

## **REQUIRED STATE AGENCY FINDINGS**

### **FINDINGS**

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 26, 2025

Findings Date: August 26, 2025

Project Analyst: Gregory F. Yakaboski

Co-Signer: Micheala Mitchell

Project ID #: F-12621-25

Facility: Fresenius Kidney Care North Gaston

FID #: 160496

County: Gaston

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

Project: Add no more than 5 in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (relocate 5 stations)

### **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**

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA), proposes to add no more than 5 in-center (IC) dialysis stations at Fresenius Kidney Care North Gaston (FKC North Gaston) pursuant to Condition 2 of the facility need methodology for a total of no more than 17 IC stations upon completion of this project and Project ID #F-12585-25 (develop a new dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 dialysis stations from FKC North Gaston and 7 dialysis stations from FMC South Gaston).

FKC North Gaston is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (FMC or Fresenius).

FKC North Gaston currently provides IC dialysis and also has both a peritoneal dialysis (PD) program and a home hemodialysis (HH) program.

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

Chapter 9 of the 2025 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 9B, page 133, the county need methodology shows there is not a county need determination for additional dialysis stations in Gaston County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2025 SMFP, if the utilization rate for the facility as reported in the 2025 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 94.0 percent or 3.76 patients per station per week, based on 64 in-center dialysis patients and 17 certified dialysis stations (64 patients / 17 stations = 3.76;  $3.76 / 4 = 0.94$  or 94.0%).

As shown in Table 9D, pages 137, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 8 additional stations; thus, the applicant is eligible to apply to add up to 8 stations during the 2025 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 5 new stations to the facility, which is consistent with the 2025 SMFP calculated facility need determination for up to 8 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2025 SMFP which is applicable to this review. Policy GEN-5: *Access to Culturally Competent Healthcare*, on pages 30-31 of the 2025 SMFP, states:

*“A certificate of need (CON) applicant applying to offer or develop 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 provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities. The delivery of culturally competent healthcare requires the implementation of systems and training to provide responsive, personalized care to individuals with diverse backgrounds, values, beliefs, customs, and languages. A certificate of need applicant shall identify the underserved populations and communities it will serve, including any disparities or unmet needs of either, document its strategies to provide culturally competent programs and services, and articulate how these strategies will reduce existing disparities as well as increase health equity.*

*CON applications will include the following:*

*The applicant shall, in its CON application, address each of the items enumerated below:*

***Item 1:*** Describe the demographics of the relevant service area with a specific focus on the medically underserved communities within that service area. These communities shall be described in terms including, but not limited to: age, gender, racial composition; ethnicity; languages spoken; disability; education; household income; geographic location and payor type.

***Item 2:*** Describe strategies it will implement to provide culturally competent services to members of the medically underserved community described in Item 1.

***Item 3:*** Document how the strategies described in Item 2 reflect cultural competence.

***Item 4:*** Provide support (e.g., best-practice methodologies, evidence-based studies with similar communities) that the strategies described in Items 2 – 3 are reasonable pathways for reducing health disparities, increasing health equity and improving the health outcomes to the medically underserved communities within the relevant service area.

***Item 5:*** Describe how the applicant will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities in underserved communities.

*In approving an application, Certificate of Need shall impose a condition requiring the applicant to implement the described strategies in a manner that is consistent with the applicant's representations in its CON application."*

**Policy GEN-5.** In Section B, pages 20-24, the applicant explains why it believes its application is conforming with Policy GEN-5.

### **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 the facility need methodology as applied from the 2025 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-5 based on:

