

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: 5/2/2024

Findings Date: 5/2/2024

Project Analyst: Yolanda W. Jackson

Co-Signer: Gloria C. Hale

Project ID #: F-12499-24

Facility: Fresenius Kidney Care Mallard Creek

FID #: 170326

County: Mecklenburg

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

Project: Add no more than six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 18 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 six dialysis stations to Fresenius Kidney Care Mallard Creek (hereinafter referred to as “FKC Mallard Creek”) pursuant to Condition 1 of the facility need methodology for a total of no more than 18 stations upon project completion.

#### **Need Determination (Condition 1)**

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 1 of the facility need methodology in the 2024 SMFP, if the facility is a “new,” “small,” or “new and small” facility as defined in the 2024 SMFP, and if the facility’s current reported utilization is at least 75%, or 3.0 patients per station in a given week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. If applying pursuant to Condition 1, the facility may only apply once during the calendar year.

In Section B, page 18, the applicant reports the following:

<b>Facility Need Methodology Condition 1 (New and Small Facilities Only)</b>	<b>Response</b>
Number of months the facility had been certified as of the data cut-off date in the SMFP	15
Number of stations in the facility as of the data cut-off date in the SMFP	12
According to Table 9A in the & SMFP, the facility is designated as new, small, or new and small	New and Small
Number of stations proposed in this application	6
Number of in-center patients per station as of the current reporting date	3.25
<b>Current Reporting Date</b> (no more than 90 days before the application is submitted)	12/31/2023
<b>Previous Reporting Date</b> (six months prior to the Current Reporting Date)	6/30/2023

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of 10 additional stations are needed at this facility, as illustrated in the following table.

<b>1</b>	# of In-center Patients as of the Current Reporting Date *	39
<b>2</b>	# of In-Center Patients as of the Previous Reporting Date **	29
<b>3</b>	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	10
<b>4</b>	Divide Line 3 by Line 2 (6-month Growth Rate)	0.34
<b>5</b>	Multiply Line 4 by 2 (Annual Growth Rate)	0.68
<b>6</b>	Multiply Line 5 by Line 1 (New Patients)	26.52
<b>7</b>	Add Line 6 to Line 1 (Total Patients)	65.52
<b>8</b>	Divide Line 7 by 2.8 (Total # of Stations Needed)	23.40
<b>9</b>	# of Stations as of the Application Deadline^	12
<b>10</b>	Subtract Line 9 from Line 8 (Additional Stations Needed)	11

\* Current Reporting date should be no more than 90 days before the date the CON application was submitted.

\*\* Previous Reporting date is six months prior to the Current Reporting date.

^ Includes all stations that were: 1) certified; 2) CON approved but not yet certified; and 3) proposed to be added in applications still under review as of the application deadline.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 11, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “*The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.*” FKC Mallard Creek proposes to add six new stations; therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

## **Policies**

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

BMA describes how it believes the proposed project will promote safety and quality in Section B.7 (a), page 21, Section N, page 75, and Section O, pages 77-80. 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**

BMA describes how it believes the proposed project will promote equitable access in Section B.7 (b), page 22, 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**

BMA describes how it believes the proposed project will maximize healthcare value in Section B.7 (c) and (d), pages 22-23, and Section N.2(a)(1), page 75. The information provided by the applicant with regard to its efforts to maximize healthcare value 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 1 of the facility need methodology as applied from the 2024 SMFP.
- The applicant adequately demonstrates how FKC Mallard Creek'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.

The applicant proposes to add six dialysis stations to FKC Mallard Creek pursuant to Condition 1 of the facility need methodology for a total of 18 stations upon project completion.

In Section C, page 25, the applicant states FKC Mallard Creek does not currently provide home peritoneal dialysis and home hemodialysis. The applicant does not project to begin offering those services in this application.

### **Patient Origin**

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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

FKC Mallard Creek				
County	Last Full FY Calendar Year 2023		Second Full FY of Operation following Project Completion Calendar Year 2027	
	# of In-Center Patients	% of Total	# of In-Center Patients	% of Total
Mecklenburg	31.0	79.5%	54.2	93.1%
Cabarrus	4.0	10.3%	4.0	6.9%
Duplin	1.0	2.6%	0.0	0.0%
Other States	3.0	7.7%	0.0	0.0%
<b>Total</b>	<b>39.0</b>	<b>100.0%</b>	<b>58.2</b>	<b>100.0%</b>

Source: Section C, pages 25-26

In Section C, pages 26-28, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant bases projected patient origin on the historical patient origin beginning projections with the facility census as of December 31, 2023.
- The applicant explains the growth projections for the Mecklenburg County patient population.

