

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 10, 2019

Findings Date: December 10, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: J-11785-19

Facility: Durham Dialysis

FID #: 955621

County: Durham

Applicant: DVA Renal Healthcare, Inc.

Project: Add no more than 5 stations for a total of no more than 22 stations upon project completion

### 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. (the applicant) proposes to add no more than five dialysis stations to its Durham Dialysis facility for a total of no more than 22 stations upon completion of this project. Durham Dialysis does not currently offer a peritoneal dialysis (PD) or a home hemodialysis (HHD) program. The parent company of DVA Renal Healthcare, Inc. is DaVita, Inc. (DaVita).

#### **Need Determination**

The 2019 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 the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there

is no county need determination for Durham County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Durham Dialysis in the July 2019 SDR is 3.92 patients per station per week. This utilization rate was calculated based on 98 in-center dialysis patients and 25 certified dialysis stations as of December 31, 2018 (98 patients /25 stations = 3.92 patients per station per week). Application of the facility need methodology indicates that five additional stations are needed for this facility, as illustrated in the following table.

<b>OCTOBER 1 REVIEW-JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		98.0%
Certified Stations		25
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>25</b>
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		98
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR1)		99
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	-1
	Multiply the difference by 2 for the projected net in-center change	-2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	-0.0202
(ii)	Divide the result of Step (i) by 12	-0.0017
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	-0.0202
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	96.0202
(v)	Divide the result of Step (iv) by 3.2 patients per station	30.0063
	and subtract the number of certified and pending stations to determine the number of stations needed	5.0063

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2019 SDR. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add five new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2019 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*, on page 31 of the 2019 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.”*

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 11-12, Section K, page 40, Section N, page 48, Section O, pages 50-51, and Exhibit O-2. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B, page 13, Section C, page 22, Section L, pages 43-45, Exhibit L-4 and Section N, page 48. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B, page 13, in supplemental information, Section F, pages 28-31, Section K, page 41, Section N, page 48 and Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

### **Conclusion**

The Agency reviewed the:

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

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

- (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

The applicant proposes to add no more than five dialysis stations for a total of no more than 22 stations upon completion of this project.

**Patient Origin**

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Durham Dialysis is in Durham County. Thus, the service area for this review is Durham County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

County	Current (CY2018)		Second Full FY of Operation following Project Completion (CY 2022)	
	Patients	% of Total	Patients	% of Total
Durham	93	94.9%	101	92.7%
Alamance	0	0.0%	1	0.9%
Cleveland	1	1.0%	0	0.0%
Franklin	0	0.0%	1	0.9%
Granville	2	2.0%	1	0.9%
Orange	1	1.0%	1	0.9%
Wake	1	1.0%	2	1.8%
Other States	0	0.0%	2	1.8%
Total	98	100.0%	109	100.0%

Source: Section C, pages 17 -18.

In Section C, pages 17-20, 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, pages 17-20, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B, page 10, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the July 2019 SDR.

- The July 2019 SDR shows that Durham Dialysis operated at a utilization rate of 98.0% (3.92 patients per station per week) as of December 31, 2018 and had 98 in-center (IC) patients and 25 certified stations. The applicant states that as of June 30, 2019 there were 95 IC patients utilizing the facility of which 87 were residents of Durham County with eight IC patients residing in other counties or out of state.
- The applicant subtracts the eight dialysis stations that were relocated to Downtown Durham Dialysis per Project I.D. #J-11273-16 and were certified as of June 17, 2019.
- The applicant projects the first full operating year of the project will be January 1, 2021 – December 31, 2021 (CY2021) and the second full operating year will be January 1, 2022 – December 31, 2022 (CY2022).
- The applicant begins the projections for the future patient population of Durham Dialysis by using the in-center patient census of 87 patients from Durham County, as of June 30, 2019.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Durham County which is 4.6%, as published in the July 2019 SDR, to project the Durham County patient population forward.
- The applicant does not project an increase in the eight patients who dialyze at the facility as of June 30, 2019 and live in other NC counties or out of state.

The information is reasonable and adequately supported for the following reasons:

- The facility need methodology from the July 2019 SDR shows a need for five additional dialysis stations at Durham Dialysis.
- The applicant bases projected utilization using historical patient data from Durham Dialysis projected forwarded by the Five-Year AACR for Durham County.

#### *Projected Utilization*

In Section C, pages 17-20, the applicant provides projected utilization as summarized in the following table.

Durham Dialysis	In-Center Patients
As of June 30, 2019, there were 87 Durham County IC patients	87
Project the Durham County IC patients forward six months to December 31, 2019, using one-half the Five-Year AACR for Durham County which is 4.6%.	$87 \times 1.023 = 89.001$
Project the Durham County IC patients forward to December 31, 2020, using the Five-Year AACR for Durham County of 4.6%.	$89.001 \times 1.046 = 93.09505$
Project the Durham County IC patients forward to December 31, 2021, using the Five-Year AACR for Durham County.	$93.09505 \times 1.046 = 97.3774$
Add the 8 patients from outside Durham County currently dialyzing at Durham Dialysis. <b>This is the IC patient census at the end of OY1.</b>	$97.3774 + 8 = 105.3774$
Project the Durham County IC patients forward to December 31, 2022, using the Five-Year AACR for Durham County.	$97.3774 \times 1.046 = 101.8567$
Add the 8 patients from other counties currently dialyzing at Durham Dialysis. <b>This is the IC patient census at the end of OY2.</b>	$101.8567 + 8 = 109.8567$

The applicant states on page 20 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2021) and OY2 (CY2022) the facility is projected to serve 105 and 109 in-center patients, respectively.