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-5 based on the following:
  - The applicant adequately describes the demographics of Gaston County, and the demographics of the patient population at FKC North Gaston by providing patient demographic data, that includes age, racial composition, disability and spoken language.
  - The applicant adequately describes its strategies to provide culturally competent services to medically underserved communities. These strategies include offering interpretation and translation services, providing training to all staff on subjects such as health equity, cultural humility, and collecting culturally sensitive demographic information. Additionally, the applicant will implement a process to regularly review health equity data to identify health equity disparities and subsequently develop plans to address these disparities.
  - In Section B, pages 22-23, the applicant describes its Health Equity Strategic Plan that outlines organizational goals, objectives, actions, and resources to ensure that as an organization, we are adequately providing culturally competent services to all members of the medically underserved community who are choosing to receive dialysis treatment within a Fresenius or Fresenius affiliated facility.
  - To support its approach to reduce health disparities and improve health outcomes in medically underserved communities, the applicant, as part of its Health Equity Strategic Plan for 2024-2026, developed a 4-part training program was developed, *Journey to Cultural Competency*, for all direct patient care clinical staff to ensure that culturally competent services are provided to members of medically underserved communities including providing its staff with the knowledge, skills, and resources necessary to provide care to patients with diverse values, beliefs, and behaviors, including the tailoring of health care delivery to meet patients' social, cultural, and linguistic needs with a better understanding of social determinants of health, moving from unconscious bias to intentional inclusion, and building trust and fostering an inclusion.

(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

The applicant proposes to add no more than 5 in-center dialysis stations at FKC North Gaston pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (develop a new

dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 dialysis stations from FKC North Gaston and 7 dialysis stations from FMC South Gaston).

### **Patient Origin**

The 2025 SMFP, on page 113, 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.*” The facility in this application is in Gaston County. Thus, the service area for this application is Gaston County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

| FKC North Gaston Historical & Projected Patient Origin |                |               |             |               |             |               |                     |               |             |               |             |               |
|--|----------------|---------------|-------------|---------------|-------------|---------------|---------------------|---------------|-------------|---------------|-------------|---------------|
| County   | Last – CY 2024 |               |             |               |             |               | Projected – CY 2029 |               |             |               |             |               |
|  | IC* Patients   |               | HH Patients |               | PD Patients |               | IC* Patients        |               | HH Patients |               | PD Patients |               |
|  | #              | %             | #           | %             | #           | %             | #                   | %             | #           | %             | #           | %             |
| Gaston   | 56.0           | 90.3%         | 17.0        | 68.0%         | 10.0        | 66.7%         | 58.7                | 90.7%         | 18.1        | 69.4%         | 10.7        | 72.7%         |
| Catawba  | 0.0            | 0.0           | 0.0         | 0.0           | 1.0         | 6.7%          | 0.0                 | 0.0           | 0.0         | 0.0           | 0.0         | 0.0           |
| Cleveland  | 0.0            | 0.0           | 3.0         | 12.0%         | 1.0         | 6.7%          | 0.0                 | 0.0           | 3.0         | 11.5%         | 1.0         | 6.8%          |
| Lincoln  | 4.0            | 6.5%          | 3.0         | 12.0%         | 2.0         | 13.3%         | 4.0                 | 6.2%          | 3.0         | 11.5%         | 2.0         | 13.6%         |
| Mecklenburg  | 1.0            | 1.6%          | 1.0         | 4.0%          | 1.0         | 6.7%          | 1.0                 | 1.5%          | 1.0         | 3.8%          | 1.0         | 6.8%          |
| Rutherford   | 0.0            | 0.0           | 1.0         | 4.0%          | 0.0         | 0.0           | 0.0                 | 0.0           | 1.0         | 3.8%          | 0.0         | 0.0           |
| South Carolina   | 1.0            | 1.6%          | 0.0         | 0.0           | 0.0         | 0.0           | 1.0                 | 1.5%          | 0.0         | 0.0           | 0.0         | 0.0           |
| <b>Total</b>   | <b>62.0</b>    | <b>100.0%</b> | <b>25.0</b> | <b>100.0%</b> | <b>15.0</b> | <b>100.0%</b> | <b>64.7</b>         | <b>100.0%</b> | <b>26.1</b> | <b>100.0%</b> | <b>14.7</b> | <b>100.0%</b> |

**Note:** Table may not foot due to rounding.

\* **Source:** Section C, page 26.

