

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: October 10, 2023

Findings Date: October 10, 2023

Project Analyst: Crystal Kearney

Co-Signer: Gloria C. Hale

Project ID #: F-12409-23

Facility: Fresenius Kidney Care North Gaston

FID #: 160496

County: Gaston

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

Project: Add no more than 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 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.

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The applicant, Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or “FKC North Gaston”), proposes to add no more than 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 stations upon project completion.

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

Chapter 9 of the 2023 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, page 135, there is no county need determination for additional dialysis stations in Gaston County.

However, the applicant is eligible to apply for additional stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, if the utilization rate for the facility as reported in the 2023 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 91.67% or 3.7 patients per station per week, based on 44 in-center dialysis patients and 12 certified dialysis stations (44 patients/12 stations = 3.7;  $3.7 / 4 = 91.67\%$ ).

As shown in Table 9D, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 15 additional stations; thus, the applicant is eligible to apply to add up to 15 stations during the 2023 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

On July 18, 2022, the applicant was issued a certificate of need to add four dialysis stations to FKC North Gaston. Therefore, the facility now has 16 in-center dialysis stations.

The applicant proposes to add no more than 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2023 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy *GEN-3*, page 30 of the 2023 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 74-75; 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, page 33; Section L, pages 66-72; 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 F, pages 43-48; 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
- 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 the following:

- The applicant adequately demonstrates that the application is consistent with Condition 2 of the facility need methodology as applied from the 2023 SMFP.
- The applicant adequately demonstrates how FKC North Gaston'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

FKC North Gaston proposes to add no more than 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 stations upon project completion.

**Patient Origin**

On page 113, the 2023 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Gaston County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patients.

FKC North Gaston Current & Projected Patient Origin												
	Last – CY 2022						Projected – CY 2026					
	IC Patients		HH Patients		PD Patients		IC Patients		HH Patients		PD Patients	
County	#	%	#	%	#	%	#	%	#	%	#	%
Gaston	51.0	86.4%	10.0	66.7%	22.0	62.9%	56.3	87.6%	11.0	68.8%	24.3	65.1%
Cleveland	1.0	1.7%	2.0	13.3%	6.0	17.1%	1.0	1.6%	2.0	12.5%	6.0	16.1%
Lincoln	6.0	10.2%	1.0	6.7%	4.0	11.4%	6.0	9.3%	1.0	6.2%	4.0	10.7%
Mecklenburg			1.0	6.7%					1.0	6.2%		
Rutherford					1.0	2.9%					1.0	2.7%
South Carolina	1.0	1.7%	1.0	6.7%	2.0	5.7%	1.0	1.6%	1.0	6.2%	2.0	5.4%
<b>Total</b>	<b>59.0</b>	<b>100.0%</b>	<b>15.0</b>	<b>100.0%</b>	<b>35.0</b>	<b>100.0%</b>	<b>64.3</b>	<b>100.0%</b>	<b>16.0</b>	<b>100.0%</b>	<b>37.3</b>	<b>100.0%</b>

Source: Section C, pages 25 - 26

In Section C, page 25-26, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s patient origin projections are reasonable and adequately supported because they are based the historical (CY2022) patient origin for the facility.

**Analysis of Need**

In Section C, pages 29-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

*“The need that this population has for the proposed services is a function of the individual patient’s need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the population to be served as 62.9 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates a utilization rate of 92.5%, or 3.7 patients per station 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 2023 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 projected growth in the patient population.

Projected Utilization for In-Center Patients

In Section C, page 27, and Section Q, pages 86-87, the applicant provides projected utilization, as illustrated in the following table.

<b>FKC North Gaston</b>	<b>In-Center patients</b>
Begin with the Gaston County patient population as of December 31, 2022.	51.0
Project the Gaston County patient population forward for one year to December 31, 2023, using the Gaston County Five-Year AACR of 2.5%.	$51.0 \times 1.025 = 52.3$
Add the patients from other counties and S.C. This is the projected ending census for Interim Year 1.	$52.3 + 8.0 = 60.3$
Project the Gaston County patient population forward for one year to December 31, 2024, using the Gaston County Five-Year AACR.	$52.3 \times 1.025 = 53.6$
Add the patients from other counties and S.C. This is the projected ending census for Interim Year 2.	$53.6 + 8.0 = 61.6$
Project the Gaston County patient population forward for one year to December 31, 2025, using the Gaston County Five-Year AACR.	$53.6 \times 1.025 = 54.9$
Add the patients from other counties and S.C. <b>This is the projected ending census for Operating Year 1.</b>	$54.9 + 8.0 = 62.9$
Project the Gaston County patient population forward for one year to December 31, 2026, using the Gaston County 5-Year AACR.	$54.9 \times 1.025 = 56.3$
Add the patients from other counties and S.C. <b>This is the projected ending census for Operating Year 2.</b>	$56.3 + 8.0 = 64.3$