**Analysis of Need**

In Section C, page 29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 29, the applicant states:

*“The applicant has identified the population to be served as 51.1 in-center dialysis patients dialyzing with the facility at the end of the first Operating Year of the project. This equates to a utilization rate of 71.0%, or 2.84 patients per station and meets the minimum required by the performance standard.”*

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

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 1 of the facility need methodology, as stated in the 2024 SMFP. The discussion regarding 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**

On Form C Utilization, in Section Q, page 83, the applicant provides historical and projected utilization, as illustrated in the following table.

<b>Form C Utilization</b>	<b>Last Full FY 2023</b>	<b>Interim Full FY 2024</b>	<b>Interim Full FY 2025</b>	<b>1<sup>st</sup> Full FY 2026</b>	<b>2<sup>nd</sup> Full FY 2027</b>
<b>In-Center Patients</b>					
# of Patients at the Beginning of the Year	20	39	40	45	51
# of Patients at the End of the Year	39	40	45	51	58
Average # of Patients during the Year	30	39	42	48	55
# of Treatments / Patient / Year	148	148	148	148	148
<b>Total # of Treatments</b>	<b>4,337</b>	<b>5,820</b>	<b>6,264</b>	<b>7,115</b>	<b>8,093</b>

In Section C, pages 26-27, and on Form C Utilization, in Section Q, page 83, the applicant provides the assumptions and methodology used to project utilization, which are summarized below:

- The applicant begins its utilization projection with the FKC Mallard Creek census as of December 31, 2023. On December 31, 2023, the facility was serving 39 in-center patients, 3.25 patient per station, or 81.25% utilization on 12 certified stations.
- The applicant projects a growth rate of 15% of the Mecklenburg County patient census. The applicant states that the growth rate of 15% is higher than the 1.1% Mecklenburg County 5-Year AACR published in the 2024 SMFP, however, it is less than the growth experienced by the facility.
- The facility also served four in-center patients residing in Cabarrus County as of December 31, 2023. The applicant states that these patients are assumed to continue dialysis with FKC Mallard Creek; however, the applicant does not project growth for this segment of the patient population. The applicant states that FKC Mallard Creek also served a patient in Duplin County; however, the applicant will not carry the patient from Duplin County and other states forward in any future projections.
- The project is scheduled to begin offering services on December 31, 2025. Operating Year 1 is Calendar Year 2026 and Operating Year 2 is Calendar Year 2027.

In Section C, page 27, and in Section Q, page 85, the applicant provides the in-center methodology used to project the patient census for Operating Year 1 and Operating Year 2 as summarized in the table below:

<b>FKC Mallard Creek Projected Utilization</b>	
The applicant begins with the Mecklenburg County population as of December 31, 2023.	31.0
The facility's Mecklenburg County patient population is projected forward for one year to December 31, 2024, using a 15% growth rate based on the facility's historical performance.	$31 \times 1.15 = 35.7$
Add the patients from Cabarrus County. This is the projected ending census for Interim Year 1.	$35.7 + 4.0 = 39.7$
The facility's Mecklenburg County patient population is projected forward for one year to December 31, 2025, using a 15% growth rate based on the facility's historical performance.	$35.7 \times 1.15 = 41.0$
Add the patients from Cabarrus County. This is the projected ending census for Interim Year 2.	$41.0 + 4.0 = 45.0$
The facility's Mecklenburg County patient population is projected forward one year to December 31, 2026, using a 15% growth rate based on the facility's historical performance.	$41.0 \times 1.15 = 47.1$
The 4 patients from outside Mecklenburg County are added to the facility's census. This is the projected ending census for Operating Year 1.	$47.1 + 4 = 51.1$
The facility's Mecklenburg County patient population is projected forward for one year to December 27, 2027, using a 15% growth rate based on the facility's historical performance.	$47.1 \times 1.15 = 54.2$
The 4 patients from outside Mecklenburg County are added to the facility's census. This is the projected ending census for Operating Year 2.	$54.2 + 4.0 = 58.2$

Summary: Based upon these calculations, BMA projects to serve the following number of patients for the Operating Year 1 and Operating Year 2.

