

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 10, 2024

Findings Date: May 10, 2024

Project Analyst: Yolanda W. Jackson

Co-Signer: Gloria C. Hale

Project ID #: F-12498-24

Facility: Metrolina Kidney Center

FID #: 955949

County: Union

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

Project: Add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion

### REVIEW CRITERIA

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “BMA” or “the applicant”) proposes to add no more than two dialysis stations to Metrolina Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 30 stations upon project completion.

#### **Need Determination (Condition 2)**

Chapter 9 of the 2024 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 9C, on page 136 of the 2024 SMFP, the county need methodology shows there is not a county need determination for additional dialysis stations anywhere in the state.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2024 SMFP, if the utilization rate for the facility as reported in the 2024 SMFP is at least 75 percent or 3.0 patients per station per week or greater, as stated in Condition 2.a. The utilization rate reported for the facility is 77.68% or 3.1 patients per station per week, based on 87 in-center dialysis patients and 28 certified dialysis stations (87 patients / 28 stations = 3.1071,  $3.1071 / 4 = 77.68\%$ ).

As shown in Table 9D, on page 138 of the 2024 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to eight additional stations; thus, the applicant is eligible to apply to add up to eight stations during the 2024 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than two new stations to the facility, which is consistent with the 2024 SMFP calculated facility need determination for up to eight stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2024 SMFP that is applicable to this review, *Policy GEN-3: Basic Principles*.

*Policy GEN-3*, page 29 of the 2024 SMFP, states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 21, Section N, page 75, Section O, pages 77 -80 and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 22, Section C, pages 32-33, Section L, pages 66-71, Section N, page 75 and

referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23, Section N, page 75 and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the application is consistent with Condition 2 of the facility need methodology as applied from the 2024 SMFP.
- The applicant adequately demonstrates how the applicant's projected volumes incorporate the concepts of safety and quality, equitable access, and maximum value for resources expended in meeting the facility need and is consistent with *Policy GEN-3*.

(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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

BMA proposes to add no more than two dialysis stations to Metrolina Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

On page 113, the 2024 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 facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

<b>Metrolina Kidney Center Historical Patient Origin CY 2023</b>						
<b>County</b>	<b>In-Center</b>		<b>Home Hemodialysis</b>		<b>Peritoneal Dialysis</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Union	92.0	100.0%	10.0	58.8%	8.0	53.3%
Anson	0.0	0.0%	4.0	23.5%	3.0	20.0%
Mecklenburg	0.0	0.0%	0.0	0.0%	2.0	13.3%
South Carolina	0.0	0.0%	3.0	17.6%	2.0	13.3%
<b>Total</b>	<b>92.0</b>	<b>100.0%</b>	<b>17.0</b>	<b>100.0%</b>	<b>15.0</b>	<b>100.0%</b>

Source: Section C, page 25

<b>Metrolina Kidney Center Projected Patient Origin CY 2027 (2<sup>nd</sup> Full FY)</b>						
<b>County</b>	<b>In-Center</b>		<b>Home Hemodialysis</b>		<b>Peritoneal Dialysis</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Union	95.7	100.0%	10.4	59.8%	8.3	54.3%
Anson	0.0	0.0%	4.0	23.0%	3.0	19.6%
Mecklenburg	0.0	0.0%	0.0	0.0%	2.0	13.1%
South Carolina	0.0	0.0%	3.0	17.2%	2.0	13.1%
<b>Total</b>	<b>95.7</b>	<b>100.0%</b>	<b>17.4</b>	<b>100.0%</b>	<b>15.3</b>	<b>100.0%</b>

Source: Section C, page 26

In Section C, pages 26-39, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin for Union County residents based on the facility’s historical patient origin. The applicant states that the Union County in-patient population has grown from 84 patients as of December 31, 2022, to 92 patients as of December 31, 2023, or 9.5% in one year.
- The applicant projects a growth of 1.0% for Union County in-center patients. The rate is higher than the 5-Year Average Annual Change Rate (AACR) of -0.006%; however, it is lower than the 9.5% growth rate that Metrolina Kidney Center has experienced over the last year.
- The applicant does not project growth for patients residing outside of Union County.