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

- OY1: 4.773 patients per station per week, or 119.33% ( $105 \text{ patients} / 22 \text{ stations} = 4.773 / 4 = 1.1933$  or 119.33%).
- OY2: 4.955 patients per station per week, or 123.88% ( $109 \text{ patients} / 22 \text{ stations} = 4.955 / 4 = 1.2388$  or 123.88%).

The projected utilization of 4.773 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 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 starts with the 87 existing Durham County patients dialyzing at Durham Dialysis as of June 30, 2019.
- The Durham County patients are projected to increase based on 4.6% per year which is the Five-Year AACR for Durham County as reported in Table D of the July 2019 SDR.
- The applicant projects no growth for patients who utilize the facility and live outside Durham County.
- The utilization rate by the end of OY1 exceeds the minimum standard of 3.2 patients per station per week.

**Access**

In Section C, page 22, 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 the handicapped, 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, handicapped persons, elderly and other under-served persons.”*

In Section L, page 45, 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.

**Durham Dialysis Payor Mix  
FY2 (CY2022)**

<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicaid*	17.7%
Medicare*	78.1%
Commercial Insurance*	4.2%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 45 of the application.

\*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the 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 or elimination of a service, or the relocation of a facility or a 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 five dialysis stations for a total of no more than 22 stations upon completion of this project.

In supplemental information, Section E, page 27, 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 have addressed the growth at the facility and thus was not the least costly or most effective alternative.
- Relocate stations from another DaVita facility- the applicant states that while four of its seven facilities in Durham County are operating at under 80% utilization in the July 2019 SDR, none of the four are viable for station relocation: Durham West's utilization is 73.15%, however its utilization is currently higher after four stations were relocated from Durham West to the Downtown Durham facility; Research Triangle Park and Durham Regional each only have 10 stations and Bull City is currently scheduled to be relocated. Therefore, this alternative was not the least costly or most effective alternative.



In supplemental information, page 27, the applicant states that its proposal is the most effective alternative because it ensures the facility will proactively address the issues of access and growth at the facility.

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
- Supplemental information requested 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 and any supplemental responses. In the event that representations conflict, DVA Renal Healthcare, Inc. shall materially comply with the last made representation.**
  - 2. Pursuant to the facility need determination in the July 2019 SDR, DVA Renal Healthcare, Inc. shall develop no more than five additional stations for a total of no more than 22 certified stations at Durham Dialysis upon project completion, 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 five dialysis stations for a total of no more than 22 stations upon completion of this project.

### **Capital and Working Capital Costs**

In supplemental information, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$8,475
<b>Total</b>	<b>\$8,475</b>

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

In Section F, page 30, the applicant states that there are no start-up costs or initial operating expenses since this is an existing facility that is already operational.

### **Availability of Funds**

In supplemental information, Section F, page 28, the applicant states that the capital cost will be funded as shown in the table below.

Type	DaVita	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$8,475	\$8,475
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$8,475</b>	<b>\$8,475</b>

\* 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, 2018. As shown on page F-6, Consolidated Statements of Cash Flow, Form 10-K, DaVita, Inc. had cash and total assets exceeding \$8 billion.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In supplemental information 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 shown in the table below.

	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year
Total Treatments	15,265	15,885
Total Gross Revenues (Charges)	\$4,274,247	\$4,448,068
Total Net Revenue	\$4,004,064	\$4,166,897
Average Net Revenue per Treatment	\$262	\$262
Total Operating Expenses (Costs)	\$2,967,231	\$3,062,652
Average Operating Expense per Treatment	\$194	\$193
Net Income	\$1,036,833	\$1,104,245

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
- Supplemental information requested by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates 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 5 dialysis stations for a total of no more than 22 stations upon completion of this project.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Durham Dialysis is in Durham County. Thus, the service area for this review 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.

<b>Durham County Dialysis Facilities</b>				
<b>Certified Stations and Utilization as of December 31, 2018</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b># of Certified Stations</b>	<b># In-Center Patients</b>	<b>Utilization</b>
Bull City Dialysis**	DaVita	16	44	68.75%
Bull City Dialysis*	DaVita	0	0	0.00%
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: Section G, page 38; July 2019 SDR, Table B.

\* Facility under development or which was not operational at the time of data collection for the July 2019 SDR.

\*\*Per Project I.D. #J-11450-18, this facility is being relocated to a new location.

In Section G, pages 33-34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. On page 34 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:

- While four of the seven operating DaVita facilities are operating at less than 80% utilization, none of the four facilities are viable options from which to relocate stations: Durham Regional and Triangle Park only have 10 stations, the minimum required, while Durham West is currently above 80% utilization after transferring four stations to Downton Durham, and Bull City is scheduled to be relocated before the end of the year.
- The applicant adequately demonstrates the need patients have for the additional dialysis stations at this specific location in addition to the approved stations.

