

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 12, 2020

Findings Date: November 12, 2020

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: L-11923-20

Facility: Forest Hills Dialysis

FID #: 020166

County: Wilson

Applicant: DVA Renal Healthcare, Inc.

Project: Add no more than 9 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations upon completion of this project and Project ID #J-11743-19 (relocate 5 stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

DVA Healthcare Renal Care, Inc., herein referred to as either (“DVA”) or (“the applicant”), proposes to add no more than 9 dialysis stations to its Forest Hills Dialysis facility pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations upon completion of this project and Project ID #J-11743-19 (relocate 5 stations). DaVita, Inc. is the ultimate parent company of DVA.

Forest Hills Dialysis provides in-center (IC) dialysis, however, currently the facility does not offer either a peritoneal dialysis (PD) program or a home hemodialysis (HH) program.

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Wilson County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Forest Hills Dialysis on page 165 of the 2020 SMFP is 91.13 percent or 3.645 patients per station per week, based on 113 in-center dialysis patients and 31 certified dialysis stations (113 patients / 31 stations = 3.645; $3.645 / 4 = 0.91125$ or 91.13%).

As shown in Table 9E on page 173 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Forest Hills Dialysis is up to 13 additional stations; thus, the applicant is eligible to apply to add up to 13 stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 9 new stations to Forest Hills Dialysis, which is consistent with the 2020 SMFP calculated facility need determination for up to 13 dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: Basic Principles.

Policy GEN-3: Basic Principles, pages 30-31 of the 2020 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

In Section B, pages 13-16, the applicant explains why it believes its application is conforming to Policy GEN-3. On pages 15-16, the applicant states:

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

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

..., established policy and procedure will continue to guide this commitment.”

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates how Forest Hills Dialysis’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.

(2) Repealed effective July 1, 1987.

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

C

DVA proposes to add no more than 9 dialysis stations to its Forest Hills Dialysis facility for a total of no more than 35 stations upon completion of this project and Project ID #J-11743-19 (relocate 5 stations).

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area*

except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.” Forest Hills Dialysis is in Wilson County. Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin for Forest Hills Dialysis.

County	Current (CY2019)		Second Full FY of Operation following Project Completion (CY2023)	
	# of Patients	% of Total	# of Patients	% of Total
Wilson	105	89.0%	93	91.2%
Nash	9	7.6%	5	4.9%
Greene	1	0.8%	1	1.0%
Johnston	1	0.8%	0	0.0%
Wayne	1	0.8%	1	1.0%
Sampson	0	0.0%	1	1.0%
Edgecombe	0	0.0%	1	1.0%
Other States	1	0.8%	0	0.0%
Total	118	100.0%	102	100.0%

Source: Section C, pages 19-20.

Note: Totals might not sum due to rounding.

In Section C.3(b), pages 20-21, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 22, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- The applicant references Section B, Question 2 of its application, and the facility need table, wherein it states that up to 13 additional dialysis stations are needed at Forest Hills Dialysis based on application of the facility need methodology and the proposed application is only for 9 additional dialysis stations.

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

- Project ID# L-11438-17 approved the relocation of five dialysis stations from Forest Hills Dialysis to Kenly Dialysis. On February 24, 2020, Kenly Dialysis was certified leaving Forest Hills Dialysis with 31 dialysis stations.
- Project ID# J-11743-19 approved the relocation of five dialysis stations from Forest Hills Dialysis to Clayton Dialysis. Clayton Dialysis is projected to be certified as of January 1, 2021 which will leave Forest Hills Dialysis with 26 dialysis stations. As part of this project 18 IC patients (13 Wilson County residents and 5 non-Wilson County residents) were projected to transfer their care from Forest Hills Dialysis to Clayton Dialysis.