In Section C, pages 26-30, and in Section Q, Form C Utilization, pages 81-84, 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’s projections are based on the historical patient origin at FKC North Gaston beginning with the facility patient census as of December 31, 2024, as reported in the 2024 ESRD Data Collection Form submitted to DHSR Planning in February 2025.
- The applicant grows the Gaston County patient census by 1.3%, the Five-Year Average Annual Change Rate (5-Year AACR) for Gaston County per the 2025 SMFP.
- The applicant assumes the six in-center patients residing in surrounding counties and South Carolina as of December 31, 2024, will continue to dialyze at FKC North Gaston by choice but does not project any growth in that patient population and adds these patients to projections of future patient populations at the appropriate time.
- The applicant will subtract one Gaston County resident who signed a letter of support expressing an interest in transferring to a proposed new dialysis facility, FKC Mt. Holly (Project ID #F-12585-25) which application is still under review. The FKC Mt. Holly facility is projected to be completed on December 31, 2027.
- The new stations are projected to be certified by December 31, 2027.

- Operating Year One (OY1) is CY 2028.
- OY2 is CY 2029.

### **Analysis of Need**

In Section C, page 31, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

*“The applicant proposes to add five dialysis stations at FKC North Gaston pursuant to Condition 2 of the Facility Need Methodology identified in Table 9D in the 2025 SMFP. The facility will be certified for a total of 17 stations upon completion of this project and Project ID# F-12585-25 (relocate 5 stations) and will continue to offer both HHD and PD training and support services. The stations proposed in this application are a backfill of five stations at FKC North Gaston pursuant to Project ID# F-12585-25 to develop the new FKC Mt. Holly Dialysis facility. That application is still under review.*

*Project ID# F-12585-25 was submitted to the Healthcare Planning and Certificate of Need Section on January 15, 2025, for FKC Mt. Holly Dialysis, to develop a new dialysis facility by relocating no more than 5 dialysis stations from FKC North Gaston and no more than 7 dialysis stations from FMC South Gaston for a total of no more than 12 stations upon project completion. That project is still under review.*

...

*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 for the proposed project. The applicant has identified the population to be served as 64.0 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates to a utilization rate of 94.1%, or 3.76 patients per station and exceeds the minimum required by the performance standard, thus justifying the need for the total number of existing, approved, and proposed in-center dialysis stations at the FKC North Gaston facility.”*

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

- The applicant demonstrates eligibility to add 8 IC dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2025 SMFP, this application proposes to add 5 IC dialysis stations. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant reports that in the last full FY (CY2024) there were 62 IC patients dialyzing at the facility which equates to a utilization rate reported for the facility is 91.25 percent or 3.65 patients per station per week, based on 62 in-center dialysis patients and 17 certified dialysis stations (62 patients / 17 stations = 3.65;  $3.65 / 4 = 0.9125$  or 91.25%).
- The applicant adequately demonstrates need based on the facility's historic patient census and projected growth in the patient population based on 17 IC dialysis stations. The facility

currently has 17 certified IC dialysis stations. However, pursuant to Project ID #F-12825-25 (still under review), 5 of the existing IC dialysis station would be relocated to a proposed new dialysis facility. The 5 dialysis stations proposed in this project are backfill for the 5 dialysis stations proposed to be relocated from FKC North Gaston pursuant to Project ID# F-12825-25 to keep FKC North Gaston at 17 IC dialysis stations.

*Projected Utilization for IC Patients*

In Section C, page 28, and Section Q, pages 81-82, the applicant provides projected IC 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, 2024.  | 56                         |
| Project the Gaston County patient population forward for one year to December 31, 2025, using the Gaston County Five-Year AACR of 1.3%.                             | $56.0 \times 1.013 = 56.7$ |
| Project the Gaston County patient population forward for one year to December 31, 2026, using the Gaston County Five-Year AACR of 1.3%                              | $56.7 \times 1.013 = 57.5$ |
| Project the Gaston County patient population forward for one year to December 31, 2027, using the Gaston County Five-Year AACR of 1.3%.                             | $57.5 \times 1.013 = 58.2$ |
| Subtract the Gaston County patients projected to transfer to the new FKC Mt. Holly Dialysis facility upon project completion and certification on December 31, 2027 | $58.2 - 1.0 = 57.2$        |
| Project the Gaston County patient population forward for one year to December 31, 2028, using the Gaston County Five-Year AACR of 1.3%.                             | $57.2 \times 1.013 = 58$   |
| Add the 6 patients from other counties and S.C. <b>This is the projected ending census for Operating Year 1.</b>  | $58 + 6.0 = 64$            |
| Project the Gaston County patient population forward for one year to December 31, 2028, using the Gaston County 5-Year AACR of 1.3%.                                | $58 \times 1.013 = 58.7$   |
| Add the 6 patients from other counties and S.C. <b>This is the projected ending census for Operating Year 2.</b>  | $58.7 + 6.0 = 64.7$        |

In Section C, pages 26-30, and Section Q, pages 81-82, the applicant provides the assumptions and methodology used to project IC utilization, which is summarized below.