**Conclusion**

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In supplemental information, Section Q, Form H Staffing, the applicant provides current and projected OY2 staffing for the proposed services in full-time equivalents (FTEs) as illustrated in the following table.

<b>POSITION</b>	<b>Current FTE Positions</b>	<b>OY2 PROJECTED FTE POSITIONS</b>
RN	3.0	3.0
Technician (Patient Care)	7.0	9.0
Administrator	1.0	1.0
Dietician	1.0	1.0
Social Worker	1.0	1.0
Administrative/ Business Office	1.0	1.0
Bio-med Technician	0.5	0.5
<b>Total</b>	<b>14.5</b>	<b>16.5</b>

Source: Supplemental information, Section Q, Form H of the application.

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in supplemental information, Form F.4, which is found in supplemental Section Q. In supplemental information, Section H.2 and H.3, pages 35 and 36, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. In supplemental information, Section H, page 36, 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. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. In Exhibits H-1 through H-4 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.
- Supplemental information requested by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all 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.1, page 37, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

<b>Durham Dialysis Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
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

In Section I.2, page 38, and Exhibit I, the applicant describes its existing and proposed relationships with other local health care and social services providers. The applicant provides supporting documentation in Exhibit I. 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.

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 to construct any new space or renovate any existing space. 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.1, page 44, the applicant provides the historical payor mix during CY2018 for the proposed services, as shown in the table below.

**Durham Dialysis Payor Mix  
Last Full OY (CY2018)**

Payor Category	Percent of Total Patients
Medicaid*	17.7%
Medicare*	78.1%
Commercial Insurance*	4.2%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 44 of the application.

\*Including any managed care plans.

In Section L, page 43, 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	43.2%	52.3%
Male	56.8%	47.7%
Unknown	0.0%	0.0%
64 and Younger	73.7%	86.9%
65 and Older	26.3%	13.1%
American Indian	0.0%	0.9%
Asian	1.1%	5.5%
Black or African-American	83.2%	37.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	15.8%	53.7%
Other Race	0.0%	2.5%
Declined / Unavailable	0.0%	0.0%

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 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, in Section L.2, page 44, the applicant states it has no obligation to provide uncompensated care, community service or access by minorities or handicapped persons.

In Section L, page 44, the applicant states that during the last five years no patient civil rights equal access complaints have been filed against the facility.

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 45, 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.

**Durham Dialysis Payor Mix  
FY2 (CY2022)**

<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicaid*	17.7%
Medicare*	78.1%
Commercial Insurance*	4.2%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 45 of the application.

\*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 78.1% of total services will be provided to Medicare patients and 17.7% to Medicaid patients.

On page 45, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant bases the projected payor mix on the facility's historical payor mix, and
- the applicant's proposed patient origin is based on historical patient origin of the facility.

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, page 45, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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 47, 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

The applicant proposes to add no more than 5 dialysis stations for a total of no more than 22 stations upon completion of this project.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Durham Dialysis is in Durham County. Thus, the service area for this review 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.

<b>Durham County Dialysis Facilities</b>				
<b>Certified Stations and Utilization as of December 31, 2018</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b># of Certified Stations</b>	<b># In-Center Patients</b>	<b>Utilization</b>
Bull City Dialysis**	DaVita	16	44	68.75%
Bull City Dialysis*	DaVita	0	0	0.00%
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: Section G, page 38; July 2019 SDR, Table B.

\* Facility under development or which was not operational at the time of data collection for the July 2019 SDR.

\*\*Per Project I.D. #J-11450-18, this facility is being relocated to a new location.

In Section N, page 48, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 48, 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.*

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Section B, supplemental information, Section F and supplemental information, Section Q of the application and any exhibits)
- Quality services will be provided (see Sections B and O of the application and any exhibits)
- Access will be provided to underserved groups (see Sections B and L of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

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

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

- (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 provides a list of the over 90 dialysis facilities in North Carolina owned and operated by DaVita.

In Section O.2, page 50, the applicant states that, during the 18 months immediately preceding the submittal of the application an incident of immediate jeopardy occurred in one of these facilities, Waynesville Dialysis Center. The applicant provides documentation regarding the deficiency and subsequent measures taken by that facility to ensure compliance with CMS Conditions for Coverage. In Section O, page 51 and in Exhibit O, the applicant states that the deficiency at Waynesville Dialysis Center has been corrected and that Waynesville Dialysis Center was back in compliance as of June 7, 2019. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- The applicant is not proposing to establish a new ESRD facility.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In supplemental information, Section C, pages 17-20, the applicant demonstrates that Durham Dialysis will serve a total of 105 in-center patients at the end of OY1 (CY 2021) for a utilization rate of 119.33% or 4.773 patients per station per week (105 patients / 22 stations = 4.773/ 4 = 1.1933 or 119.33%). 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 supplemental information, Section C, pages 17-20, the applicant provides the assumptions and methodology used to project utilization of the facility.