The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C, page 30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 30, the applicant states:

- The applicant proposes to develop new dialysis stations, filed in response to the facility need determination.
- The need the population has for this service is based on the individual patient's need for dialysis care and treatment.
- The applicant projects that 94.8 in-center dialysis patients will be served by the facility by the end of the first Operating Year of the project. This equates to a utilization rate of 79.0%, or 3.16 patients per station per week and exceeds the minimum required by the performance standard.

The information is reasonable and adequately supported based on the following:

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2024 SMFP. The discussion regarding the need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant adequately demonstrates need based on the facility's historical growth in the patient population.

### **Projected Utilization**

In Section C, pages 27-29 and Section Q, pages 83-87, the applicant provides historical and projected utilization, as illustrated in the following tables.

<b>Metrolina Kidney Center Projected Utilization In-Center Patients</b>	
Begin with the Union County patient population as of December 31, 2023.	92.0
Project the Union County patient population forward for one year to December 31, 2024, using a 1.0% growth rate based on the facility's recent experience.	$92.0 \times 1.010 = 92.9$
Project the Union County patient population forward for one year to December 31, 2025, using a 1.0% growth rate based on the facility's recent experience.	$92.9 \times 1.010 = 93.8$
Project the Union County patient population forward for one year to December 31, 2026, using a 1.0% growth rate based on the facility's recent experience. <b>This is the projected ending census for Operating Year 1.</b>	$93.8 \times 1.010 = 94.8$
Project the Union County patient population forward for one year to December 31, 2027, using a 1.0% growth rate based on the facility's recent experience. <b>This is the projected ending census for Operating Year 2.</b>	$94.8 \times 1.010 = 95.7$

<b>Metrolina Kidney Center Projected Utilization</b>	<b>Home Hemodialysis (HHD) Patients</b>	<b>Peritoneal Dialysis (PD) Patients</b>
Begin with the Union County patient population as of December 31, 2023.	10.0	8.0
Project the Union County patient population forward for one year to December 31, 2024, using a 1.0% growth rate based on the facility's recent experience.	$10 \times 1.010 = 10.1$	$8.0 \times .0101 = 8.1$
Add the patients from Anson County and South Carolina for HHD patients. Add the patients from Anson and Mecklenburg counties, and South Carolina for PD patients. This is the projected census for Interim Year 1.	$10.1 + 7.0 = 17.1$	$8.1 + 7.0 = 15.1$
Project the Union County patient population forward for one year to December 31, 2025, using a 1.0% growth rate based on the facility's recent experience.	$10.1 \times 1.010 = 10.2$	$8.1 \times 1.010 = 8.2$
Add the patients from Anson County, Mecklenburg County and South Carolina for the respective modalities. This is the projected census for Interim Year 2.	$10.2 + 7.0 = 17.2$	$8.2 + 7.0 = 15.2$
Project the Union County patient population forward for one year to December 31, 2026, using a 1.0% growth rate based on the facility's recent experience.	$10.2 \times 1.010 = 10.3$	$8.2 \times 1.010 = 8.2$ [8.3]
Add the patients from Anson County, Mecklenburg County and South Carolina. <b>This is the projected census for Operating Year 1.</b>	$10.3 + 7.0 = 17.3$	$8.2 + 7.0 = 15.2$ [8.3 + 7.0 = 15.3]
Project the Union County patient population forward for one year to December 31, 2027, using a 1.0% growth rate based on the facility's recent experience	$10.3 \times 1.010 = 10.4$	$8.2 \times 1.010 = 8.3$ [8.3 x 1.010 = 8.4]
Add the patients from Anson County, Mecklenburg County and South Carolina. <b>This is the projected census for Operating Year 2.</b>	$10.4 + 7.0 = 17.4$	$8.3 + 7.0 = 15.3$ [8.4 + 7.0 = 15.4]

Note: Project Analyst's calculations in brackets.

