

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 5, 2018

Findings Date: April 5, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11450-18

Facility: Bull City Dialysis

FID #: 180047

County: Durham

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Relocate an existing 16-station dialysis facility known as Duke Hospital Dialysis to a new location and change the name of the facility to Bull City Dialysis

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC and/or the applicant), d/b/a Bull City Dialysis proposes to relocate an existing 16-station dialysis facility to a new location and change the name of the facility from Duke Hospital Dialysis to Bull City Dialysis. The parent company of TRC is DaVita, Inc. On December 31, 2017, DaVita, Inc., acquired the existing 16-station end stage renal disease (ESRD) facility known as Duke Hospital Dialysis. One of the requirements for acquisition of the facility included the relocation of the facility within 18 months of the transaction. The existing facility is located at 1306 Morreene Road in Durham and the proposed new location for the facility is 3607 Witherspoon Boulevard in Durham. The facility currently

offers a peritoneal dialysis (PD) program, which the applicant plans to continue offering following completion of the proposed project.

Need Determination

The applicant is proposing to relocate existing dialysis stations within Durham County. Neither the county nor the facility need methodologies in the 2018 State Medical Facilities Plan (2018 SMFP) are applicable to this review. Additionally, Policy GEN-3: Basic Principles is not applicable because neither need methodology is applicable to the review.

Policies

There are two policies in the 2018 SMFP that are applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27 and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 33.

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate existing dialysis stations within Durham County, thus there will be no change to the dialysis inventory of Durham County. Therefore, the application is consistent with Policy ESRD-2

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its

certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure is greater than \$2 million, but less than \$5 million. In Section B-5, pages 11-12, Section K-1, pages 39-40, and Exhibits B-5 and K-1(d) the applicant describes how it will assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the projects plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

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.

C

The applicant proposes to relocate Duke Hospital Dialysis, an existing facility with 16 dialysis stations to a new location and change the name of the facility to Bull City Dialysis. The facility currently offers a peritoneal dialysis (PD) program which the applicant plans to continue offering following completion of the proposed project. On December 31, 2017, DaVita, Inc., acquired the existing 16-station ESRD facility. One of the requirements for acquisition of the facility was that it be relocated within 18 months of the transaction.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the 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.”* Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

The applicant states on page 18 that Duke Hospital Dialysis was acquired by DaVita, Inc., on January 1, 2018, therefore no historical data is available. However, in written correspondence submitted to Healthcare Planning, the applicant stated that DaVita, Inc., became owner of Duke Hospital Dialysis effective December 31, 2017. In clarifying information received by the Agency on March 19, 2018, the applicant states the facility was acquired as of December 31, 2017. Therefore, as Duke Hospital Dialysis was operational, its historical information is being included. According to the January 2018 Semi-Annual Dialysis Report (SDR), Duke Hospital Dialysis had a utilization rate of 70.31 percent or 2.81 patients per station per week, as of June 30, 2017. DaVita, Inc., reported the following patient origin for Duke Hospital Dialysis on its end of year data collection form as of December 31, 2017.

DUKE HOSPITAL DIALYSIS HISTORICAL PATIENT ORIGIN CY2017			
COUNTY	IC	PD	COUNTY

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	PATIENTS	PATIENTS	PATIENTS AS % OF TOTAL
Durham	33	6	65.0%
Orange	4	0	6.7%
Granville	1	2	5.0%
Wake	1	5	10.0%
Alamance	1	1	3.3%
Guilford	0	1	1.6%
Beaufort	0	1	1.6%
Brunswick	0	1	1.6%
Columbus	0	1	1.6%
Sampson	0	1	1.6%
South Carolina	0	1	1.6%
Total	40	20	100.0%

Source: 2017 Data Collection Form

As illustrated above, Duke Hospital Dialysis had an in-center (IC) patient population of 40 patients and a peritoneal dialysis (PD) patient population of 20 patients, as of December 31, 2017, according to information submitted by DaVita, Inc. A Data Collection Form dated December 18, 2017 was submitted to the Agency by Duke Hospital Dialysis indicating the facility had 22 PD patients, however, DaVita submitted a Data Collection Form dated February 9, 2018 which indicated the facility had 20 PD patients as of December 31, 2017. The table above used the most recent data obtained for Duke Hospital Dialysis. For the purpose of reviewing the proposed application to relocate the facility the variance of the 2 PD patients does not affect the review.

