

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 22, 2020

Findings Date: April 22, 2020

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: F-11841-20

Facility: Fresenius Kidney Care Indian Trail

FID #: 160339

County: Union

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Relocate no more than 2 dialysis stations from Metrolina Kidney Center for a total of no more than 12 stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA), operates two dialysis facilities in Union County: Metrolina Kidney Center and Fresenius Kidney Care Indian Trail (FKC Indian Trail). BMA proposes to relocate two dialysis stations from Metrolina Kidney Center to FKC Indian Trail for a total of 27 dialysis stations at Metrolina Kidney Center and 12 dialysis stations at FKC Indian Trail upon project completion.

#### **Need Determination**

The 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 170 in the 2020 SMFP, the county need methodology shows there is no county need determination for additional dialysis stations in Union County. An applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology

if the facility's utilization rate as reported in the latest SDR is at least 3.0 patients per station per week, or 75%. According to Table 9B on page 163 of the 2020 SMFP, FKC Indian Trail reported an average of 2.0 patients per station per week as of December 31, 2018. Therefore, neither of the two need determination methodologies in the 2020 SMFP apply to this proposal.

### **Policies**

There is one policy in the 2020 SMFP that applies to this review: Policy ESRD-2: Relocation of Dialysis Stations.

*Policy ESRD-2*, on page 20 of the 2020 SMFP 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 State Medical Facilities Plan; 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 State Medical Facilities Plan.”*

Both Metrolina Kidney Center and FKC Indian Trail are in located in Union County. The application is conforming to Policy ESRD-2.

### **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 because the relocation of two dialysis stations within Union County will have no effect on the number of dialysis stations within the county.

- (2) Repealed effective January 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 two dialysis stations from Metrolina Kidney Center to FKC Indian Trail for a total of 12 dialysis stations at FKC Indian Trail upon project completion. Both facilities are located in Union County.

The following tables, summarized from Section A.4, page 7 of the application, show the existing and proposed dialysis stations at each facility involved in this review:

FKC INDIAN TRAIL		
STATIONS	DESCRIPTION	PROJECT ID #
10	Total existing certified stations as reported in the SMFP in effect on the day this review begins	
+2	Stations to be added as part of this project	F-11841-20
12	Total stations upon completion of above project	
METROLINA KIDNEY CENTER		
STATIONS	DESCRIPTION	PROJECT ID #
29	Total existing certified stations as reported in the SMFP in effect on the day this review begins	
-2	Stations to be deleted as part of this project	F-11841-20
27	Total stations upon completion of above projects	

As shown in the table above, upon project completion, FKC Indian Trail will be certified for 12 dialysis stations, and Metrolina Kidney Center will be certified for 27 dialysis stations upon project completion.

**Patient Origin**

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

In Section C.2, page 17, the applicant provides the historical patient origin for FKC Indian Trail for in-center (IC) patients for the last full operating year (OY), calendar year (CY) 2019 as follows:

**FKC Indian Trail Historical Patient Origin, CY 2019**

COUNTY	IC PATIENTS	% OF TOTAL
Union	32	94.12%
Mecklenburg	1	2.94%
Other States	1	2.94%
<b>Totals</b>	<b>34</b>	<b>100.00%</b>

Source: Section C.2, page 17.  
Numbers may not sum due to rounding.

In Section C.3, page 17, the applicant provides a table showing projected patient origin for FKC Indian Trail in the second operating year, as summarized below:

**FKC Indian Trail Projected Patient Origin, CY 2022**

COUNTY	IC PATIENTS	% OF TOTAL
Union	39.0	97.50%
Mecklenburg	1.0	2.50%
<b>Totals</b>	<b>40.0</b>	<b>100.00%</b>

Source: Section C.2, page 17.  
Numbers may not sum due to rounding.

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

### **Analysis of Need**

In Section C, pages 18 - 19, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states the facility census “of FMC Tarboro” was 20 patients on December 31, 2018 and grew to 34 in-center patients by December 31, 2019. The Project Analyst determined that the reference to FMC Tarboro was a typographical error: the ESRD Data Collection Form for FKC Indian Trail as of December 31, 2018 reported 20 in-center patients, and the ESRD Data Collection Form for FKC Indian Trail as of December 31, 2019 reported 34 in-center patients, a growth of 70% in one year  $[(34 / 20) - 1 = 0.70]$ .
- The applicant states that, given the patient growth over the past year at FKC Indian Trail, failure to add stations could necessitate the addition of a third dialysis shift, which is not ideal for its patients.
- The applicant states the need the dialysis patient population at FKC Indian Trail has for the proposed services is a function of individual patient need for treatment. The

applicant states this proposal seeks to address the needs of the BMA patients utilizing the FKC Indian Trail facility.