Metrolina Kidney Center	Operating Year 1	Operating Year 2
In-Center Patients	94.8	95.7
Home Hemodialysis Patients	17.3	17.4
Peritoneal Dialysis Patients	15.2 [15.3]	15.3 [15.4]

Note: Project Analyst’s calculations in brackets.

Metrolina Kidney Center	# of Home Hemodialysis Patient Trained	# of Peritoneal Dialysis Patients Trained
Last Full FY: FY 2023	6.0	8.0
Interim Full FY: FY 2024	7.0	9.0
Interim Full FY: FY 2025	8.0	10.0
1 <sup>st</sup> Full FY of Operation: FY 2026	9.0	11.0
2 <sup>nd</sup> Full FY of Operation: FY 2027	10.0	12.0

In Section C, page 26-29, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

**In-Center Assumptions:**

- The applicant begins projections of the future in-center patient population to be served with the facility census as of December 31, 2023.
- The Metrolina Kidney Center Union County in-center patient population has grown from 84 patients as of December 31, 2022, to 92 patients as of December 31, 2023, or 9.5% in one year. The applicant projects a growth of 1.0% for Union County in-center patients. Union County has a 5-Year AACR of -0.006%. The rate is higher than the 5-Year AACR of -0.006%; however, it is lower than the 9.5% growth rate that Metrolina Kidney Center has experienced over the last year.
- The facility is not serving any in-center patients residing in other counties or states.

At the end of operating year 1, Metrolina Kidney Center is projected to serve 95 in-center patients and at the end of operating year 2, the facility is projected to serve 96 in-center patients on 30 stations.

The projected utilization rates for the end of first two full fiscal years are as follows:

- The applicant projects to serve 95 patients on 30 stations, which is 3.17 patients per station per week (59 patients / 30 stations = 3.17), by the end of the first full operating year.
- The applicant projects to serve 96 patients on 30 stations, which is 3.20 patients per station per week (59 patients / 30 stations = 3.20), by the end of the second full operating year.
- This meets the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

**Home Dialysis Assumptions:**

- The applicant begins projections of the future home hemodialysis patient population to be served with the facility census as of December 31, 2023.
- The Metrolina Kidney Center Union County home hemodialysis patient population has grown from nine patients as of December 31, 2022, to 10 patients as of December 31, 2023, or 11.1% in one year. The applicant projects a growth of 1.0% for Union County home hemodialysis patients. Union County has a 5-Year AACR of -0.006%. The rate is higher than the 5-Year AACR of -0.006%; however, it is lower than the 11.1% growth rate that Metrolina Kidney Center has experienced over the last year.
- The Metrolina Kidney Center Union County home peritoneal dialysis patient population has grown from seven patients as of December 31, 2022, to eight patients as of December 31, 2023, or 14.3% in one year. The applicant projects a growth of 1.0% for Union County home dialysis patients. The rate is higher than the 5-Year AACR of -0.006%; however, it is lower than the 14.3% growth rate for peritoneal dialysis patients that Metrolina Kidney Center has experienced over the last year.
- As of December 31, 2023, the facility served four Anson County and three South Carolina home hemodialysis patients. The facility also served three Anson County, two Mecklenburg County and two South Carolina peritoneal dialysis patients as of December 31, 2023. Anson County, Mecklenburg County and South Carolina are all contiguous to Union County. Thus, it is reasonable to conclude that patients residing in these areas would continue dialysis at Metrolina Kidney Center as a function of patient choice. All home dialysis patients from Anson County, Mecklenburg County and South Carolina are assumed to continue dialysis with the facility; however, the applicant does not project any growth for this segment of the patient population. These patients will be added to projections of future patient populations.

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

- The applicant projects future utilization based on historical utilization.
- The applicant's proposal to add two dialysis stations will meet the need of the projected growth of the facility's patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

**Access to Medically Underserved Groups**

In Section C, page 32, the applicant states:

*“The applicant and its parent organization, Fresenius Medical Care, has a long history of providing dialysis services to the underserved populations of North Carolina. ...*



*Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	33.6%
Racial and ethnic minorities	61.3%
Women	42.9%
Persons with disabilities	12.6%
Persons 65 and older	54.6%
Medicare beneficiaries	87.4%
Medicaid recipients	31.1%

Source: Section C, page 33

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services because Metrolina Kidney Center is an existing dialysis facility in Union County currently providing services to underserved groups.