In Section C.1, page 13, the applicant provides the projected patient origin for Bull City Dialysis for the first two years of operation following project completion for its IC patients and PD patients, as follows:

BULL CITY DIALYSIS			
	OPERATING YEAR 1 CY 2020	OPERATING YEAR 2 CY 2021	COUNTY PATIENTS AS % OF TOTAL

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COUNTY	IC PATIENTS	PD PATIENTS	IC PATIENTS	PD PATIENTS	OY 1	OY 2
Durham	43	8	45	9	68.9%	70.1%
Orange	3	1	3	1	5.4%	5.2%
Granville	1	1	1	1	2.7%	2.6%
Wake	0	4	0	4	5.4%	5.2%
Alamance	2	1	2	1	4.1%	3.9%
Guilford	0	1	0	1	1.3%	1.3%
Chatham	0	1	0	1	1.3%	1.3%
Beaufort	0	1	0	1	1.3%	1.3%
Brunswick	0	1	0	1	1.3%	1.3%
Columbus	0	1	0	1	1.3%	1.3%
Cumberland	0	1	0	1	1.3%	1.3%
Harnett	0	1	0	1	1.3%	1.3%
Mitchell	0	1	0	1	1.3%	1.3%
Sampson	0	1	0	1	1.3%	1.3%
South Carolina	0	1	0	1	1.3%	1.3%
Total	49	25	51	26	100%	100%

The applicant does not propose to serve home hemodialysis, however, the applicant projects to provide support for 25 peritoneal dialysis patients in operating year one. Home hemodialysis (HHD) was not previously offered at Duke Hospital Dialysis, nor does DaVita propose to offer those services at the purposed Bull City Dialysis facility. On page 35, the applicant states home hemodialysis services will be provided at Durham West Dialysis.

The applicant provides the assumptions and methodology for the projections above on pages 13-16. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 13-14, the applicant states the need for the proposed new Bull City Dialysis facility is based on the following factors:

- The applicant proposes to relocate the facility pursuant to Policy ESRD-2. (page 7)
- Duke Hospital Dialysis was purchased by DaVita, Inc., on or about December 31, 2017. One of the requirements for acquisition of the facility was that the facility be relocated within 18 months of the transaction. (page 3).
- The applicant proposes to serve the same population at the new Bull City Dialysis as historically served by Duke Hospital Dialysis, including the PD patient population. (page 13)

Projected Utilization

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The applicant projects that Operating Year One (OY1) and Operating Year Two (OY2) for the proposed project will be Fiscal Year (FY) 2020 and FY2021, respectively. In Section C.1, page 14, the applicant provides its methodology for projecting in-center (IC) utilization as follows:

Bull City Dialysis In-Center	
DaVita begins with the interim IC patient population as of 7/1/2017 and projects it forward using the Durham County Five Year Average Annual Change Rate of 4.0%.	$39 \times 1.04 = 40.56$
DaVita projects the IC patients forward one year to 7/1/18 using the Durham County Five Year Average Annual Change Rate of 4.0%.	$40.56 \times 1.04 = 42.18$
DaVita projects the IC patients forward one year to 7/1/19 using the Durham County Five Year Average Annual Change Rate of 4.0%.	$42.18 \times 1.04 = 43.87$
OY1: Add 6 patients from outside Durham County. This is the projected census for OY 1.	$43.87 + 6 = 49.86$
Project the Durham County patient population forward one year.	$43.87 \times 1.04 = 45.62$
OY2: Add 6 patients from outside Durham County. This is the projected census for OY 2.	$45.62 + 6 = 51.62$

On page 15, the applicant states it rounded the patient population down. Thus, the applicant projects that Bull City Dialysis will serve a total of 49 in-center patients at the end of OY1 for a utilization rate of 76.56% or 3.06 patients per station per week (49 patients / 16 stations = 3.06 / 4 = 0.7656 or 76%). On page 14, the applicant states,

“We realize that the utilization rate at the end of operating year one does not meet the requirement of at least 3.2 patients per station. However, DaVita just acquired the facility and will be in a position to offer the opportunity for any of the current patients being served by DaVita-operated facilities in Durham County to transfer their care to the relocated facility when it is completed and certified.”