	<b>Operating Year 1</b>	<b>Operating Year 2</b>
In-center Patients	51.1	58.2

- The applicant projects to serve 51 patients on 18 stations, which is 2.83 patients per station per week ( $51 \text{ patients} / 18 \text{ stations} = 2.83$ ), by the end of first full operating year.
- The applicant projects to serve 58 patients on 18 stations, which is 3.22 patient per station per week ( $58 \text{ patients} / 18 \text{ stations} = 3.22$ ) by the end of 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).

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

- The applicant projects future utilization based on historical utilization.
- Even though the applicant projects a much higher growth rate for its patient population than the Mecklenburg County 5-year AACR as published in the 2024 SMFP, it uses a projected growth rate that is lower than its recent growth rates.

**Access to Medically Underserved Groups**

In Section C, page 31, the applicant states:

*“Fresenius Medical Care and its 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. For example, Medicare (includes Medicare Advantage treatments) represented 76.77% of North Carolina dialysis treatments in Fresenius related facilities in FY 2023. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius-related facilities.”*

The applicant provides the estimated percentage of total patients for each medically underserved group during the second full fiscal year, as shown in the following table.

<b>Groups</b>	<b>Estimated % of Total Patients in FY 2</b>
Low-income persons	28.1%
Racial and ethnic minorities	43.8%
Women	46.9%
Persons with disabilities	9.4%
Persons 65 and older	62.5%
Medicare beneficiaries	37.5%
Medicaid recipients	12.5%

Source: Section C, page 32

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 based on the following:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.
- The applicant states the percentages of patients for each group listed above are based on recent facility experience.

**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.

- (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.

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In Section E, page 41, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo. The applicant states that this alternative would have resulted in a higher utilization rate. Utilization on 12 dialysis stations was projected to be 4.26 patients per station per week at the end of Operating Year 1, and 4.85 patients per station per week by the end of Operating Year 2. The applicant states that failure to apply for additional stations would lead to higher utilization rates which potentially interrupts patient admissions to the facility and is the least effective alternative.
- The applicant could have chosen to file for fewer than six stations. The applicant states that applying for fewer stations would have the same effect as not applying: higher utilization rates as the facility patient census increases. 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 application is conforming to all statutory and regulatory review criteria.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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, LLC, (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to Condition 1 of the facility need determination in the 2024 SMFP, the certificate of need holder shall develop no more than six additional in-center dialysis stations for a total of no more than 18 in-center dialysis stations at Fresenius Kidney Care Mallard Creek 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 six dialysis stations to FKC Mallard Creek pursuant to Condition 1 of the facility need methodology for a total of 18 stations upon project completion.

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

On Form F.1a, in Section Q, page 87, the applicant projects \$4,500 in capital costs for non-medical equipment, and \$18,000 in capital costs for furniture for a total capital cost of \$22,500. 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.

In Section F, page 44, the applicant states there are no start up costs or initial operating costs because FKC Mallard Creek is an existing facility.

### **Availability of Funds**

In Section F, page 43, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter, dated March 15, 2024, from the Vice-President of Corporate Tax North America for Fresenius Medical Care Holdings, Inc., the parent company of the applicant, authorizing \$22,500 for the capital needs of the project. 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 following:

- The applicant provided a letter from a company executive authorizing the use of accumulated reserves for the proposed project.
- The letter from the applicant documents that it has adequate cash and assets to fund the proposed project.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. On Form F.2 in Section Q, page 90, 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>Projected Revenues and Operating Expenses</b>		
<b>FKC Mallard Creek</b>	<b>FY 1 - CY 2026</b>	<b>FY 2 - CY 2027</b>
Total Treatments	7,115	8,093
Total Gross Revenues (Charges)	\$44,758,592	\$50,913,740
Total Net Revenue	\$2,773,649	\$3,155,078
Average Net Revenue per Treatment	\$390	\$390
Total Operating Expenses (Costs)	\$2,348,642	\$2,464,036
Average Operating Expense per Treatment	\$330	\$304
<b>Net Income</b>	<b>\$425,007</b>	<b>\$691,043</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2 and in Forms F.3 and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- 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.

