

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 18, 2020

Findings Date: June 18, 2020

Project Analyst: Mike McKillip

Team Leader: Gloria C. Hale

Project ID #: J-11888-20

Facility: Durham Dialysis

FID #: 955621

County: Durham

Applicant: DVA Renal Healthcare, Inc.

Project: Add no more than seven dialysis stations to the existing Durham Dialysis facility pursuant to the facility need determination for a total of no more than 29 stations upon completion of this project and Project I.D. # J-11785-19 (add five dialysis 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 Renal Healthcare, Inc (hereinafter referred to as “the applicant” or DaVita) proposes to add no more than seven dialysis stations to the existing Durham Dialysis facility pursuant to the facility need determination for a total of no more than 29 stations upon completion of this project and Project I.D. # J-11785-19 (add five dialysis stations).

Need Determination (Condition 2)

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 Durham 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 Durham Dialysis on page 154 of the 2020 SMFP is 98.0 percent or 3.92 patients per station per week, based on 98 in-center dialysis patients and 25 certified dialysis stations (98 patients / 25 stations = 3.92; $3.92 / 4 = 98.00\%$). [Note: Eight dialysis stations were relocated from Durham Dialysis to Downtown Durham Dialysis per Project I.D. #J-11273-16 and were certified as of June 17, 2019.]

As shown in Table 9E on page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Durham Dialysis is up to nine additional stations; thus, the applicant is eligible to apply to add up to nine stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than seven new stations to Durham Dialysis, which is consistent with the 2020 SMFP calculated facility need determination for up to nine 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 which is applicable to this review. Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 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.”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.5 (a) and (d), pages 13-16, Section N.2(b), page 51; Section O, pages 53-54; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.5 (b) and (d), pages 14-15, Section C.7, page 24; Section L, pages 46-49; Section N.2(c), page 51; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.5 (c) and (d), pages 15-16; Section N.2(a), page 51; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of safety and quality, equitable access, and maximum healthcare value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

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 reasons stated above.

- (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.

The applicant proposes to add no more than seven dialysis stations to the existing Durham Dialysis facility pursuant to the facility need determination for a total of no more than 29 stations upon completion of this project and Project I.D. # J-11785-19 (add five dialysis stations).

The following table, summarized from page 7 of the application, shows the current and projected number of dialysis stations at Durham Dialysis.

Durham Dialysis		
# of Stations	Description	Project ID #
17	Total # of existing certified stations as reported in the SMFP in effect on the day the review will begin	
7	# of stations to be added as part of this project	J-11888-20
	# of stations to be deleted as part of this project	
	# of stations previously approved to be added but not yet certified	
	# of stations previously approved to be deleted but not yet certified	
5*	# of stations proposed to be added in an application still under review	J-11785-19
	# of stations proposed to be deleted in an application still under review	
29	Total # of stations upon completion of all facility projects	

*Project I.D. # J-11785-19 proposed to add ten dialysis stations, but the Agency conditionally approved only five dialysis stations, effective January 10, 2020.

As outlined in the table above, in this application, the applicant proposes to add seven dialysis stations for a total of 29 stations upon the project completion.

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

In Section C.2, page 19, the applicant provides the patient origin for in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patients at Durham Dialysis for the last full operating year (CY2019), as summarized in the table below.

Durham Dialysis Patient Origin - CY2019

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Durham	90	91.8%	0	0.0%	0	0.0%
Wake	3	3.1%	0	0.0%	0	0.0%
Alamance	1	1.0%	0	0.0%	0	0.0%
Orange	2	2.0%	0	0.0%	0	0.0%
Virginia	1	1.0%	0	0.0%	0	0.0%
Other States	1	1.0%	0	0.0%	0	0.0%
Total	98	100.0%	0	0.0%	0	0.0%

Totals may not sum due to rounding

As indicated in the table above, Durham Dialysis does not provide home dialysis training and support and does not propose to add a home dialysis program as part of this project. The following table summarizes projected patient origin for the second full operating year (CY2023) following project completion, as provided in Section C.3, page 20.

Durham Dialysis Projected Patient Origin - CY2023

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Durham	90	91.8%	0	0.0%	0	0.0%
Wake*	3	3.1%	0	0.0%	0	0.0%
Alamance*	1	1.0%	0	0.0%	0	0.0%
Orange*	2	2.0%	0	0.0%	0	0.0%
Virginia	1	1.0%	0	0.0%	0	0.0%
Other States	1	1.0%	0	0.0%	0	0.0%
Total	98	100.0%	0	0.0%	0	0.0%

*In Section C.3, the applicant projects no change in either the total number of patients nor the patient origin of the patients at Durham Dialysis. However, in the table on page 20, the applicant erroneously lists Mecklenburg, Rowan and Stanly rather than Wake, Alamance and Orange counties. The error is corrected in the table shown above.