One of the requirements for acquisition of the facility by DaVita included the relocation of the facility within 18 months of the transaction. As such, the performance standard required by 10A NCAC 14C .2203(b) is not applicable to this review because the applicant is not proposing to establish a new facility or increase the number of dialysis stations in an existing facility.

Projected utilization for in-center patients is reasonable and adequately supported for the following reasons:

- The facility proposes to serve the same population as historically served by Duke Hospital Dialysis at the proposed Bull City Dialysis facility.
- Projected in-center patient population growth is based on the Five Year Average Annual Change Rate for Durham County.

Home Hemodialysis and Peritoneal Dialysis

On page 15 of the application, the applicant states the facility currently provides peritoneal training and that it will continue to offer those services. The applicant projects that PD patients will grow at a rate of at least one patient during OY2. Thus, the applicant projects to have 25 PD patients in OY1 and 26 PD patients in OY2. The applicant states that Duke Hospital Dialysis did not offer HHD services/training nor does the applicant propose to offer those services at Bull City Dialysis. In Section I, page 35, the applicant states that HHD training will be provided for patients at Durham West Dialysis.

The assumptions the applicant used to project PD patient utilization in Section C, page 15 is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section C, page 16, 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.”

In Section A.11, page 5, the applicant states that DaVita operates over 70 facilities in North Carolina. In Section L.1(a), pages 44-45, the applicant states that Bull City Dialysis will serve a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved 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.

Projected Payor Mix OY2

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of PD Patients
Medicare	26.5%	28.0%	10.5%
Medicaid	11.3%	12.4%	0.0%
Commercial Insurance	16.5%	13.5%	47.4%
Medicare / Commercial	25.9%	24.9%	36.8%
Medicare / Medicaid	18.9%	20.2%	5.3%

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VA	0.9%	1.0%	0.0%
Total	100.0%	100.0%	100.0%

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.

C

The applicant proposes the relocation of Duke Hospital Dialysis from 1303 Morreen Road in Durham to 3607 Witherspoon Boulevard in Durham. In addition, the applicant proposes a name change from Duke Hospital Dialysis to Bull City Dialysis. On page 3, the applicant states one of the requirements for acquisition of the facility included the relocation of the facility within 18 months of the transaction. On page 16, the applicant states that the current facility is located on the campus of Duke University. The applicant states that after a review of DaVita operated facilities within the county, the applicant selected the area near US Highway 15/501 and interstate 40 because DaVita does not have a facility in close proximity to that location. Additionally, on page 16, the applicant states the location will allow for easy patient access. On page 13, the applicant projects to continue serving the in-center and PD patient population currently served at the facility. According to Google Maps the proposed new Bull City Dialysis

facility will be 5.8 miles from the current location, thus the facility will still be accessible to the same population presently served, including underserved groups.

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 demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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

In Section E.1, page 23, the applicant states the alternative considered prior to submitting this application was to maintain the status quo. On page 23, the applicant states that its proposal is the most effective because DaVita is required to relocate the facility within eighteen months of acquiring of the facility.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because the terms of the agreement with Duke Hospital Dialysis made it necessary for the applicant to relocate the facility within 18 months of acquisition of the facility.

Conclusion

The Agency reviewed the:

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

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

- 1. Total Renal Care of North Carolina, LLC, d/b/a Bull City Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD 2, Total Renal Care of North Carolina, LLC shall relocate 16 stations from Duke Hospital Dialysis to Bull City Dialysis for a total of 16 stations at Bull City Dialysis upon project completion.**
 - 3. Total Renal Care of North Carolina, LLC, d/b/a Bull City Dialysis shall install plumbing and electrical wiring through the walls for no more than 16 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Prior to the issuance of the certificate of need Total Renal Care of North Carolina, LLC, d/b/a Bull City Dialysis shall provide documentation of the existence of ancillary and support services agreements at Bull City Dialysis.**
 - 5. Total Renal Care of North Carolina, LLC, d/b/a Bull City Dialysis 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 relocate an existing 16 station dialysis facility to a new location and to change the name of the facility from Duke Hospital Dialysis to Bull City Dialysis.