In Section C, page 26 and Section Q, pages 83-85, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The 2023 SMFP, Table 9D indicates that FKC North Gaston qualifies to apply for up to 15 additional dialysis stations pursuant to Condition 2 of the Facility Need Methodology. This is an application for one additional dialysis station.
- The applicant begins its projections of the future patient population to be served, with the facility census as of December 31, 2022. This information was reported on the 2022 ESRD Data Collection Form submitted to DHSR Planning in February 2023.

- The applicant projects growth of the Gaston County patient population using the Gaston County Five Year Average Annual Change Rate (5-Year AACR) of 2.5% as published in the 2023 SMFP.
- As of December 31, 2022, the facility was serving seven in-center patients residing in Cleveland and Lincoln counties and one in-center patient residing in South Carolina. Cleveland and Lincoln counties and the state of South Carolina are all contiguous to Gaston County; thus, it is reasonable to conclude that patients residing in these areas would continue dialysis at FKC North Gaston as a function of patient choice.
- The patients 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 at appropriate points in time.
- The new stations are projected to be certified as of December 31, 2024.

Operating Year 1 is the period from January 1-December 31, 2025.

Operating Year 2 is the period from January 1 – December 31, 2026.

#### Projected Utilization for Home Dialysis

FKC North Gaston	Home Hemodialysis	Peritoneal Dialysis
Begin with the Gaston County patient population as of December 31, 2022.	10.0	22.0
Project the Gaston County patient population forward for one year to December 31, 2023, using Gaston County Five-Year AACR of 2.5%	$10.0 \times 1.025 = 10.3$	$22.0 \times 1.025 = 22.6$
Add the patients from other counties and S.C. This is the projected ending census for Interim Year 1.	$10.3 + 5.0 = 15.3$	$22.6 + 13.0 = 35.6$
Project the Gaston County patient population forward for one year to December 31, 2024, using the Gaston County Five-Year AACR.	$10.3 \times 1.025 = 10.5$	$22.6 \times 1.025 = 23.1$
Add the patients from other counties. This is the projected ending census for Interim Year 2.	$10.5 + 5.0 = 15.5$	$23.1 + 13.0 = 36.1$
Project the Gaston County patient population forward for one year to December 31, 2025, using the Gaston County Five-Year AACR.	$10.5 \times 1.025 = 10.8$	$23.1 \times 1.025 = 23.7$
Add the patients from other counties. <b>This is the projected ending census for Operating Year 1.</b>	$10.8 + 5.0 = 15.8$	$23.7 + 13.0 = 36.7$
Project the Gaston County patient population forward for one year to December 31, 2026, using the Gaston County Five-Year AACR.	$10.8 \times 1.025 = 11.0$	$23.7 \times 1.025 = 24.3$
Add the patients from other counties. <b>This is the projected ending census for Operating Year 2.</b>	$11.0 + 5.0 = 16.0$	$24.3 + 13.0 = 37.3$

Source: Section C, pages 28-29, Section Q, page 86-87

In Section C, pages 27- 28 and Section Q, pages 85-86, the applicant provides the assumptions and methodology used to project utilization, which is summarized as follows:

- The applicant’s projections are based on historical patient origin at FKC North Gaston.
- The applicant grows the Gaston County population using the Gaston County Five Year Average Annual Change Rate (5-Year AACR) of 2.5%, as published in the 2023 SMFP.
- The facility serves four home hemodialysis patients residing in Cleveland, Lincoln, and Mecklenburg counties and one home hemodialysis patient residing in South Carolina. The facility also served 11 peritoneal dialysis patients residing in Cleveland, Lincoln, and Rutherford counties and two peritoneal dialysis patients residing in South Carolina.
- Cleveland, Lincoln, and Mecklenburg counties and the state of South Carolina are all contiguous to Gaston County; thus, it is reasonable to conclude that patients residing in these areas would continue dialysis at FKC North Gaston as a function of patient choice. Rutherford County is not continuous to Gaston County; however, the applicant

believes that the peritoneal dialysis patient from this county will also continue dialysis at the facility as a function of patient choice.