Totals may not sum due to rounding

In Section C, pages 20-22, the applicant provides the assumptions and methodology it used to project IC, HH, and PD patient origin. The applicant states that the in-center patient origin is based upon the facility census as of December 31, 2019. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.3, pages 20-22, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it assumes the patients from Durham County dialyzing at Durham Dialysis on December 31, 2019 will continue to dialyze there and will not increase through the first two operating years of the proposed project.

- The applicant assumes the patients from outside Durham County will continue to dialyze at Durham Dialysis, but does not assume any growth in patients from those counties or states.
- The project is scheduled for completion on January 1, 2022. Therefore, Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022 and OY2 is CY2023, January 1-December 31, 2023.

In-Center Projected Utilization

In Section C.3, page 22, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

The applicant begins with the Durham County in-center patients as of December 31, 2019.	90
The applicant projects the Durham County in-center patients forward one year to December 31, 2020 assuming no growth.	$90 \times 1.0 = 90$
The applicant adds eight patients from outside Durham County for a projected census for December 31, 2020.	$90 + 8 = 98$
The applicant projects the Durham County in-center patients forward one year to December 31, 2021 assuming no growth.	$90 \times 1.0 = 90$
The applicant adds eight patients from outside Durham County for a projected census for December 31, 2021.	$90 + 8 = 98$
The applicant projects the Durham County in-center patients forward one year to December 31, 2022 assuming no growth.	$90 \times 1.0 = 90$
The applicant adds eight patients from outside Durham County. This is the projected ending census for Operating Year 1 .	$90 + 8 = 98$
The applicant projects the Durham County in-center patients forward one year to December 31, 2023 assuming no growth.	$90 \times 1.0 = 90$
The applicant adds eight patients from outside Durham County. This is the projected ending census for Operating Year 2 .	$90 + 8 = 98$

The applicant projects to serve 98 in-center patients in OY1 and 98 in-center patients in OY2. Thus, the applicant projects that Durham Dialysis will have a utilization rate of 84.5% or 3.38 patients per station per week ($98 \text{ patients} / 29 \text{ stations} = 3.38 / 4 = 0.845$ or 84.5%) in OY1. The projected utilization of 3.38 patients per station per week at the end of OY1 exceeds 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 begins the projections with the existing Durham County patient census at Durham Dialysis as of December 31, 2019.
- The applicant projects the Durham County patient census at Durham Dialysis will not increase through the first two operating years of the project.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Access

In Section C.7, page 24, 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...Durham 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.3, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Durham Dialysis
 Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	3	3.1%	0.0	0.0%	0.0	0.0%
Insurance*	5	5.1%	0.0	0.0%	0.0	0.0%
Medicare*	71	72.4%	0.0	0.0%	0.0	0.0%
Medicaid*	19	19.4%	0.0	0.0%	0.0	0.0%
Other (VA)	0	0.0%	0.0	0.0%	0.0	0.0%
Total	98	100.0%	0.0	0.0%	0.0	0.0%

Totals may not sum due to rounding

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

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 projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) 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

The applicant proposes to add no more than seven dialysis stations to the existing Durham Dialysis facility pursuant to the facility need determination for a total of no more than 29 stations upon completion of this project and Project I.D. # J-11785-19 (add five dialysis stations).

In Section E.2, page 30, 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 maintaining the status quo is not an effective alternative due to the high utilization rate at the facility.
- *Relocating stations from another DaVita facility* – The applicant states that this alternative is less effective due the fact that the three other established facilities were all operating above 75 percent utilization and the three other facilities had lower utilization rates only because they were all recently established ten-station facilities.

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

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

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 reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. DVA Renal Healthcare, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the 2020 State Medical Facilities Plan, DVA Renal Healthcare, Inc. shall develop no more than seven additional dialysis stations at Durham Dialysis a total of no more than 29 certified dialysis stations upon completion of this project and Project I.D. # J-11785-19 (add five dialysis stations), which shall include any home hemodialysis training or isolation stations.**
 - 3. DVA Renal Healthcare, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than seven dialysis stations to the existing Durham Dialysis facility pursuant to the facility need determination for a total of no more than 29 stations upon completion of this project and Project I.D. # J-11785-19 (add five dialysis stations).