Capital and Working Capital Costs

In Section F.1, page 24, the applicant projects \$2,415,000 in capital costs to develop the proposed project as summarized below:

Projected Capital Costs

Sub-Total Construction Costs	\$1,630,554
Miscellaneous Costs	\$784,446
Total	\$2,415,000

In Sections F.10 - F.12, page 27, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 25, the applicant states it will finance the capital costs with accumulated reserves/owner’s equity of DaVita, Inc.

Exhibit F.1 contains a letter dated January 12, 2018, from the Chief Accounting Officer for DaVita, Inc., which authorizes and commits cash reserves for the capital costs of the proposed project in the amount of \$2,415,000.

Exhibit F-7 contains DaVita, Inc. United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2016. As of December 31, 2016, DaVita had \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets, and \$5,822,999,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	Operating Year 1 CY2020	Operating Year 2 CY2021
Total Treatments	7,188	7,410
Total Gross Revenues (Charges)	\$5,279,842	\$5,413,466
Total Net Revenue	\$5,169,117	\$5,299,561
Total Operating Expenses (Costs)	\$3,377,646	\$3,465,352

Net Income	\$1,791,471	\$1,834,209
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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
- 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 demonstrates that the capital costs is based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate an existing 16-station dialysis facility to a new location and to change the name of the facility from Duke Hospital Dialysis to Bull City Dialysis.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the 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.*” Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently eight operational dialysis facilities and three facilities under development in Durham County, as illustrated below.

DURHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2017				
Dialysis Facility/Owner	Certified Stations 12/1/17	# In-center Patients	Percent Utilization	Patients per Station
Downtown Durham Dialysis (DaVita)*	10	0	0	0
Duke Hospital Dialysis** (DaVita)	16	45	70.31%	2.8125
Durham Dialysis (DaVita)	28	101	90.18%	3.6071
Durham Regional Dialysis (DaVita)*	10	0	0	0
Durham West Dialysis (DaVita)	30	91	75.83%	3.0333
FMC Dialysis Services of Briggs Ave. (BMA)	29	91	78.45%	3.1379
FMC Dialysis Ser. W. Pettigrew (BMA)	24	67	69.79%	2.7917
Freedom Lake Dialysis Unit (BMA)	26	91	87.50%	3.5000
FMC Eno River (BMA)*	10	0	0	0
FMC South Durham (BMA)	18	60	83.33%	3.333
Research Triangle Park Dialysis (DaVita)	10	10	25.00%	1.0000
Southpoint Dialysis (DaVita)	16	79	123.44%	4.9375
Totals	227	635	69.93%	2.7973

Source: January 2018 SDR.

*New stations approved but not certified as of 12/1/17

**Acquired by DaVita on December 31, 2017

As shown in the table above, three facilities are under development, two of which are owned by DaVita. Of DaVita's operational facilities, utilization ranged from 75.83% at Durham West Dialysis to 123.44% at Southpoint Dialysis. On December 31, 2017, DaVita, Inc. submitted a request for an exemption to acquire Duke Hospital Dialysis. With the acquisition of Duke Hospital Dialysis, DaVita, Inc., will own/operate seven of the eight existing and approved dialysis facilities in Durham County. Overall, the operational facilities in Durham County owned/operated by DaVita operated with a utilization above 80%, as illustrated below.

DaVita Operational Facilities Durham County				
Dialysis Facility/Owner	Certified Stations 12/1/17	# In-center Patients	Percent Utilization	Patients per Station
Duke Hospital Dialysis* (DaVita)	16	45	70.31%	2.8125
Durham Dialysis (DaVita)	28	101	90.18%	3.6071
Durham West Dialysis (DaVita)	30	91	75.83%	3.0333
Research Triangle Park Dialysis (DaVita)	10	10	25.00%	1.0000
Southpoint Dialysis (DaVita)	16	79	123.44%	4.9375
Totals	118	386	81.78%	3.2712

*Acquired by DaVita on December 31, 2017

In Section G of the application, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis facilities in Durham County.