- BMA believes that it is reasonable to conclude that these patients will continue dialysis treatment at the facility as both home hemodialysis and peritoneal dialysis patients do not travel to a dialysis clinic three days a week for treatment once their training is completed as in-center dialysis patients.
- All of the home hemodialysis and peritoneal dialysis patients from other counties and state are assumed to continue dialysis with the facility; however, the applicant does not project any growth of this segment of the patient population. The patients will be added to projections of the future patient population at appropriate points in time.
- The new stations are projected to be certified as of December 31, 2024.

Operating Year 1 is the period from January 1 - December 31, 2025.

Operating Year 2 is the period from January 1 - December 31, 2026.

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

	Operating Year 1	Operating Year 2
In-center	62.9	64.3
Home Hemodialysis	15.8	16.0
Peritoneal Dialysis	36.7	37.3

Source: Section C, page 29 and Section Q, page 87

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

- OY1: 3.7 patients per station per week or 92.5% (62.9 patients /17 stations = 3.7;  $3.7/4 = 0.925$  or 92.5%)
- OY2: 3.78 patients per station per week or 94.55% (64.3 patients/17 stations = 3.78;  $3.78/4 = .946$  or 94.55%).
- The projected utilization of 3.7 patients per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C.2203(b).

### **Access to Medically Underserved Groups**

In Section C, pages 32 - 33, the applicant states,

*“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.*

*It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.*

*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.”*

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

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low-income persons	27.2%
Racial and ethnic minorities	59.6%
Women	39.5%
Person with disabilities	14.9%
Persons 65 and older	41.2%
Medicare beneficiaries	93.0%
Medicaid recipients	19.3%

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 based on the following:

### **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 services. 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.

CA

FKC North Gaston proposes to add no more than 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 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:

- The applicant could have chosen not to file for additional stations at FKC North Gaston. Failure to apply for additional stations leads to higher utilization rates, potentially interrupts patient admissions to the facility and is the least effective alternative.
- The applicant could have chosen to file for as many as 15 additional stations. An application for more than one station is not cost effective. The facility does not have the physical space for more than 17 dialysis stations. Even though the facility qualifies to apply for as many as 15 stations, there is no room for more than one additional dialysis station.

Based on the explanations above, the applicant determined that its project as proposed is the most 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 or conditionally 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, 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 2023 SMFP, the certificate holder shall develop no more than one additional in-center dialysis station for a total of no more than 17 in-center (and home hemodialysis) stations at FKC North Gaston.
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 February 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 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 stations upon project completion.

**Capital and Working Capital Costs**

In Section Q, page 89, the applicant projects the total capital cost of the project, as shown in table below.

Non-Medical Equipment	\$750
Furniture	\$3,000
<b>Total</b>	<b>\$3,750</b>

In Section Q, page 90, the applicant provides assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on the cost of what is required to add the one additional station. The applicant states that this includes all necessary furniture for the operation of the facility, to include patient chairs, TVs, computers, and office furniture necessary for staff. The non-medical equipment is primarily comprised of the water

treatment system necessary for dialysis operations. Other items would include signs, project communications, and ancillary medical equipment.

In Section F, page 45, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project because FKC North Gaston is an existing facility.

### **Availability of Funds**

In Section F, page 43, the applicant states that the capital cost will be funded as shown in the table below.

<b>Type</b>	<b>Bio-Medical Applications of North Carolina, Inc.</b>	<b>Total</b>
Loans	\$0	\$0
Accumulated reserves or OE *	\$3,750	\$3,750
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$3,750	\$3,750

\* OE = Owner's Equity

Exhibit F-2 contains a letter from the applicant on behalf of the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, authorizing the use of accumulated reserves for the capital needs of the project. The letter in Exhibit F-2 also states that the 2021 Consolidated Balance Sheet reflects more than \$939 million in cash, and total assets exceeding \$27.2 billion in assets to fund the capital cost of the proposed project.