- Table 9D in the 2025 SMFP indicates that FKC North Gaston qualifies to apply for up to eight additional dialysis stations pursuant to Condition 2 of the Facility Need Methodology.
- The applicant's projections are based on the historical patient origin at FKC North Gaston beginning with the facility patient census as of December 31, 2024, as reported in the 2024 ESRD Data Collection Form submitted to DHSR Planning in February 2025.

- The applicant grows the Gaston County patient census by 1.3%, the 5-Year AACR for Gaston County per the 2025 SMFP.
- The applicant assumes the six in-center patients residing in surrounding counties and South Carolina as of December 31, 2024, will continue to dialyze at FKC North Gaston by choice but does not project any growth in that patient population and adds these patients to projections of future patient populations at the appropriate time.
- The applicant will subtract one Gaston County resident who signed a letter of support expressing an interest in transferring to a proposed new dialysis facility, FKC Mt. Holly (Project ID #F-12585-25) which application is still under review. The FKC Mt. Holly facility is projected to be completed on December 31, 2027.
- The new stations are projected to be certified by December 31, 2027.
- Operating Year One (OY1) is CY 2028.
- OY2 is CY 2029.

Projected Utilization for HH and PD patients

In Section C, pages 29-30, and Section Q, pages 83-84, the applicant provides projected HH and PD utilization, as illustrated in the following table.

| <b>FKC North Gaston</b>   | <b>Home Hemodialysis</b>   | <b>Peritoneal Dialysis</b> |
|---|----------------------------|----------------------------|
| Begin with the Gaston County patient population as of December 31, 2024.  | 17                         | 10                         |
| Project the Gaston County patient population forward for one year to December 31, 2025, using Gaston County Five-Year AACR of 1.3%      | $17.0 \times 1.013 = 17.2$ | $10.0 \times 1.013 = 10.1$ |
| Project the Gaston County patient population forward for one year to December 31, 2026, using the Gaston County Five-Year AACR of 1.3%  | $17.2 \times 1.013 = 17.4$ | $10.1 \times 1.013 = 10.3$ |
| Project the Gaston County patient population forward for one year to December 31, 2027, using the Gaston County Five-Year AACR of 1.3%. | $17.4 \times 1.013 = 17.7$ | $10.3 \times 1.013 = 10.4$ |
| Project the Gaston County patient population forward for one year to December 31, 2028, using the Gaston County Five-Year AACR of 1.3%. | $17.7 \times 1.013 = 17.9$ | $10.4 \times 1.013 = 10.5$ |
| Add the patients from other counties. <b>This is the projected ending census for Operating Year 1.</b>                                  | $17.9 + 8.0 = 25.9$        | $10.5 + 4.0 = 14.5$        |
| Project the Gaston County patient population forward for one year to December 31, 2029, using the Gaston County Five-Year AACR of 1.3%. | $17.9 \times 1.013 = 18.1$ | $10.5 \times 1.013 = 10.7$ |
| Add the patients from other counties. <b>This is the projected ending census for Operating Year 2.</b>                                  | $18.1 + 8.0 = 26.1$        | $10.7 + 4.0 = 14.7$        |

Source: Section C, pages 28-30, Section Q, page 83-84.

In Section C, pages 28-30, and Section Q, pages 83-84, the applicant provides the assumptions and methodology used to project HH and PD utilization, which is summarized as follows:



- The applicant's projections are based on historical patient origin at FKC North Gaston, including 17 HH patients and 10 PD patients from Gaston County.
- The applicant grows the Gaston County population using the Gaston County 5-Year AACR of 1.3%, as published in the 2025 SMFP.
- The facility serves eight HH patients residing in Cleveland, Lincoln, Mecklenburg and Rutherford. The facility also served 5 PD patients residing in Catawba, Cleveland, Lincoln, and Mecklenburg counties.
- Cleveland, Lincoln, and Mecklenburg counties 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.
- The applicant states that the one HH patient from Catawba County is no longer being followed by FKC North Gaston.
- All of the home hemodialysis and peritoneal dialysis patients from other counties and South Carolina 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, 2027.