- The applicant begins its projections with the number of in-center patients dialyzing at FKC Indian Trail as of December 31, 2019, as reflected in the ESRD Data Collection Forms submitted to the Agency.
- The applicant assumes the Union County dialysis patient population will increase at a rate consistent with the Union County Five Year Average Annual Change Rate (AACR) of 6.8%, as reflected in Table 9C , page 169 of the 2020 SMFP.
- The applicant states the one patient residing in “other states” as of December 31, 2019 was dialyzing as a transient patient; therefore, the applicant will not include that patient in its projections.
- The applicant does not project growth of the patient population from Mecklenburg County, but adds the patient to the projections at the appropriate time. The applicant assumes the Mecklenburg County patient dialyzes at the facility by choice and will continue to choose to dialyze there.

Projected Utilization

In Section C, page 18, the applicant provides projected utilization as summarized in the following table:

The applicant begins with the Union County in-center patients as of December 31, 2019.	32
The applicant projects the Union County patients forward one year to December 31, 2020 using the Union County Five Year AACR of 6.8%.	$32 \times 1.068 = 34.2$
The applicant adds 1 Mecklenburg County patient. This is the projected starting census for OY 1 (CY 2021).	$34.2 + 1 = 35.2$
The applicant projects the Union County patients forward one year to December 31, 2021 using the Union County Five Year AACR of 6.8%.	$34.2 \times 1.068 = 36.5$
The applicant adds 1 Mecklenburg County patient. This is the projected ending census for OY 1 (CY 2021).	$36.5 + 1 = 37.5$
The applicant projects the Union County patients forward one year to December 31, 2022 using the Union County Five Year AACR of 6.8%.	$36.5 \times 1.068 = 39.0$
The applicant adds 1 Mecklenburg County patient. This is the projected ending census for OY 2 (CY 2022).	$39.0 + 1 = 40.0$

The applicant projects to serve 37.5 in-center patients in OY 1 and 40 in-center patients in OY 2. Thus, the applicant projects that FKC Indian Trail will have a utilization rate of 78.13% or 3.13 patients per station per week in OY 1 [ $37.5 \text{ patients} / 12 \text{ stations} = 3.13$ ;  $3.13 / 4 = 0.7813$  or 78.13%]. The projected utilization of 3.13 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins the projections with the existing FKC Indian Trail Union County patient census as of December 31, 2019.
- The applicant projects the Union County patient census at FKC Indian Trail will increase by the Union County Five Year AACR of 6.8%, as reported in the 2020 SMFP.
- The applicant adds the additional patient who does not reside in Union county but who dialyzes at FKC Indian Trail to the patient census projections.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

### Access

In Section C.7, pages 21 - 22, the applicant states that Fresenius operates more than 100 dialysis facilities in North Carolina, each of which has a patient population that includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. Services are provided to all patients, regardless of their ability to pay. In Section L, page 48, the applicant provides the projected payor mix during the second full fiscal year of operation following completion of the project (CY 2022) for FKC Indian Trail, as illustrated in the following table:

PAYOR SOURCE	% OF TOTAL REVENUE
Self Pay	3.41%
Insurance*	13.85%
Medicare*	41.63%
Medicaid*	0.61%
Medicare / Commercial	35.53%
Misc. (VA)	4.97%
<b>Total</b>	<b>100.00%</b>

\*Includes managed care plans.

As illustrated in the table above, the applicant projects that 77.77% of all FKC Indian Trail patients will be Medicare or Medicaid recipients, including Medicare Commercial in CY 2022. On page 48, the applicant states its projected payor mix in OY 2 is based on the facility's recent history. 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 (payer 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 two dialysis stations from Metrolina Kidney Center to FKC Indian Trail for a total of 12 dialysis stations at FKC Indian Trail upon project completion. Both facilities are located in Union County.

In Section D, pages 25 - 28, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following relocation of stations. On page 25, the applicant states the patients who remain at Metrolina Kidney Center will not be adversely impacted by the proposed reduction of stations, stating that the 2020 SMFP indicates that the facility will qualify to add one additional station in 2020. On March 16, 2020 the applicant submitted an application to add one station to Metrolina Kidney Center pursuant to the facility need methodology in the 2020 SMFP.