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 an appropriate company official committing the amount of the projected capital cost to the proposed project.
- The letter from the applicant demonstrates the availability of adequate cash and assets to fund the proposed project.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, in Section Q, page 92, 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>1<sup>st</sup> FY CY 2025</b>	<b>2nd FY CY2026</b>
Total Treatments	16,915	17,242
Total Gross Revenues (Charges)	\$106,413,529	\$108,468,673
Total Net Revenue	\$6,339,143	\$6,458,844
Average Net Revenue per Treatment	\$375	\$375
Total Operating Expenses (Costs)	\$5,452,634	\$5,544,953
Average Operating Expense per Treatment	\$322	\$322
Net Income	\$866,509	\$913,891

The assumptions used by the applicant in preparation of the pro forma financial statements are provided after Forms F.2, F.3, F.4, and H 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 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.

The applicant proposes to add no more than 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 stations upon project completion.

The 2023 SMFP, page 113, defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Gaston 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 Gaston County as of December 31, 2021. There are five kidney disease treatment centers providing dialysis services in Gaston County.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
BMA Kings Mountain	22	63	71.59%	2.86
FKC North Gaston	12	44	91.67%	3.67
FMC Belmont	19	74	97.37%	3.89
FMC Gastonia	39	123	78.85%	3.15
FMC South Gaston	28	70	62.50%	2.50

Source: Table 9A, Chapter 9, 2023 SMFP, page 122

In Section G, pages 50-51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Gaston County. The applicant states:

*“BMA is the only dialysis provider of in-center dialysis services in Gaston County. This application is to add one dialysis station to an existing dialysis facility based upon the performance and demonstrated need at the Fresenius Kidney Care North Gaston facility. The need addressed by this application is not specific to Gaston County as a whole. The stations are needed by the patient population projected to be served by the facility. The projections of future patient populations to be served begin with the current patient population of the facility and an increase of that population at a rate of 2.5%, commensurate with the Gaston County 5-Year AACR.”*

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 stations are needed in addition to the existing or approved dialysis stations.
- The applicant proposes to increase the number of dialysis stations in Gaston County based on Condition 2 of the facility need determination in the 2023 SMFP.

**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 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 stations upon project completion.

In Section Q, pages 101-102, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 6/15/2023	2nd Full Fiscal Year CY 2026
Administrator (FMC Clinical Manager)	1.00	1.00
Registered Nurses (RNs)	3.00	3.00
Home Training Nurse	3.00	3.00
Technicians (PCT)	8.00	8.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Maintenance	0.50	0.50
Administrative/Clerical	1.00	1.00
Other (FMC Director of Operations)	0.70	0.70
Other (FMC Chief Technician)	0.70	0.70
Other (FMC In-Service)	0.70	0.70
<b>TOTAL</b>	<b>20.60</b>	<b>20.60</b>

Source: Section Q, pages 101-102 of Form H

The assumptions and methodology used to project staffing are provided in Section Q, pages 101-102. Adequate expense 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 programs.

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

- FKC of North Gaston is an existing facility in Gaston County that has demonstrated its ability to attract qualified staff by offering a wide range of personnel benefits and maintain competitive salaries.
- The COVID-19 pandemic has impacted healthcare staff availability. As a result of competition for staffing (among various health care agencies), Fresenius Medical Care, parent to BMA, has implemented initiatives such as sign on and retention bonuses, increased starting salaries, corporate review of salary scales, intensified recruiting efforts, comprehensive offerings of Total Rewards to aid in benefiting the employee and their families (i.e. Employee Assistance Program).
- The applicant adequately describes its training programs.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on the 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 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 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 describes the necessary ancillary and support services and explains how they will be provided and by whom.

## **Coordination**

In Section I, page 59, the applicant describes its existing and proposed 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 based on its statement that it has established relationships with other physicians and hospitals in the area and agreements in place for lab services, hospital affiliation and transplant services.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons 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 2022 for the proposed services, as shown in the table below.