Operating Year 1 is the period from January 1 - December 31, 2028.

Operating Year 2 is the period from January 1 - December 31, 2029.

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

|                     | Operating Year 1 | Operating Year 2 |
|---------------------|------------------|------------------|
| In-center           | 64.0             | 64.7             |
| Home Hemodialysis   | 25.9             | 26.1             |
| Peritoneal Dialysis | 14.5             | 14.7             |

Source: Section C, page 30 and Section Q, page 84.

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

- The applicant bases the projections of future patient population to be served on the historic patient census as of December 31, 2024.
- The applicant grows the Gaston County population using the Gaston County 5-Year AACR of 1.3%, as published in the 2025 SMFP.
- The applicant does not grow the patients dialyzing at FKC North Gaston who reside outside of Gaston County.
- The applicant accounts for the one IC patient projected to transfer their care to FKC Mt. Holly upon completion of that proposed dialysis facility.

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

In Section C, page 34, 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.”*

In Section C, page 34, the applicant provides the estimated percentage of total patients to be served for each medically underserved group, as shown in the following table.

| <b>Medically Underserved Groups</b> | <b>Estimated Percentage of Total Patients during the Second Full Fiscal Year</b> |
|-------------------------------------|--|
| Low-income persons                  | 27.2%  |
| Racial and ethnic minorities        | 42.1%  |
| Women                               | 39.5%  |
| Persons with Disabilities           | 14.9%  |
| Persons 65 and older                | 41.2%  |
| Medicare beneficiaries              | 93.0%  |
| Medicaid recipients                 | 19.3%  |

Source: Table page 34 of the application.

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 applicant’s history of providing services to medically underserved groups.

### **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.

**CA**

The applicant proposes to add no more than 5 in-center dialysis stations at FKC North Gaston pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (develop a new dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 dialysis stations from FKC North Gaston and 7 dialysis stations from FMC South Gaston).

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 could have chosen not to file for additional stations at FKC North Gaston. Failure to apply for additional stations would result in higher utilization rates [projected utilization at the facility of 5.33 patients per station at the end of Operating Year 1, and 5.39 patients per year at the end of Operating Year 2] which would potentially interrupt patient admissions to the facility and potentially require an evening shift which may not be convenient or accessible for the patients and would thus be the least effective alternative.

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 methodology in the 2025 SMFP the applicant shall add no more than 5 in-center dialysis stations at FKC North Gaston pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (develop a new dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 dialysis stations from FKC North Gaston and 7 dialysis stations from FMC South 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 February 15, 2026.**
  - 4. The certificate holder shall develop and implement strategies to provide culturally competent services to members of its defined medically underserved community that are consistent with representations made in the certificate of need application.**
  - 5. 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 5 in-center dialysis stations at FKC North Gaston pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (develop a new dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 dialysis stations from FKC North Gaston and 7 dialysis stations from FMC South Gaston).

### **Capital and Working Capital Cost**

In Section F.1 and F.2, pages 42-43, and Form F.1a, the applicant states the proposed project does not require any capital costs.

In Section F.3, page 44, the applicant states there will be no start-up costs or initial operating expenses because FKC North Gaston is an existing facility.

### **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, 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:

#### **FKC North Gaston**

|   | <b>First Full FY<br/>CY2028</b> | <b>Second Full FY<br/>CY2029</b> |
|---|---------------------------------|----------------------------------|
| Total Treatment                         | 15,367                          | 15,533                           |
| Total Gross Revenues (Charges)          | \$96,676,122                    | \$97,715,042                     |
| Total Net Revenue                       | \$5,848,562                     | \$5,910,435                      |
| Average Net Revenue Per Treatment       | \$381                           | \$381                            |
| Total Operating Expenses (Costs)        | \$4,586,737                     | \$4,647,124                      |
| Average Operating Expense per Treatment | \$298                           | \$299                            |
| Net Income                              | \$1,261,825                     | \$1,263,311                      |

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Forms F.2, 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 because the applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

### C

The applicant proposes to add no more than 5 in-center dialysis stations at FKC North Gaston pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (develop a new dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 dialysis stations from FKC North Gaston and 7 dialysis stations from FMC South Gaston).