- The applicant states upon Clayton Dialysis becoming certified as of January 1, 2021 Forest Hills will be serving 91 in-center patients on 26 certified stations. This is a utilization rate of 82.5%, or 3.3 patients per station per week. [$91/26 = 3.5$; $3.5/4 = 0.875$ or 87.5%]
- The applicant demonstrates the need for additional stations at Forest Hills Dialysis based on its existing and future patient population.
- Table 9E of the 2020 SMFP, page 73, indicates that Forest Hills Dialysis has a facility need for 13 dialysis stations. This application is for nine dialysis stations. The discussion regarding the facility need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section C, page 21 and in Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table.

	In-Center Patients
The applicant begins with the 93 Wilson County patients as of June 30, 2020.	93
The facility's Wilson County patient census is projected forward 6 months to December 31, 2020 at half of the Wilson County Five-Year AACR of 4.2%.	$93 \times 1.021 = 94.953$
The 13 Wilson County patients projected to transfer their care to Clayton Dialysis as of January 1, 2021 per Project ID#J-11743-19 are subtracted from the patient census of Wilson County residents.	$94.953 - 13 = 81.953$
The facility's Wilson County patient census is projected forward a year to December 31, 2021 at the Wilson County Five Year AACR of 4.2%.	$81.853 \times 1.042 = 85.395$
The facility's Wilson County patient census is projected forward a year to December 31, 2022 at the Wilson County Five Year AACR of 4.2%.	$85.395 \times 1.042 = 88.982$
The 9 patients from outside Wilson County are added to the patient census per Project ID#J-11743-19 (5 of 14 patients transferred to Clayton Dialysis leaving 9 patients.) This is the ending census as of the end of OY1.	$88.982 + 9 = \mathbf{97.982 \text{ or } 97}$
The facility's Wilson County patient census is projected forward a year to December 31, 2023 at the Wilson County Five Year AACR of 4.2%.	$88.982 \times 1.042 = 92.719$
The 9 patients from outside Wilson County are added to the patient census per Project ID#J-11743-19 (5 of 14 patients transferred to Clayton Dialysis leaving 9 patients.) This is the ending census as of the end of OY2.	$92.719 + 9 = \mathbf{101.719 \text{ or } 101}$

In both Section C, pages 20-21, and Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).

- As of June 30, 2020, the patient census at Forest Hills Dialysis was 107 IC patients: 93 patients from Wilson County and 14 patients from outside Wilson County.
- The applicant begins its projections with the 93 patients residing in Wilson County.
- Subtract 18 IC patients (13 Wilson County patients and 5 patients from outside of Wilson County) who will transfer their care to Clayton Dialysis as of January 1, 2021. See Project ID#J-11743-19 (develop a new 10-station dialysis facility).
- The dialysis patients who do not reside in Wilson County will be carried forward into projections of future patient census however, the applicant does not project any growth of the non-Wilson County patients.
- Projected growth of the patient census for patients residing in Wilson County was based on the 4.2% Five-Year Average Annual Change Rate (AACR) for Wilson County, as published in the 2020 SMFP.

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2022) the facility is projected to serve 97 in-center patients and at the end of OY2 (CY2023) the facility is projected to serve 101 in-center patients.

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

- OY1: 2.8 patients per station per week or 70.0% ($97 \text{ patients} / 35 \text{ stations} = 2.8/4 = 0.70$ or 70.0%).
- OY2: 2.9 patients per station per week or 72.5% ($101 \text{ patients} / 35 \text{ stations} = 2.9/4 = 0.725$ or 72.5%).
- Forest Hills Dialysis Center currently is certified for 31 dialysis stations. As of January 1, 2021, based upon projected certification of Clayton Dialysis (Project J-11743-19 [develop a new 10-station dialysis facility including relocation of 5 stations from Forest Hills Dialysis Center]) Forest Hills Dialysis Center will have 26 certified dialysis stations.
- In this application, the applicant seeks to add 9 dialysis stations to Forest Hills Dialysis Center for a total of 35 dialysis stations upon completion of this project and Project J-11743-19 (relocate 5 stations).

