

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 28, 2019

Findings Date: October 28, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: F-11742-19

Facility: Marshville Dialysis Center

FID #: 060374

County: Union

Applicant: DVA Healthcare Renal Care, Inc.

Project: Relocate facility for a total of 16 stations upon project completion of this project and Project ID# F-11490-18 (relocation of 4 stations from Union County Dialysis to Marshville Dialysis Center), and develop a home training program

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Healthcare Renal Care, Inc. (hereinafter known as “DVA” or “the applicant”) proposes to relocate the existing 12-station Marshville Dialysis Center (also referred to in this application as Indian Trail Dialysis) facility from Marshville to a new location in Indian Trail for a total of no more than 16 dialysis stations at the new location upon completion of this project and Project ID# F-11490-18 (relocation of 4 stations from Union County Dialysis to Marshville Dialysis Center), and develop a home training program. The new site for the facility will be 6044 West Highway 74 in Indian Trail and the facility will be renamed Indian Trial Dialysis.

The facility does not currently offer a peritoneal dialysis (PD) program nor does it offer a home hemodialysis (HH) program. The parent company of DVA is DaVita, Inc. (DaVita).

### **Need Determination**

Neither the county nor the facility need methodologies in the July 2019 Semiannual Dialysis Report (SDR) and the 2019 State Medical Facilities Plan (SMFP) are applicable to this review.

### **Policies**

There are two policies in the 2019 SMFP which are applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations, on page 25 and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31.

### **Policy ESRD-2**

Policy ESRD-2 states:

*“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 a contiguous county 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 Marshville Dialysis Center facility to a new location in Union County. The relocated facility would be a 16-station dialysis facility upon completion of this project and Project ID # F-11490-18 (relocation of 4 stations from Union County Dialysis to Marshville Dialysis Center). Upon relocation, the facility would be renamed Indian Trail Dialysis. The existing Marshville Dialysis Center facility, the Union County Dialysis facility and the proposed new location are all located within Union County.

According to Table D of the July 2019 SDR, Union County has a projected surplus of one dialysis station. However, this project proposes a relocation of existing dialysis stations within Union County; thus, the surplus will not be affected. There would be no change in the number of dialysis stations in Union County. Therefore, the application is consistent with Policy ESRD-2.

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 31 of the 2019 SMFP, 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 are required to submit a plan of 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.”*

In Section B, pages 13-15, the applicant explains why it believes its application is conforming with Policy GEN-4. On page 14, the applicant states that its development department is working to align new facilities with Village Green 2020 Environmental Goals that include implementing strategies to reduce water use by 30% per treatment and conserve energy by reducing energy use and carbon emissions by 10% per treatment.

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes 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 the existing 12-station Marshville Dialysis Center facility from Marshville to a new location in Indian Trail for a total of no more than 16 dialysis stations at the new location upon completion of this project and Project ID# F-11490-18 (relocation of 4 stations from Union County Dialysis to Marshville Dialysis Center), and develop a home training program.

**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.” Thus, the service area is Union County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected in-center (IC) and PD patient origin.

**Marshville Dialysis Center: Current and Projected Patient Origin**

County	Last Full Operating Year [CY 2018]		Operating Year 2 (OY2) [CY2022]		County Patients as a % of Total	
	IC Patients	PD Patients	IC Patients	PD Patients	OY1	OY2
Union	19	0	39	3	65.5%	100.0%
Anson	8	0	0	0	27.6%	0.0%
Stanley	1	0	0	0	3.4%	0.0%
Other States	1	0	0	0	3.4%	0.0%
<b>Total</b>	<b>29</b>	<b>0</b>	<b>39</b>	<b>3</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Tables on pages 17 and 18 of the application.

In Section C, pages 18-21, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 21-22, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states that multiple reasons support the need to relocate Marshville Dialysis Center to a new location:

- The proposed location would better align county stations with current and future need and bring services to a fast-growing area.
- The facility is currently underutilized.
- As part of Project ID #H-11545-18 some Marshville Dialysis Center patients will transfer their care to Dialysis Care of Anson County.

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

- The applicant demonstrates the need to relocate the dialysis facility by relocating existing dialysis stations consistent with Policy ESRD-2. The discussion regarding Policy ESRD-2 found in Criterion (1) is incorporated herein by reference.
- The applicant has considered an option other than relocation and provides reasonable and adequately supported information to justify the choice to relocate the facility.
- The applicant bases the need to relocate the facility on factors such as the county five-year average annual change rate (AACR), known non-Union County patient transfers to another facility and population growth in and around the proposed new location.
- The applicant provided copies of signed patient letters from existing DVA IC patients who reside in Union County that they would be better served by a facility in the proposed location in Indian Trail and that they would be interested in transferring to the proposed relocated facility in Indian Trail.