The 2025 SMFP, on page 113, 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.”* The facility in this application is in Gaston County. Thus, the service area for this application is Gaston County. Facilities may serve residents of counties not included in their service area.

According to 2025 SMFP, Table 9A, page 123, there are 5 existing dialysis facilities in Gaston County, as shown in the following table:

|                    | <b>Certified<br/>Stations as of<br/>12/31/2023</b> | <b>Number of In-<br/>center<br/>Patients as of<br/>12/31/2023</b> | <b>Utilization by<br/>Percent as of<br/>12/31/2023</b> | <b>Facility Station<br/>Need<br/>Determination</b> |
|--------------------|--|---|--|--|
| BMA Kings Mountain | 26   | 75  | 72.12%   | 0  |
| FKC North Gaston   | 17   | 64  | 94.12%   | 8  |
| FMC Belmont        | 19   | 74  | 97.37%   | 0  |
| FMC Gastonia       | 39   | 99  | 63.46%   | 0  |
| FMC South Gaston   | 28   | 76  | 67.86%   | 0  |

In Section G, pages 48-49, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in New Hanover County. The applicant states:

*“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 FKC North Gaston facility. The projections for future patient populations to be served begin with the patient population at the facility as of December 31, 2024, and an increase of that population at a rate of 1.3%, commensurate with the Gaston County 5-Year AACR. The applicant is not projected to serve patients currently being served in another facility or served by another provider. These stations are needed to support the growing patient census at the FKC North Gaston facility.*

*As of the date this application was prepared and submitted, FKC North Gaston was certified for 17 stations. The additional stations proposed in this application will backfill five existing stations proposed for relocation to the new FKC Mt. Holly Dialysis facility, pursuant to CON Project ID# F-12585-25. That project was submitted to the Healthcare Planning and Certificate of Need Section in January 2025 and is still under review.*

*BMA does not believe adding five stations will duplicate any services because pending approval of CON Project ID# F-12585-25 and pending approval of this application to backfill five stations, FKC North Gaston will still be certified for 17 stations. This application will ensure continued adequate access to dialysis care for the patient population in Gaston County.*

*Further, the overall utilization for facilities in Gaston County was 3.01 patients per station or 75.19%, as of December 31, 2023. It is not uncommon for a facility to have lower utilization while another facility in the same county is well utilized. While some capacity does exist at other BMA facilities in Gaston County, these facilities are strategically located to serve other patients of the county. It is much more convenient for patients to choose dialysis at the facility closest to their residence location opposed to traveling further for the same dialysis care and treatment, especially where traffic congestion is also a concern. Congestion leads to longer commute times, even when the travel distance may be relatively short.”*

The applicant adequately demonstrates that the proposal will 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 at FKC North Gaston based on Condition 2 of the facility need determination in the 2025 SMFP.
- The applicant adequately demonstrates that the 5 proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Gaston County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 5 in-center dialysis stations at FKC North Gaston pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (develop a new dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 dialysis stations from FKC North Gaston and 7 dialysis stations from FMC South Gaston).

In Section Q, Form H, pages 96-97, 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 1/30/2025   | First Full FY (CY2028) | Second Full FY (CY2029) |
| Administrator                      | 1.00              | 1.00                   | 1.00                    |
| Registered Nurses (RNs)            | 3.00              | 3.00                   | 3.00                    |
| Home Training Nurse                | 3.00              | 3.00                   | 3.00                    |
| Technicians (PCT)                  | 8.00              | 8.00                   | 8.00                    |
| Dietician                          | 0.50              | 0.50                   | 0.50                    |
| Social Worker                      | 1.00              | 1.00                   | 1.00                    |
| Maintenance                        | 0.50              | 0.50                   | 0.50                    |
| Administration/Clerical            | 1.00              | 1.00                   | 1.00                    |
| Other (FMC Director of Operations) | 0.15              | 0.15                   | 0.15                    |
| Other (FMC Chief Technician)       | 0.15              | 0.15                   | 0.15                    |
| Other (FMC In-Service)             | 0.10              | 0.10                   | 0.10                    |
| <b>Total</b>                       | <b>18.40</b>      | <b>18.40</b>           | <b>18.40</b>            |

The assumptions and methodology used to project staffing are provided in Section Q, pages 96-98. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H, pages 50-51, 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 facility is an existing facility, and the applicant bases its staffing on its historical experience providing dialysis services with 17 IC dialysis stations at the facility.