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

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

- The applicant projects future utilization based on historical utilization at Forest Hills Dialysis Center.
- The applicant utilized the Five-Year AACR for Wilson County, 4.2%, as published in the 2020 SMFP to project growth of the IC patients residing in Wilson County.
- The applicant conservatively does not project growth for its patients who do not reside in Wilson County.
- The applicant accounts for the 5 dialysis stations and 18 patients (13 Wilson County patients and 5 patients from outside of Wilson County) who are projected to transfer to Clayton Dialysis as of January 1, 2021 as part of Project I.D. #J-11743-19.

Access to Medically Underserved Groups

In Section C, page 23, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

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

Forest Hills Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, disabled persons, elderly and other under-served persons.”

In Section L, page 46, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**Forest Hills Dialysis
Projected Payor Mix CY2023**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Insurance*	4.2%	0.0%	0.0%
Medicare*	88.1%	0.0%	0.0%
Medicaid*	3.4%	0.0%	0.0%
Other (VA)	4.2%	0.0%	0.0%
Total	100.0%	0.0%	0.0%

Totals may not sum due to rounding

*Including any managed care plans

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.

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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose a reduction, elimination or relocation of a facility or service; therefore, Criterion (3a) is not applicable to this review.

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

CA

DVA proposes to add no more than 9 dialysis stations to its Forest Hills Dialysis facility for a total of no more than 35 stations upon completion of this project and Project ID #J-11743-19 (relocate 5 stations).

In Section E, page 29, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo*- The applicant states that this alternative would not address the growth rate at the facility. Thus, this is not the most effective alternative.

- *Relocate Stations from another DaVita Facility*-The applicant states that there are three other DaVita dialysis facilities in Wilson County: Sharpsburg Dialysis, Kenly Dialysis and Wilson Dialysis. Sharpsburg Dialysis and Kenly Dialysis are both newly certified 10-station facilities. Wilson Dialysis had a utilization rate of 87.8% according to the December 2019 ESRD Data Collection forms. Relocating dialysis stations from any of these three dialysis facilities would negatively impact patients. Therefore, this is not the most effective alternative.

In Section B, page 10, Section C, page 21 and Section E, page 29, the applicant states that its proposal is the most effective alternative because there is a facility need for up to 13 dialysis stations at Forest Hills Dialysis and projected patient growth supports the development of 9 additional dialysis stations.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. DVA Renal Healthcare, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than 9 additional in-center dialysis stations for a total of no more than 35 in-center stations at Forest Hills Dialysis upon completion of this project and Project ID# J-11743-19 (relocate 5 stations to Clayton Dialysis).**
 - 3. 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

DVA proposes to add no more than 9 dialysis stations to its Forest Hills Dialysis facility for a total of no more than 35 stations upon completion of this project and Project ID #J-11743-19 (relocate 5 stations).

Capital and Working Capital Costs

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

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$42,346
Total	\$42,346

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

In Section F.3, pages 31-32, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project because Forest Hills Dialysis is an operational facility.

Availability of Funds

In Section F, page 30, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	DaVita	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$42,346	\$42,346
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$42,346	\$42,346

* OE = Owner's Equity

Exhibit F-1 contains a letter dated July 31, 2020 from Chief Accounting Officer of DaVita, the parent company of Forest Hills Dialysis, authorizing and committing cash reserves in the amount of \$42,346, along with any other funds necessary, for the capital costs of the project. Exhibit F-2 contains DaVita's Form 10-K for the Fiscal Year ended December 31, 2019 showing DaVita Inc. with a consolidated balance sheet total cash and cash equivalents of \$1,102,372,000, current assets exceeding \$17 billion, and equity of \$2.3 billion.