#### *Projected Utilization*

In Section C, pages 18-20, the applicant describes its need methodology and assumptions for IC patient projected utilization for the proposed facility summarized as follows:

- Operating Year 1 (OY1) = Calendar Year (CY) 2021
- Operating Year 2 (OY2) = Calendar Year (CY) 2022
- A total of 22 patients who are residents of Union County and who currently receive their dialysis care at DaVita facilities in Union County have signed letters indicating that the proposed new location for the Marshville Dialysis Center facility would be more convenient for them and that they would consider transferring their dialysis care to the proposed relocated facility in Indian Trail.
- A total of 13 patients who are residents of Union County and who currently receive their dialysis care at DaVita facilities in Mecklenburg County have signed letters indicating that the proposed new location for the Marshville Dialysis Center facility

would be more convenient for them and that they would consider transferring their dialysis care to the proposed relocated facility in Indian Trail.

- As of December 31, 2018, 29 IC patients were dialyzing at Marshville Dialysis Center, 19 were residents of Union County and 10 were non-Union County residents ( Anson, Stanley and Other States).
- Per Project ID #H-11545-18, eight IC patients who are residents of Anson County and currently dialyzing at Marshville Dialysis Center are expected to transfer their care to Dialysis Care of Anson County upon certification of that facility projected to be January 1, 2020.
- The applicant assumes the 35 patients will transfer their dialysis care to the relocated Marshville Dialysis Center facility site in Indian Trail upon certification of that facility which is documented by the signed patient letters of support provided in Exhibit C which state that, *“Since Indian Trail Dialysis would be more convenient for me and I will have access to the same services that have become so important to me at my current facility, I would be willing to transfer my care to Indian Trail Dialysis.”*
- The applicant uses the Five-Year AACR for Union County which is 6.8%, as published in the July 2019 SDR, to project the Union County patient population forward.
- The applicant projects no IC patients who are non-Union County residents.

The table below summarizes the beginning patient census on January 1, 2021 and its growth through the ending patient census on December 31, 2022.

<b>Marshville Dialysis Center</b>	<b>In-Center Patients</b>
Begin January 1, 2021 with 35 Union County IC patients	35
Project the Union County IC patients forward one year to December 31, 2021, using the Five-Year Average Annual Change Rate (AACR) for Union County. <b>This is the IC patient census at the end of OY1</b>	$35 \times 1.068 = \mathbf{37.38}$
Project the Union County IC patients forward one year to December 31, 2022, using the Five-Year AACR for Union County. <b>This is the IC patient census at the end of OY2.</b>	$37.38 \times 1.068 = \mathbf{39.92}$

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 37 and 39 in-center patients, respectively.

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

- OY1: 2.3 patients per station per week, or 57.81% ( $37 \text{ patients} / 16 \text{ stations} = 2.3125 / 4 = 0.5781$  or 57.81%).

- OY2: 3.4 patients per station per week, or 85.0% (39 patients/16 stations = 2.4375/4 = 0.6094 or 60.94%).

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

- The applicant projects the starting patient census for the proposed facility based on existing Union County IC patients who currently dialyze at DaVita facilities in Union and Mecklenburg counties, each of whom has signed a letter expressing an intent to consider transferring dialysis care to the proposed facility because it would be more convenient for them.
- The applicant's growth projections assume that the dialysis patient census will increase annually by 6.8%, which is consistent with the five-year AACR for Union County, as reported in the July 2019 SDR, Table D.
- The minimum standard of 3.2 in-center patients per station per week required by the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2203(b) are not applicable to this review.

#### *PD Patient Utilization*

In Section C, page 21, the applicant provides the assumptions and the methodology used to project utilization of PD patients for the first two years of operation following the completion of the project.

