is increased by 8.1% and in-center patient conversions to home are added to the census.	$10.26 \times 1.081 = 11.092$ $11.092 + 1 = 12.092$	$50.90 \times 1.081 = 55.028$ $55.028 + 2 = 57.03$
The home patients from outside Wilson County are added. This is the ending census for the third full interim year.	$12.092 + 7 = 19.09$	$57.03 + 15 = 72.03$
One-half of DaVita's Wilson County home patients are projected to be on the waiting list for Wooten Blvd. HT on 12/31/2024.	$19.09 \times 0.5 = 9.54510$	$72.03 \times 0.5 = 36.015$
Wooten Blvd. HT is projected to be certified on 1/1/2025 and begins with DaVita's Wilson County home patients projected to be on the waiting list.	10	36
The Wooten Blvd. HT patient population is projected forward a year to 12/31/2025. It is increased by 8.1% and in-center patient conversions to home are added to the census. This is the ending census as of the end of OY1.	$10 \times 1.081 = 10.806$ $10.806 + 1 = 11.81$	$36 \times 1.081 = 38.916$ $38.916 + 2 = 40.92$
The Wooten Blvd. HT patient population is projected forward a year to 12/31/2026. It is increased by 8.1% and in-center patient conversions to home are added to the census. This is the ending census as of the end of OY2.	$10.81 \times 1.081 = 12.7591$ $12.76 + 1 = 13.76$	$40.92 \times 1.081 = 44.230$ $44.230 + 2 = 46.23$

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 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 2017, 2018, 2019, 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>
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<b>12/31/2017</b>	18303		16032		2271	
<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>12/31/2021</b>	19495	-1.928%	16685	-0.91%	2810	3.73%
<b>5-year AACR</b>		1.61%		1.02%		5.48%

Source: Page 24 of the application

- The applicant states the home patient population in DaVita’s two facilities located in Wilson County increased by 20% over the past five years and has a five-year average annual change rate of 8.1% as illustrated in the table below.

	<b>HHD &amp; PD Patients at DaVita Facilities in Wilson County</b>	<b>% Change</b>
12/31/2017	58	
12/31/2018	46	-20.7%
12/31/2019	71	54.3%
12/31/2020	79	11.3%
12/31/2021	69	-12.7%
<b>5-year AACR</b>		<b>8.1%</b>

Source: Page 25 of the application

- The applicant assumes that the Wilson County Home patient population and support at the Wooten Blvd. HT program will grow by the five-year AACR 8.1% and assumes no growth for patients living outside of Wilson County.
- The applicant assumes three IC patients from Wilson County will transfer to home dialysis each year.
- The applicant assumes patients in the home training programs at Wooten Blvd. HT will grow at a rate of 8.1% during the period of growth.

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

<b>Wooten Blvd. HT Program</b>	
	<b>HH Patients Trained*</b>
1 <sup>st</sup> Full FY (CY 2024)	14
2 <sup>nd</sup> Full FY (CY 2025)	17.5

\*Represents the number of patients who will receive training but may not complete it.  
 The second FY reflects a 25% increase.

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

- The applicant begins projections with the existing Wilson County home patients receiving home dialysis training and support at Wilson Dialysis located in Wilson County which is the only DaVita facility currently with a home program.

- In the past five years the statewide home patient population has increased by 25% and the home patient population in DaVita’s one facility located in Wilson County has increased by 20%.

**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.”*

.....

*Wooten Blvd. 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 under-served persons.”*

On page 31, 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	92.4%
Racial and ethnic minorities	60.5%
Women	40.3%
Persons with disabilities	100.0%
Persons 65 and older	44.5%
Medicare beneficiaries	87.4%
Medicaid recipients	4.2%

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, and handicapped persons. elderly, or other traditionally underserved persons.
- The applicant’s estimated percentage for each underserved group is based upon the percentages for Wilson 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 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

Dovehurst Dialysis, LLC (hereinafter referred to as “the applicant” proposes to develop a new dialysis facility, Wooten Boulevard Home Training in Wilson dedicated exclusively to home hemodialysis and peritoneal dialysis training and support by relocating two existing stations from Wilson Dialysis in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

In Section D, pages 37-38, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following the completion of the project.

On page 38, the applicant provides a table that shows the projected Wilson Dialysis relocation of two stations to the proposed facility, Wooten Blvd. HT.