- The applicant has existing policies regarding recruitment, qualifications for staff, training, and continuing education. 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).

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

## **C**

The applicant proposes to add no more than 5 in-center dialysis stations at FKC North Gaston pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (develop a new dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 dialysis stations from FKC North Gaston and 7 dialysis stations from FMC South Gaston).

### **Ancillary and Support Services**

In the table in Section I, page 52, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 52-57, the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the services the applicant currently provides at FKC Gaston.

### **Coordination**

In Section I.2, page 57, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- FKC North Gaston is an existing facility. The applicant discusses its existing relationships with local health care and social service providers
- The applicant has agreements in place coordinating lab services, hospital services, 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.

- (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 64, the applicant provides the historical payor mix at FKC North Gaston for the last full fiscal year (CY2024), as shown in the table below.

| FKC North Gaston Historical Payor: Last FY (CY2024) |             |               |             |               |             |               |
|---|-------------|---------------|-------------|---------------|-------------|---------------|
| Payment Source                                      | IC          |               | HH          |               | PD          |               |
|   | # Patients  | % Patients    | # Patients  | % Patients    | # Patients  | % Patients    |
| Self-Pay  | 1.5         | 2.4%          | 0.8         | 3.2%          | 0.7         | 4.9%          |
| Insurance*  | 3.5         | 5.6%          | 3.9         | 15.5%         | 3.8         | 25.5%         |
| Medicare*   | 51.7        | 83.4%         | 20.3        | 81.3%         | 9.4         | 62.6%         |
| Medicaid*   | 3.7         | 5.9%          | 0.0         | 0.0%          | 0.0         | 0.0%          |
| Other   | 1.6         | 2.7%          | 0.0         | 0.0%          | 1.1         | 7.0%          |
| <b>Total</b>  | <b>62.0</b> | <b>100.0%</b> | <b>25.0</b> | <b>100.0%</b> | <b>15.0</b> | <b>100.0%</b> |

\*Including any managed care plans

In Section L, page 66, the applicant provides the following population comparison of the service area.

**FKC North Gaston: Last Full FY prior to submission of application**

|                                     | <b>Percentage of Total Patients Served</b> | <b>Percentage of the Population of the Service Area *</b> |
|-------------------------------------|--|---|
| Female                              | 39.5%                                      | 51.6%   |
| Male                                | 60.5%                                      | 48.4%   |
| Unknown                             |  |   |
| 64 and Younger                      | 58.8%                                      | 83.2%   |
| 65 and Older                        | 41.2%                                      | 16.8%   |
| American Indian                     | 0.0%                                       | 0.7%  |
| Asian                               | 0.9%                                       | 1.9%  |
| Black or African American           | 40.4%                                      | 19.9%   |
| Native Hawaiian or Pacific Islander | 0.9%                                       | 0.1%  |
| White or Caucasian                  | 57.9%                                      | 74.9%   |
| Other Race                          | 0.0%                                       | 12.7%   |
| Declined / Unavailable              | 0.0%                                       |   |

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 67, the applicant states that FKC North Gaston 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 67, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against FKC North Gaston.