The applicant proposes to add up to six dialysis stations to FKC Mallard Creek pursuant to Condition 1 of the facility need methodology for a total of 18 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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

As of December 31, 2022, there were 22 existing or approved facilities providing dialysis and/or dialysis home training and support in Mecklenburg County. Information on these 23 dialysis facilities is provided in the table below.

<b>Mecklenburg 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>
BMA Beatties Ford	41	90	54.88%
BMA Nations Ford	28	90	80.36%
BMA of East Charlotte	32	105	82.03%
BMA West Charlotte	29	87	75.00%
Brookshire Dialysis	11	40	90.91%
Charlotte Dialysis	33	79	59.85%
Charlotte East Dialysis	34	102	75.00%
DSI Charlotte Latrobe Dialysis	24	70	72.92%
DSI Glenwater Dialysis	42	88	52.38%
FMC Charlotte	48	88	45.83%
FMC Matthews	21	80	95.24%
FMC of North Charlotte	40	136	85.00%
FKC Mallard Creek	12	20	41.67%
FKC Regal Oaks	17	56	82.35%
FKC Southeast Mecklenburg	17	49	72.06%
FMC Aldersgate	16	51	79.69%
FMC Southwest Charlotte	26	67	64.42%
Huntersville Dialysis	27	65	60.19%
Mint Hill Dialysis	21	56	66.67%
North Charlotte Dialysis Center	33	94	71.21%
South Charlotte Dialysis	27	72	66.67%
Sugar Creek Dialysis	21	39	46.43%

Source: Table 9A, Chapter 9, 2024 SMFP; Agency records

In Section G, page 50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved services in Mecklenburg County. The applicant states:

*“The applicant is not projecting to serve patients currently being served in another facility or served by another provider. These stations are needed to support the growing patient population census at the FKC Mallard Creek facility.”*

*“... FKC Mallard Creek has been growing exponentially since it was first certified on June 13, 2022. Specifically, the facility census has increased 95% over the last year from 20 in-center patients as of December 31, 2022, to 39 in-center patients as of December 31, 2023. This equates to 3.25 patients per station or 81.25% utilization. In addition, the Mecklenburg County in-center patient census at the facility has increased by 121.4% from 14 Mecklenburg County in-center patients of December 31, 2022, to 31 Mecklenburg County in-center patients as of December 31, 2023. Given the utilization and growth of the facility, BMA does not believe adding six stations will duplicate any services. Rather, the additional stations will ensure continued adequate access to dialysis care for the patient population of the area.”*

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 proposes to increase the number of dialysis stations in Mecklenburg County based on Condition 1 of the facility need determination in the 2024 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Mecklenburg County.

### **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.

C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 18 stations upon completion of this project.

On Form H in Section Q, pages 98-99, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

<b>FKC Mallard Creek Current and Projected Staffing</b>		
	<b>As of 2/16/2024</b>	<b>Projected – OYs 1-2 (CYs 2026-2027)</b>
Administrator	1.00	1.00
Registered Nurses	2.50	2.50
Patient Care Technicians	2.00	4.00
Dietician	.20	.20
Social Worker	.20	.20
Maintenance	.50	.50
Administrative/Clerical	1.00	1.00
Director of Operations	0.11	0.11
Chief Technician	0.10	0.10
FKC In-service	0.11	0.11
<b>TOTAL</b>	<b>7.72</b>	<b>9.72</b>

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. 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 projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

**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.

The applicant proposes to add no more than six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 18 stations upon completion of this project.

### **Ancillary and Support Services**

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, 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 based on the following:

- The facility is an existing facility already providing the necessary ancillary and support services.
- The applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

### **Coordination**

In Section I, page 59, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit H-4. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The facility is an existing facility that has existing relationships with local health care and social service providers.
- The applicant provides a letter from the medical director of the facility attesting to the relationship between the medical director's physician practice and the facility.

### **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.



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 a new space or renovate an 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 its existing services, as shown in the table below.

<b>FKC Mallard Creek Historical Payor Sources CY 2023</b>		
<b>Payor Source</b>	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	0.2	0.58%
Insurance*	2.8	7.06%
Medicare*	34.5	88.36%
Medicaid*	1.3	3.44%
Misc. (including VA)	0.2	0.58%
<b>Total</b>	<b>39.0</b>	<b>100.00%</b>

\* Including any managed care plans.