**Last Full FY before Submission of Application  
 01/01/2022 to 12/31/2022**

Primary Payor Source at Admission	FKC North Gaston					
	In-center Dialysis		Home Hemodialysis **		Peritoneal Dialysis **	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	3.1	5.28%	0.4	2.9%	0.0	0.0%
Insurance *	4.1	6.92%	2.0	13.4%	4.8	13.8%
Medicare *	47.2	79.97%	12.5	83.1%	28.5	81.5%
Medicaid *	3.4	5.81%	0.0	0.0%	0.0	0.0%
Other (Miscellaneous including VA)	1.2	2.02%	0.1	0.7%	1.7	4.8%
<b>Total</b>	<b>59.0</b>	<b>100.0%</b>	<b>15.0</b>	<b>100.0%</b>	<b>35.0</b>	<b>100.0%</b>

\* Including any managed care plans.

\*\* This is **not** the number of patients trained in a year. This is the total number of patients performing their hemodialysis or peritoneal dialysis in a location other than the dialysis facility.

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

FKC North Gaston	Percentage of Total Patients Served (All modalities combined)	Percentage of the Population of the Service Area where the Stations will be Located or Services Offered*
Female	39.5%	51.6%
Male	60.5%	48.4%
Unknown		
64 and Younger	58.8%	83.6%
65 and Older	41.2%	16.4%
American Indian	0.0%	0.7%
Asian	0.9%	1.7%
Black or African-American	40.4%	19.1%
Native Hawaiian or Pacific Islander	0.9%	0.1%
White or Caucasian	57.9%	76.0%
Other Race	0.0%	10.7%
Declined / Unavailable		

\*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

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:

*“The facility is not obligated under any applicable federal regulations 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.

**Projected Payor Mix during the 2<sup>nd</sup> Full FY  
 01/01/2026 to 12/31/2026**

Primary Payor Source at Admission	FKC North Gaston					
	In-center Dialysis		Home Hemodialysis **		Peritoneal Dialysis **	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	3.4	5.28%	0.5	2.9%	0.0	0.0%
Insurance *	4.4	6.92%	2.1	13.4%	5.1	13.8%
Medicare *	51.4	79.97%	13.3	83.1%	30.4	81.5%
Medicaid *	3.7	5.81%	0.0	0.0%	0.0	0.0%
Other (Miscellanies including VA)	1.3	2.02%	0.1	0.7%	1.8	4.8%
<b>Total</b>	<b>64.3</b>	<b>100.0%</b>	<b>16.0</b>	<b>100.0%</b>	<b>37.3</b>	<b>100.0%</b>

\* Including any managed care plans.

\*\* This is **not** the number of patients trained in a year. This is the total number of patients performing their hemodialysis or peritoneal dialysis in a location other than the dialysis facility.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 5.28% of total IC dialysis services and 2.9% of HH services will be provided to self-pay patients. The applicant projects that 79.97% of total IC dialysis services, 83.1% of HH services, and 81.5% of PD services will be provided to Medicare patients and that 5.81% of total IC dialysis services will be provided to Medicaid patients.

On pages 70 - 71, 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 calculates payor mix based upon treatment volumes as opposed to the number of patients. The applicant considers the possible change in payor source during the fiscal year.
- Payor mix projections are based on recent facility performance.

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.

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 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 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 will have access to the facility for training purposes based on the following:

- The facility has a history of allowing health-related education and training programs visit the facility to observe the operation of the unit while patients receive treatment.
- The applicant provides a copy of a letter sent to Gaston College encouraging the school to include FKC North Gaston 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 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 17 stations upon project completion.

On page 113, the 2023 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Gaston 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 Gaston County as of December 31, 2021. There are five kidney disease treatment centers providing dialysis services in Gaston County.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
BMA Kings Mountain	22	63	71.59%	2.86
FKC North Gaston	12	44	91.67%	3.67
FMC Belmont	19	74	97.37%	3.89
FMC Gastonia	39	123	78.85%	3.15
FMC South Gaston	28	70	62.50%	2.50

Source: Table 9A, Chapter 9, 2023 SMFP, page 122

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 FKC North Gaston.”*

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

*“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:

*“Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”*

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.”*

See also Sections B 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

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, pages 104-108, 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 these facilities. 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.

- (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- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard 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 25 and Section Q, page 87, the applicant projects that FKC North Gaston will serve 62.9 in-center patients on 17 stations, or a rate of 3.7 in-center patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projection 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 25-29, and Section Q, pages 83-87, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.