- OY 1 is projected to be CY2021; and OY 2 is projected to be CY2022.
- The applicant states it is reasonable to assume that the Marshville Dialysis Center PD program will grow at a rate of at least one patient per year during the period of growth.
- Two existing DVA PD patients who currently reside in Union County but receive their support in Mecklenburg County at Charlotte East Dialysis have signed letters indicating that the proposed new location for the Marshville Dialysis Center facility would be more convenient for them and that they would consider transferring their dialysis care to the proposed relocated facility in Indian Trail.
- The applicant projects an increase of one patient per year during the growth period, beginning with two PD patient as of January 1, 2021 and reaching 4 PD patients by the end of OY2.
- The applicant averages the beginning and ending census for the year to reach an average number of patients per year for financial calculations.

The table below summarizes the beginning patient census on January 1, 2021 and its growth through the ending patient census on December 31, 2022, as presented by the applicant on page 17 of the application.

	# Patients, Beginning	# Patients, Ending	Average # Patients
As of January 1, 2021, with 2 PD patients utilizing Marshville Dialysis Center. Increase the PD patient census by 1, projecting the PD patients forward one year to December 31, 2012. <b>This is the PD patient census at the end of OY1.</b>	2	3	2.5
Project the PD patients forward one year to December 31, 2021 adding 1 PD patient. <b>This is the PD patient census at the end of OY2.</b>	3	4	3.5

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

- The applicant starts with the two existing DVA PD patients utilizing Marshville Dialysis Center upon certification of that facility at its new proposed site in Indian Trail based on signed letters from the 2 DVA PD patients.
- The applicant projects growth at a rate of at least one patient per year during the period of growth.

**Access**

In Section C, page 23, the applicant states:

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

*We will make every reasonable effort to accommodate all patients, especially those with special needs such as 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.*

*Indian Trail Dialysis will continue to 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, elderly, and other under-served persons”*

In Section L, page 47, 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.



**Marshville Dialysis Center Payor Mix  
FY2 (CY2022)**

<b>Payor Category</b>	<b>IC Patients as a Percent of Total Patients</b>	<b>PD Patients as a Percent of Total Patients</b>
Medicaid	6.9%	10.0%
Medicare	79.3%	72.5%
Insurance	10.3%	17.5%
Other -VA	3.4%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 47 of the application.

Note: Totals might foot due to rounding.

The projected payor mix is reasonable and adequately supported.

**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 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 to relocate the existing 12-station Marshville Dialysis Center facility from Marshville to a new location in Indian Trail for a total of no more than 16 dialysis stations at the new location upon completion of this project and Project ID# F-11490-18 (relocation of

4 stations from Union County Dialysis to Marshville Dialysis Center), and develop a home training program.

In Section D, page 27, the applicant states that it will relocate the entire dialysis facility to a new location and will no longer offer dialysis services at the current location.

In Section D, page 27, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 27, the applicant states: *“The patient need in Union County will be met through services offered at the relocated Indian Trail Dialysis facility as well as the Union County Dialysis center. Additionally, some Marshville Dialysis Centers patients will transfer to the relocated Dialysis Care of Anson County...and no longer need to travel outside of Anson County to receive treatment.”*

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to relocate the existing 12-station Marshville Dialysis Center facility from Marshville to a new location in Indian Trail for a total of no more than 16 dialysis stations at the new location upon completion of this project and Project ID# F-11490-18 (relocation of 4 stations from Union County Dialysis to Marshville Dialysis Center), and develop a home training program.

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

- Maintain status quo – the applicant states that this alternative is not effective because maintaining an underutilized facility is an ineffective use of certified stations. Maintaining the status quo does not address neither the changing demographics of

Union County nor the current and future underutilization of the facility. Therefore, this was not the least costly or most effective alternative.

On page 29, the applicant states relocating the facility is the most cost-effective approach to better serve current and projected patient population.

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, and
- exhibits to the application.

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

- 1. DVA Healthcare Renal Care, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, DVA Healthcare Renal Care, Inc. shall relocate 16 stations from the existing location of Marshville Dialysis Center to the proposed new site for a total of no more than 16 stations at Marshville Dialysis Center (to be renamed Indian Trail Dialysis) upon completion of this project and Project ID# F-11490-18 (relocation of 4 stations from Union County Dialysis to Marshville Dialysis Center).**
- 3. DVA Healthcare Renal Care, Inc. shall develop a PD home training program as part of this project.**
- 4. DVA Healthcare Renal Care, Inc. shall install plumbing and electrical wiring through the walls for no more than 16 dialysis stations, which shall include any home training and isolation stations.**
- 5. DVA Healthcare Renal Care, 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 relocate the existing 12-station Marshville Dialysis Center facility from Marshville to a new location in Indian Trail for a total of no more than 16 dialysis stations at the new location upon completion of this project and Project ID# F-11490-18 (relocation of 4 stations from Union County Dialysis to Marshville Dialysis Center), and develop a home training program.