<b>Wilson Dialysis</b>		
	<b>ICHD Stations</b>	<b>ICHD Patients</b>
Wilson Dialysis begins with 119 patients dialyzing on 44 stations at the facility as of 01/01/2022	44	119

The facility's patient census is projected forward a year to 12/31/2022 and is increased by 0%. This is the ending census as of the end of Interim Year 1.		119 x 1.0 = 119
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 2.		119 x 1.0 = 119
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 3.		119 x 1.0 = 119
Wooten Blvd HT is projected to be certified on 01/01/2025. Two stations are projected to transfer to Wooten Blvd HT from Wilson Dialysis.	44 - 2 = 42	
This is the station count and in-center census on 01/01/2025.	42	119
The facility's patient census is projected forward a year to 12/31/2025 and is increased by 0%. Ending census as of the end of OY 1.		119 x 1.0 = 119

As shown in the table above, Wilson Dialysis is projected to serve 119 in-center HD patients on 42 stations as of the date the stations are projected to be relocated. Thus, the applicant projects that Wilson Dialysis will have a utilization rate of 2.83 patients per station per week (119 patients / 42 stations = 2.83333 / 4 = 0.7083 or 70.83%).

On page 37, the applicant states: that the growth was stagnant at the facility over the past few years. Therefore, to be conservative, the applicant assumes no growth.

*“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 the full capacity of stations.”*

**Access to Medically Underserved Groups**

In Section D, page 39, the applicant states:

*“Wilson Dialysis by the 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.*

....

*Wilson 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 dialysis services at Wilson Dialysis will be adequately met following the 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, the 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 of the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

Dovehurst Dialysis, LLC (hereinafter referred to as “the applicant”) proposes to develop a new dialysis facility, Wooten Boulevard Home Training in Wilson dedicated exclusively to home hemodialysis and peritoneal dialysis training and support by relocating two existing stations from Wilson Dialysis in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

In Section E.2, page 42, 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 four DaVita-operated facilities in Wilson County. Adding home training services to Forest Hills Dialysis or Wilson Dialysis would require significant renovations and expansion of the existing older footprint. These campuses are older facilities and the renovations would be costly and interrupt the day-to-day operations. It is possible to add home training at Kenly Dialysis or Sharpsburg Dialysis, but it would not be an ideal location to serve current populations. Therefore, this is not the most effective alternative.

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. Dovehurst 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 freestanding home dialysis training and support program for home hemodialysis and peritoneal dialysis to be known as Wooten Boulevard Home Training by relocating no more than two in-center and home hemodialysis stations from Wilson Dialysis Center.**
- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify two stations at Wilson Dialysis Center in Wilson for a total of no more than 42 hemodialysis stations upon completion of this project.**
- 4. Prior to issuance of the Certificate of Need, the certificate holder shall provide the Agency with documentation that an effort has been made to accommodate the clinical needs of health professional training programs in the area at Wooten Boulevard Home Training.**
- 5. Progress Reports:**

- a. **Under 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 April 1, 2023.**
6. **The certificate holder shall install plumbing and electrical wiring through the walls for no more than two home hemodialysis stations.**
  7. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing before the 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 any charges for providing health services by the person proposing the service.

C

Dovehurst Dialysis, LLC (hereinafter referred to as “the applicant”) proposes to develop a new dialysis facility, Wooten Boulevard Home Training in Wilson dedicated exclusively to home hemodialysis and peritoneal dialysis training and support by relocating two existing stations from Wilson Dialysis in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

**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 Cost**

Site Costs	\$34,762
Construction Costs	\$857,453
Architect	\$64,620
Medical Equipment	\$38,983
Non-Medical Equipment	\$41,495
Furniture	\$46,240
Interest during Construction	\$34,674
<b>Total</b>	<b>\$1,118,225</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 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 46 the applicant states it projects \$185,753 in start-up costs and \$595,679 in initial operating expenses, for total working capital required of \$781,432.

**Availability of Funds**

In Section F, pages 44 and 46, the applicant states that the capital and working capital cost, respectively, will be funded by Dovehurst Dialysis, LLC, as shown in the tables below.

**Sources of Capital Cost Financing**

Type	Dovehurst Dialysis, LLC
Accumulated reserves or OE *	\$ 1,118,225
<b>Total Financing</b>	<b>\$ 1,118,225</b>