The applicant provides the assumptions with which it projects utilization at Metrolina Kidney Center following the relocation of two stations, summarized as follows:

- The applicant begins its projections of future patients to be served with 85 in-center patients: the facility census as of December 31, 2019, as reported in the ESRD Data Collection Form submitted to the Agency in February 2020.
- The applicant assumes that the Union County in-center patient census will increase at 6.8% consistent with the Union County Five Year AACR as reported in the 2020 SMFP.
- The applicant states Metrolina Kidney Center also has a home dialysis program, and one station at the facility is dedicated to providing home dialysis training and support. The applicant states the relocation of two in-center stations as proposed in this

application will not impact the home training program or the patients who receive their home training and support at Metrolina Kidney Center.

- The applicant projects that the station relocation will be complete by December 31, 2020, and begins its projections of future patients as of that date, as illustrated in the following table:

The applicant begins with the Union County in-center patients as of December 31, 2019.	85
The applicant projects the Union County in-center patients forward one year to December 31, 2020 using the 6.8% Union County Five Year AACR.	$85 \times 1.068 = 90.8$

The applicant projects that Metrolina Kidney Center will dialyze 90.8 Union County in-center patients on 27 in-center stations, for a utilization of 84.0% or 3.36 patients per station, per week [ $90.8 / 27 = 3.36$ ;  $3.36 / 4 = 0.840$  or 84.0%].

On page 27, the applicant states,

*“This relocation will not have any impact on the patients dialyzing at the facility ... . As demonstrated above, the projected utilization of the facility after relocation of the stations will continue to allow for admission to the facility. And, BMA has committed to filing a CON application for additional stations.”*

Projected utilization is reasonable and adequately supported based on the following reasons:

- The applicant begins its utilization projections with the existing Union County patients currently served at Metrolina Kidney Center.
- The applicant projects the Union County in-center patient population will increase at the 6.8% Union County Five Year AACR as reported in the 2020 SMFP.

On page 27, the applicant states the proposed relocation of stations will not have any effect upon the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care, that the proposed relocation of stations will not have an effect upon access to care for any patient.

### **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

The applicant proposes to relocate two dialysis stations from Metrolina Kidney Center to FKC Indian Trail for a total of 12 dialysis stations at FKC Indian Trail upon project completion. Both facilities are located in Union County.

In Section E.1, page 29, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because it ignores the growth of 70% in the past year, in which the patient census increased from 20 in-center patients to 34 in-center patients. The applicant states that failing to add stations would necessitate a third dialysis shift, which is not ideal for patients.
- Relocate fewer dialysis stations – The applicant states that fewer stations would be inadequate to meet the projected need at FKC Indian Trail.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than two dialysis stations from Metrolina Kidney**

**Center, for a total of no more than 12 dialysis stations at Fresenius Kidney Care Indian Trail.**

- 3. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify two dialysis stations at Metrolina Kidney Center for a total of no more than 27 dialysis stations at Metrolina Kidney Center upon project completion, which shall include any home hemodialysis stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the 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 two dialysis stations from Metrolina Kidney Center to FKC Indian Trail for a total of 12 dialysis stations at FKC Indian Trail upon project completion. Both facilities are located in Union County.

**Capital and Working Capital Costs**

In Form F.1(a), page 72, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	AMOUNT
Construction Costs	\$0
Non-Medical Equipment	\$1,500
Furniture	\$6,000
<b>Total</b>	<b>\$7,500</b>

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

**Availability of Funds**

In Section F.2, page 30, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	SOURCE
Loans	0
Accumulated Reserves or OE*	\$7,500
Other (Specify)	0
<b>Total</b>	<b>\$7,500</b>

\*OE = Owner's Equity

Exhibit F-2 contains a letter dated January 15, 2020 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc. (FMCH), parent company of FKC Indian Trail, authorizing and committing cash reserves in the amount of \$7,500 for the capital costs of the project. The letter states that FMCH currently has \$1.8 billion in cash and cash equivalents and \$20 billion in total assets.

**Financial Feasibility**

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

	OY 1 (CY2021)	OY 2 (CY2022)
Total In-Center Treatments	5,378.02	5,733.66
Total Gross Revenues (Charges)	\$33,833,134	\$36,070,475
Total Net Revenue	\$2,154,086	\$2,296,533
Average Net Revenue per Treatment	\$400.53	\$400.53
Total Operating Expenses (Costs) (From Form A)	\$1,828,405	\$1,851,535
Average Operating Expense per Treatment	\$339.98	\$322.92
<b>Net Income</b>	<b>\$325,681</b>	<b>\$444,998</b>

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.