The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved dialysis services in the service area for the following reasons:

- The proposal would not result in an increase in the number of dialysis stations in Durham County.
- The applicant adequately demonstrates that the proposed relocation of existing dialysis stations is needed in addition to the existing or approved dialysis stations in Durham County.

Conclusion

The Agency reviewed the:

- Applications
- Exhibits in 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.

In Section H, page 31, the applicant provides current and projected staffing in full time equivalents (FTEs) for Bull City Dialysis. The applicant does not project a change in its FTE staff, as DVA is seeking to relocate an existing facility.

POSITION	CURRENT # FTEs	PROJECTED # FTEs
Registered Nurse	3.00	3.00
Technician (PCT))	6.00	6.00
Administrator	1.00	1.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Home Training RN	1.00	1.00
Admin Assistant	1.00	1.00
Biomed Tech	0.50	0.50
Total	13.50	23.00

The assumptions and methodology used to project staffing are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, Section R. In Section H.7, page 34, the applicant provides the projected direct care staff for Bull City Dialysis in OY2 (CY2021). In Section H.6, page 34, the applicant states that dialysis services will be available Monday through Saturday from 6:00am – 4:00pm.

In Section I, page 36, the applicant identifies Dr. David I. Ortiz Melo as the Medical Director of the facility. Exhibit I, of the application contains a signed letter from Dr. Ortiz Melo of Duke University Medical Center stating his willingness to serve as the Medical Director. In Section H, pages 32-33, the applicant describes the methods used to recruit and fill vacant or new positions.

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
- 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.

- (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.

CA

In Section I, page 35, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I contains a letter from the medical director of the proposed facility expressing his support and willingness to serve in that role. The applicant discusses coordination with the existing health care system on page 37. Exhibits I-1 contains a laboratory services agreement with DaVita Laboratory Services, Inc.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above and subject to Condition #5 in Criterion 4 of these findings.

- (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.

C

In Section K, page 40, the applicant states, the proposed facility is projected to consist of a 5,440 square foot treatment space which will include space for an isolation room. The applicant provides line drawings of the proposed facility in Exhibit K-1(a). The drawing depicts a 10,955 square foot facility, including office space, two peritoneal dialysis rooms, fifteen dialysis stations located in open space and one isolation dialysis station in an enclosed room, for a total of 16 in-center stations. In Section F.1, page 24, the applicant lists its projected costs, including \$1,630,554 for construction and \$784,446 for miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$2,415,000. In Section B.5, pages 11-12, the applicant describes its plans to assure improved energy-efficiency and water conservation. Costs and charges are described by the applicant in Section F, pages 24-25, and in Section R pro forma financial statements. On pages 41-42, the applicant identifies the proposed site and provides information about the current owner, zoning

and special use permits for the site and the availability of water, sewer, waste disposal and power at the site.

Conclusion

The Agency reviewed the:

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

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

- (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.7, page 48 of the application, the applicant provides the historical payor mix for Duke Hospital Dialysis during CY 2017.

Payor Mix CY2017

Payment Category	Percent of Total Patients	Percent of IC Patients	Percent of PD Patients
Medicare	26.5%	28.0%	10.5%
Medicaid	11.3%	12.4%	0.0%
Commercial Insurance	16.5%	13.5%	47.4%
Medicare / Commercial	25.9%	24.9%	36.8%
Medicare/Medicaid	18.9%	20.2%	5.3%
VA	0.9%	1.0%	0.0%
Total	100.0%	100.0%	100.0%

The IPRO ESRD Network of the South Atlantic (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states, and is representative of North Carolina patient profiles.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

The Agency reviewed the:

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

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

- The facility is an existing facility with a historical payor mix.
- DaVita proposes to serve the same in-center patient population as previously served by Duke Hospital Dialysis.
- The applicant adequately demonstrates the extent to which medically underserved populations currently use DaVita's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved.

¹<http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- (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.3, page 47, the applicant states:

“Bull City Dialysis has no obligation under any applicable federal regulations, to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 47, the applicant states that there have been no patient civil rights complaints filed within in the past five years.