Capital and Working Capital Costs

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

ITEM	AMOUNT
Construction Costs	\$0
Equipment and Furniture	\$14,364
Miscellaneous Costs	\$0
Total	\$14,364

In Section F.3, pages 32-33, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project because Durham Dialysis is an operational facility.

Availability of Funds

In Section F.2, page 31, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	DAVITA, INC.
Loans	\$0
Accumulated Reserves or OE*	\$14,364
Other (Specify)	\$0
Total	\$14,364

*OE = Owner's Equity

Exhibit F-2 contains a copy of a letter from the Chief Accounting Officer of DaVita which states that DaVita is the parent and 100% owner of DVA Renal Healthcare, Inc. and that DaVita has committed cash reserves for the capital costs of the project and will make those funds available to DVA Renal Healthcare, Inc. Further, Exhibit F-2 also contains a copy of Form 10K for DaVita, Inc., for year ending December 31, 2019. The Consolidated Balance Statements for DaVita, Inc. indicate it had cash and cash equivalents of \$1.1 billion and total assets exceeding \$17 billion as of December 31, 2019.

Financial Feasibility

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

Durham Dialysis Projected Revenue and Operating Expenses		
	OY 1 CY2022	OY 2 CY2023
Total Treatments (IC)	14,524	14,524
Total Gross Revenue (charges)	\$4,062,162	\$4,062,162
Total Net Revenue	\$3,809,161	\$3,809,161
Average Net Revenue per Treatment	\$262	\$262
Total Operating Expenses (costs)	\$3,307,239	\$3,344,023
Average Operating Expense per Treatment	\$228	\$230
Net Income / Profit	\$501,921	\$465,138

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 for the following reasons:

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

C

The applicant proposes to add no more than seven dialysis stations to the existing Durham Dialysis facility pursuant to the facility need determination for a total of no more than 29 stations upon completion of this project and Project I.D. # J-11785-19 (add five dialysis 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.*” Thus, the service area for this application is Durham County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Durham County as of December 31, 2018.

Durham County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	# of Certified Stations	# In-Center Patients	Utilization
Bull City Dialysis	DaVita	16	44	68.75%
Downtown Durham Dialysis*	DaVita	0	0	0.00%
Durham Dialysis	DaVita	25	98	98.00%
Durham Regional Dialysis	DaVita	10	14	35.00%
Durham West Dialysis	DaVita	27	79	73.15%
Hope Valley Dialysis*	DaVita	0	0	0.00%
Research Triangle Park Dialysis	DaVita	10	21	52.50%
Southpoint Dialysis	DaVita	16	69	107.81%
FMC Dialysis Services of Briggs Avenue	BMA	29	105	90.52%
FMC Dialysis Services West Pettigrew	BMA	24	74	77.08%
Freedom Lake Dialysis Center	BMA	26	94	90.38%
FKC Eno River*	BMA	0	0	0.00%
FMC South Durham Dialysis	BMA	18	66	91.67%

Source: 2020 SMFP, Table 9B.

*Facility under development

In Section G.2, page 37, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. The applicant states:

“While adding stations at this facility does increase the number of stations in Durham 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 addition of stations, 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 an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a facility need determination at Durham Dialysis, as calculated using the methodology in the 2020 SMFP, for the proposed seven additional dialysis stations.
- The applicant adequately demonstrates that the seven proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

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 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 Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Durham Dialysis, as summarized below.

POSITION	FTE Positions as of 12/31/19	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.00	1.00	1.00
Registered Nurses	3.00	4.00	4.00
Technicians (PCT)	7.00	11.00	11.00
Dietitian	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Administrative	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
Total	14.50	19.50	19.50

Source: Section Q, Form H

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 Operating Costs. In Section H, pages 38-39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 39, the applicant identifies the current medical director for the facility. In Exhibit H-4, the applicant provides a letter from the medical director indicating his intent to continue to serve as medical director for the proposed services.

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 40, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

Durham Dialysis Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	To be available on premises
Self-care training (in-center)	To be available on premises
Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program	Durham West Dialysis
Psychological counseling	To be available on premises
Isolation – hepatitis	To be available on premises
Nutritional counseling	To be available on premises
Social Work services	To be available on premises
Acute dialysis in an acute care setting	Duke University Hospital
Emergency care	Duke University Hospital
Blood bank services	Duke University Hospital
Diagnostic and evaluation services	Duke University Hospital
X-ray services	Duke University Hospital
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Duke University Hospital
Vascular surgery	Duke University Hospital
Transplantation services	Duke University Hospital
Vocational rehabilitation & counseling	Durham Department of Vocational Rehabilitation
Transportation	Access, Absolute, and H2GO

Source: Table on page 40 of the application.