- The applicant adequately demonstrates 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 two dialysis stations from Metrolina Kidney Center to FKC Indian Trail for a total of 12 dialysis stations at FKC Indian Trail upon project completion. Both facilities are located in Union County.

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

Currently, there are five existing and approved dialysis facilities in Union County. Two are owned by Fresenius Medical Care (FMC). DaVita operates two dialysis facilities in Union County, and has been approved to relocate one of those facilities. See the following table that summarizes the Union County dialysis facilities:

UNION COUNTY DIALYSIS FACILITIES					
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 12/31/18	# PTS. AS OF 12/31/2018	UTILIZATION AS OF 12/31/18
FKC Indian Trail	FMC	Indian Trail	10	20	50.00%
Metrolina Kidney Center	FMC	Monroe	22	88	100.00%
Marshville Dialysis Center*	DaVita	Marshville	12	29	60.42%
Indian Trail Dialysis*	DaVita	Marshville	0	0	0.00%
Union County Dialysis	DaVita	Monroe	33	104	78.79%

Source: Table 9B, 2020 SMFP.

\*Effective November 28, 2019, DaVita was approved to relocate Marshville Dialysis Center and rename it Indian Trail Dialysis.

As shown in the table above, one of the two dialysis facilities operated by FMC was utilized at 100% as of December 31, 2018. The other facility, FKC Indian Trail, was utilized at 50% as of that date.

In Section G.2, 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 the application proposes to relocate existing stations and thus does not propose a change in the inventory of dialysis stations in Union County.

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

- The application proposes a relocation of two existing dialysis stations from one Fresenius Medical Care facility to another in Union County, and therefore would not result in an increase in the number of dialysis stations in Union County.
- The applicant adequately demonstrates that the proposed dialysis station relocation is needed.

**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 Form H, page 83, the applicant provides current full-time equivalent (FTE) staffing for the proposed services. The applicant does not propose to add any additional FTE positions as a result of the relocation of stations.

POSITION	CURRENT FTE POSITIONS
Medical Director	NA*
Administrator (FMC Clinic Manager)	1.00
Registered Nurse	2.00
Patient Care Technician	5.00
Dietician	0.50
Social Worker	0.50
Maintenance	0.50
Director of Operations	0.15
In-Service	0.10
Chief Technician	0.10
<b>Total</b>	<b>9.85</b>

\*The applicant states the medical director is a contract position and not an employee.

The assumptions and methodology used to project staffing are provided in Form H. 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, page 36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 37, the applicant identifies the medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating his interest in continuing to serve in that capacity.

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

### C

In Section I.1, page 38, the applicant includes a list of providers of the necessary ancillary and support services, as shown in the following table:

<b>FKC INDIAN TRAIL ANCILLARY AND SUPPORT SERVICES</b>	
<b>SERVICES</b>	<b>PROVIDER</b>
In-center dialysis/maintenance	FKC Indian Trail
Self-care training (in-center)	Refer to Metrolina Kidney Center (BMA Monroe)
<b>Home Training</b>	
HH PD Accessible follow-up program	Refer to Metrolina Kidney Center (BMA Monroe)
Psychological counseling	Referral to Daymark Recovery Services
Isolation – hepatitis	Provided by the facility
Nutritional counseling	Provided by the facility
Social Work services	Provided by the facility
Acute dialysis in an acute care setting	Referral to Atrium Health - Union
Emergency care	Provided by facility staff until ambulance arrives
Blood bank services	Referral to Atrium Health - Union
Diagnostic and evaluation services	Referral to Atrium Health - Union
X-ray services	Referral to Atrium Health - Union
Laboratory services	Provided by the facility; on site blood draw – analysis by Spectra Labs
Pediatric nephrology	Referral to Atrium Health - Charlotte
Vascular surgery	Referral to Metrolina Vascular Access Center; Sanger Heart and Vascular
Transplantation services	Referral to Atrium Health - Charlotte
Vocational rehabilitation & counseling	Referral to Daymark Counseling
Transportation	Union County Transportation

In Section I.1, page 38, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1.2, I-1.3 and I-1.4.

In Section I.2, page 39, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1.2, I-1.3 and I-1.4.

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 for the reasons stated above.

- (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 January 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space associated with the relocation of two stations as proposed in this application. Therefore, Criterion (12) is not applicable to this review.