**Capital and Working Capital Costs**

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

Site Costs	\$78,150
Construction Costs	\$1,262,728
Miscellaneous Costs	\$748,873
<b>Total</b>	<b>\$2,089,751</b>

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

In Section F, pages 31-32, the applicant projects that there will be no working capital costs because this is an existing facility that is already operational.

**Availability of Funds**

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

**Sources of Capital Cost Financing**

Type	DaVita	Total
Loans	\$	\$
Accumulated reserves or OE *	\$2,089,750	\$2,089,750
Bonds	\$	\$
Other (Specify)	\$	\$
<b>Total Financing</b>	<b>\$2,089,750</b>	<b>\$2,089,750</b>

\* OE = Owner's Equity

Exhibit F-2 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 10K, DaVita, Inc. had adequate cash and assets to fund the capital and working capital cost of the proposed project.

**Financial Feasibility**

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

	<b>1<sup>st</sup> Full Fiscal Year</b>	<b>2<sup>nd</sup> Full Fiscal Year</b>
Total Treatments	5,706	6,178
Total Gross Revenues (Charges)	\$2,040,778	\$2,218,265
Total Net Revenue	\$1,943,781	\$2,113,231
Average Net Revenue per Treatment	\$341	\$342
Total Operating Expenses (Costs)	\$1,844,761	\$1,882,412
Average Operating Expense per Treatment	\$323	\$305
Net Income	\$99,020	\$230,819

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 are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate the existing 12-station Marshville Dialysis Center facility from Marshville to a new location in Indian Trail for a total of no more than 16 dialysis stations at the new location upon completion of this project and Project ID# F-11490-18 (relocation of

4 stations from Union County Dialysis to Marshville Dialysis Center), and develop a home training program.

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.” Thus, the service area is Union County. Facilities may also serve residents of counties not included in their service area.

DVA operates two of the four dialysis facilities in Union County, as shown in the table below.

**Union County Dialysis Facilities  
 as of December 31, 2018**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Marshville Dialysis Center*	DVA	29	Marshville	12	4	60.42%
Union County Dialysis*	DVA	104	Monroe	33	-4	78.79%
Metrolina Kidney Center**	BMA	88	Monroe	22	7	100.00%
Fresenius Kidney Care Indian Trail	BMA	20	Indian Trail	10	0	50.00%

Source: Table B, July 2019 SDR

\*Marshville Dialysis Center was conditionally approved to relocate 4 dialysis stations from Union County Dialysis for a total of 16 dialysis stations. (Project ID #F-11490-18).

\*\*Metrolina Kidney Center was conditionally approved to add 7 dialysis stations for a total of 29 dialysis stations. (Project ID #F-11664-19).

In Section G, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Union County. The applicant states:

*“This certificate of need application does not propose to increase the number of stations in Union County. Relocating the existing and approved stations from Marshville Dialysis Center to a different location will allow DaVita to better serve its current and projected patients, but will not result in the duplication of existing services.”*

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

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

## **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.

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

### C

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

Position	Current FTE Staff	Projected FTE Staff
	12/31/2018	2nd Full Fiscal Year (1/01/2022 – 12/31/2022)
Registered Nurses (RN's)	2.0	2.0
Home Training Nurse	0.0	0.5
Technician (PCT)	4.0	5.0
Administrator	1.0	1.0
Dietician	0.5	0.5
Social Worker	0.5	0.5
Administration/Business Office	0.5	1.0
Biomed Technician	0.5	0.5
<b>TOTAL</b>	<b>9.0</b>	<b>11.0</b>

Source: Sections Q, Form H, page 53 and Form H Staffing, page 63 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 Form F.4, which is found in Section Q. In Section H.2 and H.3, pages 36-37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 37, the applicant identifies the current medical director. In Exhibit H, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibit H, the applicant provides supporting documentation.

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

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for 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, page 38, the applicant states that the following ancillary and support services are necessary for the proposed services:

<b>Marshville Dialysis Center 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	Charlotte East Dialysis To be available on premises To be available on premises
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	Carolinas Healthcare System
Emergency care	Carolinas Healthcare System
Blood bank services	Carolinas Healthcare System
Diagnostic and evaluation services	Carolinas Healthcare System
X-ray services	Carolinas Healthcare System
Laboratory services	DaVita Laboratories Services, Inc.
Pediatric nephrology	Carolinas Healthcare System
Vascular surgery	Carolinas Healthcare System
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehab Services
Transportation	Union County Transportation System



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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (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 41 and clarifying information, the applicant states that the project involves up fitting 11,934 square feet of new leased space at 6044 West Highway 74 in Indian Trail. Line drawings are provided in Exhibit K-1.