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.3, page 67, the applicant projects the payor mix for the proposed services during the second full fiscal year of operation (CY2029) following completion of the project, as summarized in the table below.

| FKC North Gaston Projected Payor: 2 <sup>nd</sup> FFY (CY2029) |             |               |             |               |             |               |
|--|-------------|---------------|-------------|---------------|-------------|---------------|
| Payment Source   | IC          |               | HH          |               | PD          |               |
|  | # Patients  | % Patients    | # Patients  | % Patients    | # Patients  | % Patients    |
| Self-Pay   | 1.5         | 2.4%          | 0.8         | 3.2%          | 0.7         | 4.9%          |
| Insurance*   | 3.6         | 5.6%          | 4.0         | 15.5%         | 3.7         | 25.5%         |
| Medicare*  | 54.0        | 83.4%         | 21.3        | 81.3%         | 9.2         | 62.6%         |
| Medicaid*  | 3.8         | 5.9%          | 0.0         | 0.0%          | 0.0         | 0.0%          |
| Other  | 1.7         | 2.7%          | 0.0         | 0.0%          | 1.0         | 7.0%          |
| <b>Total</b>   | <b>64.7</b> | <b>100.0%</b> | <b>26.1</b> | <b>100.0%</b> | <b>14.7</b> | <b>100.0%</b> |

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that for IC dialysis services 2.4% of will be provided to self-pay patients, 83.4% to Medicare recipients and 5.9% to Medicaid recipients.

On pages 67-68, 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 bases payor mix upon treatment volumes rather than patients
- The applicant bases future payor mix percentages 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.

C

In Section L, page 69, 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 5 in-center dialysis stations at FKC North Gaston pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (develop a new dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 stations from FKC North Gaston and 7 dialysis stations from FMC South Gaston).

In Section M, page 70, 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 applicant currently provides applicable health professional training programs in the area with access to the facility.
- In Exhibit M-2 the applicant provides a copy of a letter to the Carolinas College of Health Services documenting its willingness to provide applicable health professional training programs in the area with access to the facility.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

## **C**

The applicant proposes to add no more than 5 in-center dialysis stations at FKC North Gaston pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (develop a new dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 dialysis stations from FKC North Gaston and 7 dialysis stations from FMC South Gaston).

The 2025 SMFP, on page 113, 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.”* The facility in this application is in Gaston County. Thus, the service area for this application is Gaston County. Facilities may serve residents of counties not included in their service area.

According to 2025 SMFP, Table 9A, page 123, there are 5 existing dialysis facilities in Gaston County, as shown in the following table:

|                    | <b>Certified<br/>Stations as of<br/>12/31/2023</b> | <b>Number of In-<br/>center<br/>Patients as of<br/>12/31/2023</b> | <b>Utilization<br/>Percent as<br/>12/31/2023</b> | <b>by<br/>of</b> | <b>Facility Station<br/>Need<br/>Determination</b> |
|--------------------|--|---|--|------------------|--|
| BMA Kings Mountain | 26   | 75  | 72.12%   |                  | 0  |
| FKC North Gaston   | 17   | 64  | 94.12%   |                  | 8  |
| FMC Belmont        | 19   | 74  | 97.37%   |                  | 0  |
| FMC Gastonia       | 39   | 99  | 63.46%   |                  | 0  |
| FMC South Gaston   | 28   | 76  | 67.86%   |                  | 0  |

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 71, the applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Gaston County. 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 72, 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 72, the applicant states:

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

*‘We deliver 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 72, the applicant states:



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

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

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant 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
- Information which was publicly available during the review and used by the Agency

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

The applicant proposes to add no more than 5 in-center dialysis stations at FKC North Gaston pursuant to Condition 2 of the facility need methodology for a total of no more than 17 in-center stations upon completion of this project and Project ID #F-12585-25 (develop a new dialysis facility, FKC Mt. Holly Dialysis, by relocating 5 dialysis stations from FKC North Gaston and 7 dialysis stations from FMC South Gaston).

In Section Q Form O, pages 99-102, 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 129 dialysis facilities owned, operated, or managed by a Fresenius Medical Care related entity located in North Carolina.

In Section O, page 77, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy 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 128 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 Services 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 North Gaston is an existing facility. Therefore, this Rule is not applicable to this review.

*(a) 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 26 and 28, and in Section Q, page 82, the applicant projects to serve 64.7 IC patients on 17 stations, or a rate of 3.76 in-center patients per station per week (64 patients / 17 stations = 3.76:  $3.76/4 = 0.94$  or 94.0%), by the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*
- NA- The applicant does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training. Therefore, this Rule does not apply.
- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*
- NA- The applicant does not propose to increase the number of home hemodialysis stations. Therefore, this Rule does not apply.
- (e) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 26-30, and in Section Q, pages 81-84, 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.