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

C

In Section L.1, page 46, the applicant provides the historical payor mix during CY 2018 at FKC Indian Trail, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL
Self-Pay	3.41%
Insurance*	13.85%
Medicare*	41.63%
Medicaid*	0.61%
Medicare/Commercial	35.53%
Miscellaneous (Incl. VA)	4.97%
<b>Total</b>	<b>100.00%</b>

\*Includes any managed care plans

Percentages may not sum due to rounding

In Section L, page 45, the applicant provides the following comparisons:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	45.5%	50.8%
Male	54.5%	49.2%
Unknown	0.0%	0.0%
64 and Younger	42.4%	87.3%
65 and Older	57.6%	12.7%
American Indian	0.0%	0.6%
Asian	3.0%	3.4%
Black or African-American	42.4%	12.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	48.5%	71.6%
Other Race	6.1%	12.0%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 47, the applicant states Fresenius related facilities are under no obligation to provide uncompensated care or community service under any federal regulations.

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

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 48, the applicant provides the projected payor mix during the second full fiscal year of operation following completion of the project (CY 2022) for FKC Indian Trail, as illustrated below.

PAYOR SOURCE	PERCENT OF TOTAL REVENUE
Self Pay	3.41%
Insurance*	13.85%
Medicare*	41.63%
Medicaid*	0.61%
Medicare / Commercial	35.53%
Misc. (VA)	4.97%
<b>Total</b>	<b>100.00%</b>

\*Includes any managed care plans  
Percentages may not sum due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 3.41% of total services will be provided to self-pay patients, 77.16% to Medicare patients (including Medicare/commercial) and 0.61% to Medicaid patients.

On page 48 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 projected payor mix is based on the historical experience of FKC Indian Trail.

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 50, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective January 1, 1987.  
(16) Repealed effective January 1, 1987.  
(17) Repealed effective January 1, 1987.  
(18) Repealed effective January 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 two dialysis stations from Metrolina Kidney Center to FKC Indian Trail for a total of 12 dialysis stations at FKC Indian Trail upon project completion. Both facilities are located in Union County.

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

Currently, there are five existing and approved dialysis facilities in Union County. Two are owned by Fresenius Medical Care (FMC). DaVita operates two dialysis facilities in Union County, and has been approved to relocate one of those facilities. See the following table that summarizes the Union County dialysis facilities:

UNION COUNTY DIALYSIS FACILITIES					
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 12/31/18	# PTS. AS OF 12/31/2018	UTILIZATION AS OF 12/31/18
FKC Indian Trail	FMC	Indian Trail	10	20	50.00%
Metrolina Kidney Center	FMC	Monroe	22	88	100.00%
Marshville Dialysis Center*	DaVita	Marshville	12	29	60.42%
Indian Trail Dialysis*	DaVita	Marshville	0	0	0.00%
Union County Dialysis	DaVita	Monroe	33	104	78.79%

Source: Table 9B, 2020 SMFP.

\*Effective November 28, 2019, DaVita was approved to relocate Marshville Dialysis Center and rename it Indian Trail Dialysis.

As shown in the table above, one of the two dialysis facilities operated by FMC was utilized at 100% as of December 31, 2018. The other facility, FKC Indian Trail, was utilized at 50% as of that date.

In Section N, pages 51 - 53, 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 51, the applicant states:

*“The applicant does not expect this proposal to have effect on the competitive climate in Union County. The applicant does not project to serve dialysis patients currently being served by another provider.*

...

*Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 52, the applicant states Fresenius related facilities have historically provided service to all persons in need of dialysis, regardless of any grouping, category or basis for being an underserved person.

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, C, D, K, N and Q of the application and any exhibits)
- Quality services will be provided (see Sections N and O of the application and any exhibits)

- Access will be provided to underserved groups (see Sections C, D, L and N of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available 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 January 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

In Section Q, Form A, the applicant provides a list of Fresenius related dialysis facilities located in North Carolina.

In Section O.2, page 57, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no quality of care incidents that resulted in a finding of “*Immediate Jeopardy*” (IJ) in any of the Fresenius-related facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius-related 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 January 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

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

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.*
- NA- The applicant is not proposing to establish a new ESRD facility.
- (b) *An applicant proposing to increase the number of dialysis stations in:*  
(1) *an existing dialysis facility; or*  
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*
- C- In Section C, pages 18 - 19, the applicant demonstrates that FKC Indian Trail will serve a total of 37.5 in-center patients at the end of OY 1 (CY 2021) for a utilization rate of 78.1% or 3.125 patients per station per week ( $37.5 \text{ patients} / 12 \text{ stations} = 3.125$ ;  $3.125 / 4 = 0.7813$  or 78.1%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected..*
- C- In Section C, pages 18 - 20, the applicant provides the assumptions and methodology used to project utilization of the facility.