\* OE = Owner’s Equity

**Sources of Working Capital Financing**

Type	Dovehurst Dialysis, LLC
Loans	\$0
Accumulated reserves or OE *	\$ 745,933
Bonds	\$0
Other (Specify)	\$0
<b>Total Financing</b>	<b>\$ 745,933</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 September 14, 2022, from the Chief Accounting Officer for DaVita Kidney Care, parent company to Dovehurst 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 the 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>Wooten Blvd. HT Projected Revenue and Operating Expenses</b>		
	<b>1<sup>st</sup> Full Fiscal Year CY2025</b>	<b>2<sup>nd</sup> Full Fiscal Year CY2026</b>
Treatments	7,314	8,349
Gross Patient Revenue	\$3,172,337	\$3,623,918
Net Patient Revenue	\$3,026,047	\$3,456,935
Average Net Revenue per Treatment	\$414	\$414
Total Operating Expenses	\$1,211,657	\$1,318,583
Average Operating Expense per Treatment	\$166	\$158
Net Income	\$1,814,390	\$2,138,352

Totals may not sum due to rounding

The assumptions used by the applicant in the 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 the 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

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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 Wooten Blvd. HT and Wilson Dialysis are located in Wilson County. Thus, the service area for this application is Wilson County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 133 of the 2022 SMFP, there are four existing dialysis facilities in Wilson County all of which are owned and operated by DaVita. Only one of the four facilities provides training and support for home hemodialysis and peritoneal dialysis alongside their in-center program. Information on these dialysis facilities, from Table 9A of the 2022 SMFP is summarized below.

**Wilson 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
Forest Hills Dialysis	DaVita	31	108	87.10%	3.48
Kenly Dialysis	DaVita	10	19	47.50%	1.90
Sharpsburg Dialysis	DaVita	10	10	25.00%	1.00
Wilson Dialysis	DaVita	37	131	88.51%	3.54
<b>Total</b>		<b>88</b>	<b>268</b>	<b>76.14%</b>	

In Section G, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wilson County. The applicant states:

*“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 DaVita’s admitting nephrologists. The proposed project, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”*

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

- The proposal would not result in an increase of existing stations in Wilson 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 Wilson County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information that 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

Dovehurst Dialysis, LLC (hereinafter referred to as “the applicant”) proposes to develop a new dialysis facility, Wooten Boulevard Home Training in Wilson dedicated exclusively to home hemodialysis and peritoneal dialysis training and support by relocating two existing stations from Wilson Dialysis in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

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.

**Wooten Blvd. HT**

<b>POSITION</b>	<b>PROJECTED FTE POSITIONS CY2025</b>	<b>PROJECTED FTE POSITIONS CY2026</b>
Administrator	1.00	1.00
Home Training Nurse	1.00	1.00
Technicians	.75	.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
<b>Total</b>	<b>4.50</b>	<b>4.50</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 54-55, 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 Wooten Blvd. HT.
- 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 healthcare system.

## C

Dovehurst Dialysis, LLC (hereinafter referred to as “the applicant” proposes to develop a new dialysis facility, Wooten Boulevard Home Training in Wilson dedicated exclusively to home hemodialysis and peritoneal dialysis training and support by relocating two existing stations from Wilson Dialysis in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

### **Ancillary and Support Services**

In Section, I, page 57, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 57-60, 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 Wilson County.
- The applicant discusses how it will provide each necessary ancillary and support service at Wooten Blvd. HT.

### **Coordination**

In Section, I, page 60, 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 healthcare system based on the following:

- The applicant discusses its relationships with local healthcare 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

Dovehurst Dialysis, LLC (hereinafter referred to as “the applicant”) proposes to develop a new dialysis facility, Wooten Boulevard Home Training in Wilson dedicated exclusively to home hemodialysis and peritoneal dialysis training and support by relocating two existing stations

from Wilson Dialysis in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

In Exhibits K.1-3, the applicant provides line drawings and documents the project will involve the renovation of 3,590 square feet of space to be leased in an existing building. The proposed floor plan is provided in Exhibit K.3.

On page 68, 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 65-68, 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 a 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 66, 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 66-67, the applicant identifies applicable energy-saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K-3.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low-income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced

difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

C

Dovehurst Dialysis, LLC (hereinafter referred to as “the applicant”) proposes to develop a new dialysis facility, Wooten Boulevard Home Training in Wilson dedicated exclusively to home hemodialysis and peritoneal dialysis training and support by relocating two existing stations from Wilson Dialysis in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

- (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.

Wooten Blvd. HT will be a new facility and therefore has no history. In Section L.1, page 72, the applicant provides the historical payor mix for CY2021 for Wilson Dialysis, as shown in the table below.