### **Conclusion**

The Agency reviewed the:

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

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

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

The applicant proposes to add no more than two dialysis stations to Metrolina Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

In Section E, page 42, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo. The applicant states that this alternative was dismissed because it would result in higher utilization rates and potentially interrupt patient admissions to the facility. This is the least effective alternative.
- Apply for more than two stations. The applicant states that the facility does not have the physical space for more than two dialysis stations, even though the facility qualifies to apply for as many as eight stations. Thus, this is not a more effective alternative.

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

- The applicant's proposal is in response to a facility need pursuant to Condition 2 of the facility need methodology, as reported in the 2024 SMFP.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

### **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. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

2. Pursuant to Condition 2 of the facility need determination in the 2024 SMFP, the certificate holder shall develop no more than two additional dialysis stations for a total of no more than 30 stations at Metrolina Kidney Center upon project completion.
3. Progress Reports
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
  - b. The certificate holder shall complete all sections of the Progress Report form.
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
  - d. The first progress report shall be due on October 1, 2024.
4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than two dialysis stations to Metrolina Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

**Capital and Working Capital Costs**

On Form F.1a, in Section Q, page 89, the applicant projects the total capital cost of the project, as shown in the table below.

<b>Metrolina Kidney Center</b>	
Non-Medical Equipment	\$1,500
Furniture	\$6,000
<b>Total Capital Cost</b>	<b>\$7,500</b>

Immediately following Form F.1a in Section Q, the applicant provides the assumptions used to project capital costs. The applicant's projected capital costs are reasonable and adequately supported because they are based on the cost of the necessary furniture and equipment and are based on the applicant's experience.

In Section F, page 45, the applicant states that there will be no start-up costs or initial operating expenses because this is an existing operational facility.

### **Availability of Funds**

In Section F, page 44, the applicant states that the capital cost will be funded with corporate accumulated reserves.

Exhibit F-2 contains a letter dated March 15, 2024, from the Vice President of Corporate Tax – North America of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, stating its commitment to fund the project through its cash reserves. The letter states that the 2022 Consolidated Balance Sheet for Fresenius Medical Care Holdings, Inc. shows more than \$446 million in cash and total assets exceeding \$25 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Exhibit F-2.

### **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, F.3, and F.4, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

<b>Metrolina Kidney Center</b>	<b>1<sup>st</sup> Full FY CY 2026</b>	<b>2<sup>nd</sup> Full FY CY 2027</b>
Total Treatments	18,762	18,929
Total Gross Revenues (Charges)	\$118,033,404	\$119,083,388
Total Net Revenue	\$7,535,481	\$7,600,111
Average Net Revenue per Treatment	\$401.64	\$401.51
Total Operating Expenses (Costs)	\$4,930,211	\$4,986,182
Average Operating Expense per Treatment	\$262.78	\$263.42
Net Income	\$2,605,270	\$2,613,930

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - 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 revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

## C

The applicant proposes to add no more than two dialysis stations to Metrolina Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

On page 113, the 2024 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 facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Union County as of December 31, 2022, as reported in the 2024 SMFP.

<b>Union County Dialysis Facilities Certified Stations and Utilization as of December 31, 2022</b>			
<b>Dialysis Facility</b>	<b># of Certified Stations</b>	<b># of In-Center Patients</b>	<b>Utilization</b>
Crooked Creek Dialysis	16	10	15.63%
Fresenius Kidney Care Indian Trail	16	37	57.81%
Metrolina Kidney Center	28	87	77.68%
Union County Dialysis	37	87	58.78%

Source: Table 9A on page 129 of the 2024 SMFP and Section G, page 50

In Section G, page 50, 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 application is to add two dialysis stations to an existing dialysis facility based upon the performance and demonstrated need at the Metrolina Kidney Center facility. The need addressed by this application is not specific to Union County as a whole. The station is needed by the patient population projected to be served by the facility.”*

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

- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved dialysis stations in the service area.
- There is a facility need determination in the 2024 SMFP for eight dialysis stations at Metrolina Kidney Center.