Financial Feasibility

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

	1st Full Fiscal Year	2nd Full Fiscal Year
Total Treatments	14,255	14,798
Total Gross Revenues (Charges)	\$4,258,895	\$4,421,032
Total Net Revenue	\$4,044,071	\$4,198,029
Average Net Revenue per Treatment	\$284	\$284
Total Operating Expenses (Costs)	\$2,854,719	\$2,934,632
Average Operating Expense per Treatment	\$200	\$198
Net Income	\$1,189,352	\$1,263,397

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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

DVA proposes to add no more than 9 dialysis stations to its Forest Hills Dialysis facility for a total of no more than 35 stations upon completion of this project and Project ID #J-11743-19 (relocate 5 stations).

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Forest Hills Dialysis is in Wilson County. Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

Currently, there are four existing dialysis facilities in Wilson County, as shown in the following table:

Wilson County Dialysis Facilities				
IC Patients, Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Location	# of IC Patients	# of Certified Stations	Utilization
Forest Hills Dialysis	Wilson	113	31	91.13%
Wilson Dialysis	Wilson	126	40	78.75%
Sharpsburg Dialysis ^{^/^^}	Sharpsburg	5	10	12.50%
Kenly Dialysis*	Kenly	0	0	0.00%

Source: 2020 SMFP, Table 9B, page 165

^{^/^^} Designated as both a new and a small facility per Condition 1.a. in the facility need determination methodology

*Kenly Dialysis, Project ID #L-11438-17 (develop a new 10-station dialysis facility) was certified effective February 24, 2020.

In Section G, page 35, 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:

“While adding stations at the facility does increase the number of stations in Wilson County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists.”

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

- There is a facility need determination in the 2020 SMFP for up to 13 dialysis stations at Forest Hills Dialysis. The proposed project is for 9 dialysis stations.
- The applicant adequately demonstrates that the proposed new dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information which was publicly available during the review and used by the Agency

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

- (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

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

Position	Current (As of 12/31/2019)	Projected	
		Operating Year 1 (CY2022)	Operating Year 2 (CY2023)
Administrator	1.00	1.00	1.00
Registered Nurse (RNs)	4.00	4.50	4.50
Technicians (PCT)	11.75	13.00	13.00
Dieticians	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Administration/Business Office	1.00	1.00	1.00
Other: Biomedical Tech	0.50	0.50	0.50
TOTAL	20.25	22.00	22.00

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H.2 and H.3, pages 36- 37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 37, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibit H-3, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

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

In Section I, page 38, the applicant states that the following ancillary and support services are necessary for the proposed services:

Forest Hills Dialysis – Ancillary and Support Services		
Services	Provider	Explanation/Supporting Documentation
Self-care training (performed in-center)	On site	
Home Hemodialysis training and follow-up program	Wilson Dialysis	Exhibit I-1
Peritoneal dialysis training and follow-up program	Wilson Dialysis	Exhibit I-1
Isolation – hepatitis B	On site	
Psychological counseling	On site by RN	
Nutritional counseling	On site by RD	
Social work services	On site by MSW	
Laboratory services	DaVita Laboratory Services, Inc.	Exhibit I-1
Acute dialysis in an acute care setting	Wilson Medical Center	Exhibit I-1
Emergency care	Wilson Medical Center	Exhibit I-1
Blood bank services	Wilson Medical Center	Exhibit I-1
Diagnostic and evaluation services	Wilson Medical Center	Exhibit I-1
X-ray services	Wilson Medical Center	Exhibit I-1
Pediatric nephrology	Wilson Medical Center	Exhibit I-1
Vascular surgery	Wilson Medical Center	Exhibit I-1
Transplantation services	Vidant Medical Center	Exhibit I-1
Vocational rehabilitation counseling and services	Wilson County Vocational Rehabilitation	Long Term, Established Relationship
Transportation	Wilson Transportation, Medx Transport, City of Wilson Partransit	Long Term, Established Relationship

On page 38, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit 1-1.

In Section I, pages 38-39, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by

other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose any construction or renovation with this project. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 45, the applicant provides the historical payor mix during for the proposed service during the last full operating year (CY2019), as shown in the table below.