<b>Wilson Dialysis Historical Payor Mix CY 2021</b>						
<b>Payor Source</b>	<b>IC</b>		<b>HH</b>		<b>PD</b>	
	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	1.0	0.8%	0.0	0.0%	0.0	0.0%
Insurance*	6.0	5.0%	3.0	21.4%	9.0	16.4%
Medicare*	104.0	87.4%	11.0	78.6%	41.0	74.5%
Medicaid*	5.0	4.2%	0.0	0.0%	3.0	5.5%
Misc. (including VA)	3.0	2.5%	0.0	0.0%	2.0	3.6%
<b>Total</b>	<b>119.0</b>	<b>100.0%</b>	<b>14.0</b>	<b>100.0%</b>	<b>55.0</b>	<b>100.0%</b>

\*Including any managed care plans

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

In section L, page 73, the applicant provides the following comparison.

	Percentage of Total Wilson Dialysis Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	40.3%	52.3%
Male	59.7%	47.7%
Unknown	0.0%	0.0%
64 and Younger	55.5%	81.0%
65 and Older	44.5%	19.0%
American Indian	0.8%	0.8%
Asian	0.0%	1.2%
Black or African American	57.1%	40.5%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	39.5%	55.5%
Other Race	2.5%	2.0%
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 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 the 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 73, 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 18 months. In addition, there have been no civil rights access complaints filed against Wilson Dialysis within the last 18 months.

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

**Wooten Blvd. HT Projected Payor Mix CY2026**

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	0.0%
Insurance*	0.0	0.0%	2.95	21.4%	7.56	16.4%
Medicare*	0.0	0.0%	10.81	78.6%	34.44	74.5%
Medicaid*	0.0	0.0%	0.00	0.0%	2.52	5.5%
Other (VA)	0.0	0.0%	0.00	0.0%	1.68	3.6%
<b>Total</b>	<b>0.0</b>	<b>100.0%</b>	<b>13.76</b>	<b>100.0%</b>	<b>46.20</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 fiscal year of operation, the applicant projects that 0.0% of HHD and 0.0% of PD services will be provided to self-pay patients; 78.6% of HHD and 74.5% of PD services to Medicare patients; and 0.0% of HHD, and 5.5% of PD services to Medicaid patients.

On page 74, the applicant provides the assumptions and methodology used to project payor mix during the second fiscal full year of operation following the 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 Wilson 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 75, 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.

CA

Dovehurst Dialysis, LLC (hereinafter referred to as “the applicant”) proposes to develop a new dialysis facility, Wooten Boulevard Home Training in Wilson dedicated exclusively to home hemodialysis and peritoneal dialysis training and support by relocating two existing stations from Wilson Dialysis in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

In Section M, page 77, 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 because the applicant states that the training agreement between Wilson Community College and Wilson Dialysis, provided in exhibit M.2 will be amended to include Wooten Blvd. HT when the facility is certified.

**As Conditioned in Criterion (4), the applicant shall provide documentation that an effort has been made to accommodate the clinical needs of health professional training programs in the area at Wooten Blvd. HT prior to being issued a certificate of need for this proposed project.**

**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 on 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

Dovehurst Dialysis, LLC (hereinafter referred to as “the applicant”) proposes to develop a new dialysis facility, Wooten Boulevard Home Training in Wilson dedicated exclusively to home hemodialysis and peritoneal dialysis training and support by relocating two existing stations from Wilson Dialysis in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

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 Wooten Blvd. HT and Wilson Dialysis are located in Wilson County. Thus, the service area for this application is Wilson County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 133 of the 2022 SMFP and the information provided by the applicant in Section G page 51, there are four existing dialysis facilities in Wilson County all of which are owned and operated by DaVita. One facility provides training and support for home hemodialysis and peritoneal dialysis alongside their in-center program. Information on these dialysis facilities, from Table 9A of the 2022 SMFP is summarized below.

### **Wilson 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
Forest Hills Dialysis	DaVita	31	108	87.10%	3.48
Kenly Dialysis	DaVita	10	19	47.50%	1.90
Sharpsburg Dialysis	DaVita	10	10	25.00%	1.00
Wilson Dialysis	DaVita	37	131	88.51%	3.54
<b>Total</b>		<b>88</b>	<b>268</b>	<b>76.14%</b>	

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 80, 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.*

*The bottom line is Wooten Blvd HT will enhance accessibility and/or convenience to dialysis for our 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.”*

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 Wooten Blvd 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 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 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 that 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

Dovehurst Dialysis, LLC (hereinafter referred to as "the applicant" proposes to develop a new dialysis facility, Wooten Boulevard Home Training in Wilson dedicated exclusively to home hemodialysis and peritoneal dialysis training and support by relocating two existing stations from Wilson Dialysis in Wilson. The facility will not provide in-center (IC) dialysis. DaVita, Inc. is the parent company of Dovehurst Dialysis, LLC.

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 84, 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.