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

<b>FKC Mallard Creek</b>	<b>Percentage of Total Patients Served by FKC Mallard Creek during CY 2023</b>	<b>Percentage of the Population of the Service Area</b>
Female	40.5%	51.6%
Male	59.5%	48.4%
Unknown		
64 and Younger	50.0%	87.8%
65 and Older	50.0%	12.2%
American Indian		0.9%
Asian		6.7%
Black or African-American	92.9%	33.2%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	7.1%	56.4%
Other Race		17.1%
Declined / Unavailable		

**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 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 69, the applicant states it has no such obligation.

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 FKC Mallard Creek.

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 during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>FKC Mallard Creek Historical Payor Sources CY 2027</b>		
<b>Payor Source</b>	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	0.3	0.58%
Insurance*	4.1	7.06%
Medicare*	51.4	88.36%
Medicaid*	2.0	3.44%
Misc. (including VA)	0.3	0.58%
<b>Total</b>	<b>58.2</b>	<b>100.00%</b>

\* Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, 88.36% of services will be provided to Medicare patients, and 3.44% of services will be provided to Medicaid patients.

On page 70, the applicant provides the assumptions and methodology it uses 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 it is based on recent facility history of treatment volumes at FKC Mallard Creek.

### **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.

- (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.

### **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.

- (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 six dialysis stations to FKC Mallard Creek pursuant to Condition 1 of the facility need methodology for a total of 18 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 the following:

- The applicant provides a copy of a letter sent to Central Piedmont Community College offering the facility as a training site for nursing students.
- The applicant states that all health-related education and training programs are welcome to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment.

**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 six dialysis stations to FKC Mallard Creek pursuant to Condition 1 of the facility need methodology for a total of 18 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 Mecklenburg County. Facilities may serve residents of counties not included in their service area.

As of December 31, 2022, there were 22 existing or approved facilities providing dialysis and/or dialysis home training and support in Mecklenburg County. Information on these 22 dialysis facilities is provided in the table below.

<b>Mecklenburg 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>
BMA Beatties Ford	41	90	54.88%
BMA Nations Ford	28	90	80.36%
BMA of East Charlotte	32	105	82.03%
BMA West Charlotte	29	87	75.00%
Brookshire Dialysis	11	40	90.91%
Charlotte Dialysis	33	79	59.85%
Charlotte East Dialysis	34	102	75.00%
DSI Charlotte Latrobe Dialysis	24	70	72.92%
DSI Glenwater Dialysis	42	88	52.38%
FMC Charlotte	48	88	45.83%
FMC Matthews	21	80	95.24%
FMC of North Charlotte	40	136	85.00%
FKC Mallard Creek	12	20	41.67%
FKC Regal Oaks	17	56	82.35%
FKC Southeast Mecklenburg	17	49	72.06%
FMC Aldersgate	16	51	79.69%
FMC Southwest Charlotte	26	67	64.42%
Huntersville Dialysis	27	65	60.19%
Mint Hill Dialysis	21	56	66.67%
North Charlotte Dialysis Center	33	94	71.21%
South Charlotte Dialysis	27	72	66.67%
Sugar Creek Dialysis	21	39	46.43%

Source: Table 9A, Chapter 9, 2024 SMFP; Agency records

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.”*

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

*“This is a proposal to add six dialysis stations to the FKC Mallard Creek facility. 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. This is an immediate and significantly positive impact to the patients of the area.”*

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:

*“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 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:

*“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. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius-related facilities.”*

See also Sections B and L of the application.

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 and the applicant's record of providing quality care in the past.
- 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

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

The applicant proposes to add six dialysis stations to FKC Mallard Creek pursuant to Condition 1 of the facility need methodology for a total of 18 stations upon project completion.

On Form O in Section Q, 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 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 125 facilities, the applicant provides 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 promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as 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- FKC Mallard Creek 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, pages 27-28, and on Form C in Section Q, the applicant projects that FKC Mallard Creek will serve 51 patients on 18 stations, or a rate of 2.8 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 shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C, pages 26-28, and immediately following Form C in Section Q, 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.