### **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 all the reasons described 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.

The applicant proposes to add no more than two dialysis stations to Metrolina Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

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

Metrolina Kidney Center	Current Staff	Projected FTE Staff	
	as of 02/16/2024	1 <sup>st</sup> Full FY CY 2026	2 <sup>nd</sup> Full FY CY 2027
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	4.00	4.00	4.00
Licensed Practical Nurses (LPNs)	1.00	1.00	1.00
Home Training Nurse	2.00	2.00	2.00
Technicians (PCT)	6.00	8.00	8.00
Dieticians	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Administrative/Clerical	1.00	1.00	1.00
FMC Director of Operations	0.10	0.10	0.10
FMC Chief Technician	0.10	0.10	0.10
FMC In-Service	0.10	0.10	0.10
<b>TOTAL</b>	<b>18.30</b>	<b>20.30</b>	<b>20.30</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 102. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 52-53, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant states that the facility is able to offer a wide range of personnel benefits and maintain competitive salaries to attract qualified staff.
- Each new employee is required to successfully complete a 10-week training program. The In-Service Coordinator will provide training and orientation to new employees.
- The In-Service Coordinator is responsible for the training of other direct care employees.

**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 described 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

The applicant proposes to add no more than two dialysis stations to Metrolina Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

#### **Ancillary and Support Services**

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 54-59, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because it currently provides the necessary services as an existing, operational facility and states it will continue to do so.

#### **Coordination**

In Section I, page 59, the applicant describes its existing relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because it has longstanding relationships with local and social service providers and has agreements in place with other ESRD-related service providers.

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], 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 66, the applicant provides the historical payor mix during CY 2023 for the proposed services, as shown in the table below.

<b>Metrolina Kidney Center Historical Payor Mix 01/01/2023-12/31/2023</b>						
<b>Payor Source</b>	<b>In-center Dialysis</b>		<b>Home Hemodialysis</b>		<b>Peritoneal Dialysis</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	4.2	4.54%	0.0	0.0%	0.5	3.4%
Insurance*	11.8	12.78%	3.9	22.7%	2.1	13.9%
Medicare*	66.2	71.96%	12.1	71.3%	12.4	82.7%
Medicaid*	7.9	8.55%	0.0	0.0%	0.0	0.0%
Other Misc. including VA	2.0	2.17%	1.0	6.0%	0.0	0.0%
<b>Total</b>	<b>92.0</b>	<b>100.00%</b>	<b>17.0</b>	<b>100.00%</b>	<b>15.0</b>	<b>100.00%</b>

\*Including any managed care plans.

In Section L, page 68, the applicant provides the following comparison.

	<b>Last Full Operating Year</b>	
	<b>Percentage of Total Patients Served (All modalities combined)</b>	<b>Percentage of the Population Service Area where the Stations will be Located or Services Offered</b>
<b>Metrolina Kidney Center</b>		
Female	42.9%	50.2%
Male	57.1%	49.8%
Unknown	0.0%	0.0%
64 or Younger	45.4%	86.2%
65 or Older	54.6%	13.8%
American Indian	0.0%	0.7%
Asian	0.0%	4.7%
Black or African-American	44.5%	12.7%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	38.7%	79.5%
Other Race	16.8%	14.7%
Declined / Unavailable	0.0%	0.0%

^ All patients (in-center, home hemodialysis, and peritoneal dialysis).

\* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>.

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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L, page 69, the applicant states that the facility is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 69, the applicant states that during the 18 months immediately preceding the application deadline, 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 69, 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.