On page 41, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On pages 41-42, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section B, pages 14-15 and In Section K, page 42, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 43-44, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Exhibit K-4 documents the location of the site, the availability of the site and the zoning for permitted uses.

### **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.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the

State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 46, the applicant provides the historical payor mix during the last full fiscal year for the proposed services during 1/01/2018 to 12/31/2018, as shown in the table below.

**Last Full Operating Year  
CY2018**

Payor Category	IC Patients as a Percent of Total Patients	PD Patients as a Percent of Total Patients
Medicaid	6.9%	0.0%
Medicare	79.3%	0.0%
Insurance	10.3%	0.0%
Other -VA	3.4%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 46 of the application.

Note: Totals might foot due to rounding.

In Section L, page 45, 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	41.8%	50.8%
Male	58.2%	49.2%
Unknown	0.0%	0.0%
64 and Younger	62.1%	87.3%
65 and Older	27.9%	12.7%
American Indian	0.0%	0.6%
Asian	0.0%	3.4%
Black or African-American	75.9%	12.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	24.1%	71.6%
Other Race	0.0%	11.4%
Declined / Unavailable	0.0%	0.6%

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 46, the applicant states it has no obligation to provide uncompensated care, community service or access by minorities or handicapped persons.

In Section L.2, page 46, 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 47, 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.

**Marshville Dialysis Center Payor Mix  
FY2 (CY2022)**

<b>Payor Category</b>	<b>IC Patients as a Percent of Total Patients</b>	<b>PD Patients as a Percent of Total Patients</b>
Medicaid	6.9%	10.0%
Medicare	79.3%	72.5%
Insurance	10.3%	17.5%
Other -VA	3.4%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 47 of the application.

Note: Totals might foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that for IC patients 79.3% of total services will be provided to Medicare patients and 6.9% to Medicaid patients.

On page 47, 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 because the applicant's proposed patient origin is comparable to the last full year of the facilities from which the patients are being relocated.

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

The Agency reviewed the:

- application, and
- 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 49, 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 relocate the existing 12-station Marshville Dialysis Center facility from Marshville to a new location in Indian Trail for a total of no more than 16 dialysis stations at the new location upon completion of this project and Project ID# F-11490-18 (relocation of 4 stations from Union County Dialysis to Marshville Dialysis Center), and develop a home training program.

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.*” Thus,

the service area is Union County. Facilities may also serve residents of counties not included in their service area.

The applicant operates two of the four dialysis facilities in Union County, as shown in the table below.

**Union County Dialysis Facilities  
 as of December 31, 2018**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Marshville Dialysis Center*	DVA	29	Marshville	12	4	60.42%
Union County Dialysis*	DVA	104	Monroe	33	-4	78.79%
Metrolina Kidney Center**	BMA	88	Monroe	22	7	100.00%
Fresenius Kidney Care Indian Trail	BMA	20	Indian Trail	10	0	50.00%

Source: Table B, July 2019 SDR

\*Marshville Dialysis Center was conditionally approved to relocate 4 dialysis stations from Union County Dialysis for a total of 16 dialysis stations. (Project ID #F-11490-18).

\*\*Metrolina Kidney Center was conditionally approved to add 7 dialysis stations for a total of 29 dialysis stations. (Project ID #F-11664-19).

In Section N, page 50, 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 50, the applicant states:

*“The relocation of the Marshville Dialysis Center will enhance accessibility to dialysis for current and projected patients, and by reducing the economic and physical burden 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 Sections F and Q 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 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 52, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities, Southeastern Dialysis Center-Wilmington and Waynesville Dialysis Center. The applicant provides documentation regarding the deficiencies and subsequent measures taken by those facilities to ensure compliance with CMS Conditions for Coverage. In Section O, page 53 and in Exhibit O, the applicant states that all the problems at Southeastern Dialysis Center-Wilmington and Waynesville Dialysis Center have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and 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.

### NA

The applicant proposes to relocate its existing facility to leased space approximately 19.6 miles from its current location. 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 or to add stations to an existing facility.