In Section I, pages 40-41, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I of the application.

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 47, the applicant provides the historical payor mix for Durham Dialysis patients during CY2019 for its existing services, as shown in the table below.

Durham Dialysis Payor Mix CY2019

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	3	3.1%	0.0	0.0%	0.0	0.0%
Insurance*	5	5.1%	0.0	0.0%	0.0	0.0%
Medicare*	71	72.4%	0.0	0.0%	0.0	0.0%
Medicaid*	19	19.4%	0.0	0.0%	0.0	0.0%
Other (VA)	0	0.0%	0.0	0.0%	0.0	0.0%
Total	98	100.0%	0.0	0.0%	0.0	0.0%

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

In Section L.1(a), page 46, the applicant provides comparison of the demographical information on Durham Dialysis patients and the service area population during CY2019, as summarized below.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	36.7%	52.3%
Male	63.3%	47.7%
Unknown	0.0%	0.0%
64 and Younger	72.2%	86.9%
65 and Older	27.8%	13.1%
American Indian	0.0%	0.9%
Asian	1.1%	5.5%
Black or African-American	82.2%	37.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	2.2%	53.7%
Other Race	14.4%	2.5%
Declined / Unavailable	0.0%	0.0%

Conclusion

The Agency reviewed the:

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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 47, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 47, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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.3, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Durham Dialysis
 Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	3	3.1%	0.0	0.0%	0.0	0.0%
Insurance*	5	5.1%	0.0	0.0%	0.0	0.0%
Medicare*	71	72.4%	0.0	0.0%	0.0	0.0%
Medicaid*	19	19.4%	0.0	0.0%	0.0	0.0%
Other (VA)	0	0.0%	0.0	0.0%	0.0	0.0%
Total	98	100.0%	0.0	0.0%	0.0	0.0%

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

As shown in the table above, in the second full year of operation, the applicant projects that 3.1% of in-center dialysis services will be provided to self-pay patients, 72.4% to Medicare patients and 19.4% to Medicaid patients.

On page 48, 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, stating the payor mix is based upon the actual payor mix from the most recent operating year (CY2019).

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Durham Dialysis.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 48-49, 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 50, 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.

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

The applicant proposes to add no more than seven dialysis stations to the existing Durham Dialysis facility pursuant to the facility need determination for a total of no more than 29 stations upon completion of this project and Project I.D. # J-11785-19 (add five dialysis 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.*” Thus, the service area for this application is Durham County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Durham County as of December 31, 2018.

Durham County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	# of Certified Stations	# In-Center Patients	Utilization
Bull City Dialysis	DaVita	16	44	68.75%
Downtown Durham Dialysis*	DaVita	0	0	0.00%
Durham Dialysis	DaVita	25	98	98.00%
Durham Regional Dialysis	DaVita	10	14	35.00%
Durham West Dialysis	DaVita	27	79	73.15%
Hope Valley Dialysis*	DaVita	0	0	0.00%
Research Triangle Park Dialysis	DaVita	10	21	52.50%
Southpoint Dialysis	DaVita	16	69	107.81%
FMC Dialysis Services of Briggs Avenue	BMA	29	105	90.52%
FMC Dialysis Services West Pettigrew	BMA	24	74	77.08%
Freedom Lake Dialysis Center	BMA	26	94	90.38%
FKC Eno River*	BMA	0	0	0.00%
FMC South Durham Dialysis	BMA	18	66	91.67%

Source: 2020 SMFP, Table 9B.

*Facility under development

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 51, the applicant states:

“The expansion of Durham Dialysis will have no effect on competition in Durham County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, 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, quality, and access to medically underserved groups, in Section N.2, page 51, the applicant states:

“As discussed in Section B, 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. The expansion of Durham 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. 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.”

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 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.2, pages 53-54, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in one DaVita facility; Waynesville Dialysis Center. The applicant states that a plan of correction was prepared and accepted, and that Waynesville Dialysis Center is currently back 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.

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.

(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.3, page 22, the applicant projects that Durham Dialysis will serve 98 in-center patients on 29 stations, or a rate of 3.38 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

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

-C- In Section C.3, pages 20-22, the applicant provides the assumptions and methodology it used to project utilization of the facility.