<b>Metrolina Kidney Center Projected Payor Mix 01/01/2027-12/31/2027 (2<sup>nd</sup> Full FY)</b>						
<b>Payor Source</b>	<b>In-center Dialysis</b>		<b>Home Hemodialysis</b>		<b>Peritoneal Dialysis</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	4.3	4.54%	0.0	0.0%	0.5	3.4%
Insurance*	12.2	12.78%	3.9	22.7%	2.1	13.9%
Medicare*	68.9	71.96%	12.4	71.3%	12.7	82.7%
Medicaid*	8.2	8.55%	0.0	0.0%	0.0	0.0%
Other Misc. including VA	2.1	2.17%	1.0	6.0%	0.0	0.0%
<b>Total</b>	<b>95.7</b>	<b>100.0%</b>	<b>17.4 [17.3]</b>	<b>100.0%</b>	<b>15.3</b>	<b>100.0%</b>

\*Including any managed care plans.  
 Note: Project Analyst's calculation in brackets.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 4.54% of total in-center and 3.4% of peritoneal dialysis services will be provided to self-pay patients, 71.96% of total in-center dialysis, 71.3% of home hemodialysis, and 82.7% of peritoneal dialysis to Medicare patients and 8.55% of total in-center dialysis services will be provided to Medicaid patients. Neither home hemodialysis nor peritoneal dialysis services are projected to be provided to Medicaid patients.

On page 70, 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 based on the following:

- The applicant projects payor mix based upon Metrolina Kidney Center's recent history of actual treatment volumes of the facility.
- Patients are calculated as partial patients based on multiple payor sources applied to one patient during a fiscal year.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, page 71, 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

The applicant proposes to add no more than two dialysis stations to Metrolina Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

In Section M, page 73, 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 applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on a letter to South Piedmont Community College encouraging the school to include the dialysis facility in their clinical rotations for nursing students.

**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 described above.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than two dialysis stations to Metrolina Kidney Center pursuant to Condition 2 of the facility need methodology for a total of no more than 30 dialysis stations upon project completion.

On page 113, the 2024 SMFP defines the service area for dialysis stations as “...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Union County. Facilities may serve residents of counties not included in their service area.

As of December 31, 2022, there were four existing or approved facilities providing dialysis and/or dialysis home training and support in Union County. Information on these four dialysis facilities is provided in the table below.

<b>Union County Dialysis Facilities</b>			
<b>Certified Stations and Utilization as of December 31, 2022</b>			
<b>Dialysis Facility</b>	<b># of Certified Stations</b>	<b># of In-Center Patients</b>	<b>Utilization</b>
Crooked Creek Dialysis	16	10	15.63%
Fresenius Kidney Care Indian Trail	16	37	57.81%
Metrolina Kidney Center	28	87	77.68%
Union County Dialysis	37	87	58.78%

Source: Table 9A on page 129 of the 2024 SMFP and Section G, page 50

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, the applicant states:

*“The applicant does not project to serve dialysis patients currently being served by another provider.”*

*“With this application, the applicant seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at Metrolina Kidney Center.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 75, the applicant states:

*The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval of this application will allow the facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment.”*

See also Sections B, F and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 75, the applicant states:

*“Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment. Our organizational mission statement captures this sentiment very well:*

*‘We deliver the superior care that improves the quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.’”*

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 75, the applicant states:

*“It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or any other factor that would classify a patient as underserved.*

*Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”*

See also Sections B, C, and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

## **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 based on all the reasons described 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 O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 125 of this type of facility located in North Carolina.

In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of the Fresenius Medical Care related facilities in North Carolina. After reviewing and considering information provided by the applicant, 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.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

### C

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



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

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 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, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- Metrolina Kidney Center is an existing facility. Therefore, this rule is not applicable to this review.
- (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, page 30, and Section Q, page 83, the applicant projects that Metrolina Kidney Center will serve 95 in-center patients on 30 stations, or a rate of 3.16 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*
- NA- The applicant does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis and does not plan to begin offering those services in this application. Therefore, this Rule does not apply.
- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*
- NA- The applicant does not propose to increase the number of home hemodialysis stations or peritoneal dialysis stations and does not plan to begin offering those services in this application. Therefore, this Rule does not apply.
- (e) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section C, pages 26-29, and Section Q, pages 84-86, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.