**Forest Hills Dialysis
Historical Payor Mix CY2019**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Insurance*	4.2%	0.0%	0.0%
Medicare*	88.1%	0.0%	0.0%
Medicaid*	3.4%	0.0%	0.0%
Other (VA)	4.2%	0.0%	0.0%
Total	100.0%	0.0%	0.0%

Totals may not sum due to rounding

*Including any managed care plans

In Section L, page 44, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	44.7%	52.6%
Male	55.3%	47.4%
Unknown	0.0%	0.0%
64 and Younger	31.6%	81.3%
65 and Older	68.4%	18.7%
American Indian	0.0%	0.6%
Asian	0.0%	1.3%
Black or African-American	78.1%	40.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	19.3%	55.8%
Other Race	2.6%	1.6%
Declined / Unavailable	44.7%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 45, that it has no obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L.2, page 45, the applicant states no patient civil rights access complaints have been filed against Forest Hills Dialysis within the last five years.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

In Section L, page 46, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Forest Hills Dialysis
Projected Payor Mix CY2023**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Insurance*	4.2%	0.0%	0.0%
Medicare*	88.1%	0.0%	0.0%
Medicaid*	3.4%	0.0%	0.0%
Other (VA)	4.2%	0.0%	0.0%
Total	100.0%	0.0%	0.0%

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 88.1% of its services will be to Medicare patients and 3.4% will be to Medicaid patients.

On page 46, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Forest Hills Dialysis.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, pages 46-47, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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

In Section M, page 48, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall

demonstrate that its application is for a service on which competition will not have a favorable impact.

C

DVA proposes to add no more than 9 dialysis stations to its Forest Hills Dialysis facility for a total of no more than 35 stations upon completion of this project and Project ID #J-11743-19 (relocate 5 stations).

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Forest Hills Dialysis is in Wilson County. Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

Currently, there are four existing dialysis facilities in Wilson County, as shown in the following table:

Wilson County Dialysis Facilities IC Patients, Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Location	# of IC Patients	# of Certified Stations	Utilization
Forest Hills Dialysis	Wilson	113	31	91.13%
Wilson Dialysis	Wilson	126	40	78.75%
Sharpsburg Dialysis ^{^/^^}	Sharpsburg	5	10	12.50%
Kenly Dialysis*	Kenly	0	0	0.00%

Source: 2020 SMFP, Table 9B, page 165

^{^/^^} Designated as both a new and a small facility per Condition 1.a. in the facility need determination methodology

*Kenly Dialysis, Project ID #L-11438-17 (develop a new 10-station dialysis facility) was certified effective February 24, 2020.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 49, the applicant states:

“The expansion of Forest Hills Dialysis will have no effect on competition in Wilson County. ... this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 49 the applicant states:

“The expansion of Forest Hills Dialysis will enhance accessibility to dialysis for current and projected patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

Regarding the impact of the proposal on quality, in Section N, page 49, the applicant states:

“Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 49, the applicant states:

“...DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients.”

Considering all the information in the application, 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 (see Sections B, C, F, N and Q of the application and any exhibits)
- Quality (see Sections B, C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections B, C, L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q, Form A, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies over 100 dialysis facilities owned, operated, or managed by a DaVita related entity located in North Carolina.

In Section O.2, pages 51-52, the applicant states that, during the 18 months immediately preceding the submittal of the application, one facility, Waynesville Dialysis Center, had an

incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*”. The applicant further states that Waynesville Dialysis Center is currently in compliance. 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.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.
- NA- The applicant is not proposing to establish a new kidney disease treatment center or dialysis facility. Therefore, this Rule is not applicable to this review.
- (b) An applicant proposing to increase the number of dialysis stations in:
- (1) an existing dialysis facility; or
 - (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

- C- In Section C, page 21, and on Form C in Section Q, the applicant projects that Forest Hills Dialysis Center will serve 97 patients on 35 stations, or a rate of 2.8 patients per station per week, as of the end of the first operating year following project completion, which meets the performance standard. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

- C- In Section C, pages 20-21, and in Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.