The Agency reviewed the:

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

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

- (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.1(b), page 45 of the application, the applicant provides the information required by this criterion. The following table illustrates the projected payor mix during the second full fiscal year.

Projected Payor Mix OY2

Payment Source	Percent of Total	Percent of IC	Percent of PD
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	Patients	Patients	Patients
Medicare	26.5%	28.0%	10.5%
Medicaid	11.3%	12.4%	0.0%
Commercial Insurance	16.5%	13.5%	47.4%
Medicare / Commercial	25.9%	24.9%	36.8%
Medicare / Medicaid	18.9%	20.2%	5.3%
VA	0.9%	1.0%	0.0%
Total	100.0%	100.0%	100.0%

On page 45, the applicant states that the payor mix projections are based on historical payment source of DaVita operated facilities in Durham County for CY2017. The projected payor mix for the facility is also identical to the historical payor mix for Duke Hospital Dialysis.

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.

- (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.4, page 47, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Bull City Dialysis. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies ... The patient ... will be referred to a qualified nephrologist for final evaluation and then admission ...”

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.

- (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 49, the applicant states that Bull City Dialysis has offered the facility as a site for clinical rotations for Durham Technical Community College's nursing students. Exhibit M.2 contains a letter from DaVita offering the proposed Bull City Dialysis as a clinical training site.

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 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 relocate an existing 16-station dialysis facility to a new location and to change the name of the facility from Duke Hospital Dialysis to Bull City Dialysis.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the 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.*” Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently eight operational dialysis facilities and three facilities under development in Durham County, as illustrated below.

DURHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2017				
Dialysis Facility/Owner	Certified Stations 12/1/17	# In-center Patients	Percent Utilization	Patients per Station
Downtown Durham Dialysis (DaVita)*	10	0	0	0
Duke Hospital Dialysis** (DaVita)	16	45	70.31%	2.8125
Durham Dialysis (DaVita)	28	101	90.18%	3.6071
Durham Regional Dialysis (DaVita)*	10	0	0	0
Durham West Dialysis (DaVita)	30	91	75.83%	3.0333
FMC Dialysis Services of Briggs Ave. (BMA)	29	91	78.45%	3.1379
FMC Dialysis Ser. W. Pettigrew (BMA)	24	67	69.79%	2.7917
Freedom Lake Dialysis Unit (BMA)	26	91	87.50%	3.5000
FMC Eno River (BMA)*	10	0	0	0
FMC South Durham (BMA)	18	60	83.33%	3.333
Research Triangle Park Dialysis (DaVita)	10	10	25.00%	1.0000
Southpoint Dialysis (DaVita)	16	79	123.44%	4.9375
Totals	227	635	69.93%	2.7973

Source: January 2018 SDR.

*New stations approved but not certified as of 12/1/17

**Acquired by DaVita on December 31, 2017

As shown in the table above, three facilities are under development, two of which is owned by DaVita. Of DaVita’s operational facilities, utilization ranged from 75.83% at Durham West Dialysis to 123.44% at Southpoint Dialysis. On December 1, 2017, DaVita, Inc. submitted a request for an exemption to acquire Duke Hospital Dialysis. With the acquisition of Duke Hospital

Dialysis, DaVita, Inc., will own/operate seven of the eight existing and approved dialysis facilities in Durham.

In Section N.1, page 50, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

“The relocation of Bull City Dialysis will have no effect on competition in Durham County. The relocation of Bull City Dialysis will address the physical inadequacy of the existing facility and the requirement to relocate the facility by July 1, 2019.”

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 Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

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.

- (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 A.11, page 5, the applicant states that DaVita Inc., operates over 70 facilities North Carolina. In Section O, page 51 and Exhibit O.3, the applicant identifies the one kidney disease treatment center located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation

during the 18 month look-back period. Goldsboro South Dialysis had an immediate jeopardy citation. The facility is back in compliance with the Medicare conditions of participation as of November 20, 2017. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision.

After reviewing and considering information provided by the applicant and the quality of care provided at all 70 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.

NA

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are not applicable to this review because the applicant does not propose to establish a new end stage renal disease facility nor does that applicant propose to add stations to an existing facility.