

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 3, 2024

Findings Date: September 3, 2024

Project Analyst: Cynthia Bradford

Co-Signer: Lisa Pittman

Project ID #: F-12531-24

Facility: Fresenius Medical Care of North Charlotte

FID #: 955213

County: Mecklenburg

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

Project: Add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 40 stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility)

### REVIEW CRITERIA

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

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

### C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “BMA” or “the applicant”) proposes to add no more than six dialysis stations to Fresenius Medical Care of North Charlotte (FMC of North Charlotte) pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility).

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

Chapter 9 of the 2024 State Medical Facilities Plan (SMFP) provides a county need methodology, and a facility need methodology for determining the need for new dialysis stations. According to Table 9C, on page 136 of the 2024 SMFP, the county need methodology

shows there is not a county need determination for additional dialysis stations anywhere in the state.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2024 SMFP, if the utilization rate for the facility as reported in the 2024 SMFP is at least 75 percent or 3.0 patients per station per week or greater, as stated in Condition 2.a. The utilization rate reported for the facility is 85.00% or 3.4 patients per station per week, based on 136 in-center dialysis patients and 40 certified dialysis stations (136 patients / 40 stations = 3.4, 3.4 / 4 = 85.00%).

As shown in Table 9D, on page 137 of the 2024 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to six additional stations; thus, the applicant is eligible to apply to add up to six stations during the 2024 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

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

### **Policies**

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

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

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

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 21, Section N, page 74, Section O, pages 77-78 and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 22, Section C, pages 31-32, Section L, pages 69-70, Section N, page 74, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

#### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23, Section N, page 74. 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 2024 SMFP.
- The applicant adequately demonstrates how the applicant's projected volumes incorporate the concepts of safety and quality, equitable access, and maximum value for resources expended in meeting the facility need and is consistent with *Policy GEN-3*.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

### C

The applicant proposes to add no more than six dialysis stations to FMC of North Charlotte pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis

stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility).

**Patient Origin**

On page 113, the 2024 SMFP defines the service area for dialysis stations as “the county in which the dialysis station is located”. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

FMC of North Charlotte Current & Projected Patient Origin				
County	Last Full FY 01/01/2023 to 12/31/2023		Second Full FY 01/01/2028 to 12/31/2028	
	IC Patients		IC Patients	
	#	%	#	%
Mecklenburg	124.0	93.2%	125.9	94.0%
Cabarrus	6.0	4.5%	6.0	4.5%
Gaston	1.0	0.8%	1.0	0.7%
Iredell	1.0	0.8%	1.0	0.7%
Rowan	1.0	0.8%		
<b>Total</b>	<b>133.0</b>	<b>100%</b>	<b>133.9</b>	<b>100.0%</b>

Source Section C, page 25, 26

Totals may not sum due to rounding

In Section C, pages 26-28, and the Form C Utilization subsection of Section Q pages 82-85, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the historical (CY2023) patient origin for the facility.

**Analysis of Need**

In Section C, pages 28-29, 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 proposed project. The applicant has identified the population to be served as 132.5 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 82.8%, or 3.31 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 2024 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant adequately demonstrates need based on the facility’s projected growth in the patient population.

Projected Utilization

In Section C, pages 27-28, and in Form Utilization C Section Q, pages 82-85, the applicant provides the in-center projected utilization for FMC of North Charlotte, as illustrated in the following table.

FMC of North Charlotte	In-Center patients
Begin with the Mecklenburg County patient population as of December 31, 2023.	124.0
Project the Mecklenburg County patient population forward 1 year to December 31, 2024, using the Mecklenburg County 5-Year AACR, 1.1%.	$124.0 \times 1.011 = 125.4$
Add the patients from other counties. This is the projected ending census for Interim Year 1.	$125.4 + 8 = 133.4$
Project the Mecklenburg County patient population forward to December 31, 2025, using the Mecklenburg County 5-Year AACR.	$125.4 \times 1.011 = 126.7$
Add the patients from other counties. This is the projected ending census for Interim Year 2.	$126.7 + 8 = 134.7$
Project the Mecklenburg County patient population forward to December 31, 2026, using the Mecklenburg County 5-Year AACR.	$126.7 \times 1.011 = 128.1$
Subtract the patient projected to transfer to the new FKC Huntersville facility upon certification on December 31, 2026.	$128.1 - 5 = 123.1$
Add the patients from other counties. <b>This is the projected ending census Interim Year 3.</b>	$123.1 + 8 = 131.1$
Project the Mecklenburg County patient population forward for one year to December 31, 2027, using the Mecklenburg County 5-Year AACR.	$123.1 \times 1.011 = 124.5$
Add the patients from other counties. <b>This is the projected ending census for Operating Year 1.</b>	$124.5 + 8 = 132.5$
Project the Mecklenburg County patient population forward for one year to December 31, 2028, using the Mecklenburg County 5-Year AACR.	$124.5 \times 1.011 = 125.9$
Add the patients from other counties. <b>This is the projected ending census for Operating Year 2.</b>	$125.9 + 8.0 = 133.9$

Source: Section C, pages 27-28

In Section C, pages 28-29, and in the Form C Utilization subsection of Section Q pages 82-85, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the patient census on December 31, 2023. The applicant states that on December 31, 2023, its in-center patient census was comprised of 124 Mecklenburg County patients.
- The applicant projects growth of the Mecklenburg County Patient population using the Mecklenburg Five Year Average Annual Change Rate (5-Year AACR) of 1.1%, as published in the 2024 SMFP.
- All dialysis patients from other counties are assumed to continue dialysis with the facility; however, the applicant does not project any growth for this segment of the patient population. The 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, 2026, therefore Operating Year 1 is the period from January 1- December 31, 2027, and Operating Year 2 is the period from January 1- December 31, 2028.

At the end of PY1, FMC of North Charlotte is projected to serve 132.5 patients, and at the end of PY2 the facility is projected to serve 133.9 patients on 40 stations. The projected utilization rates for the end of the first two operating years are as follows

- OY1: 132.5 patients per station per week or 82.8% [ $132.5 \text{ patients} / 40 \text{ stations} = 3.31$ ;  $3.31 / 4 = .8281$  or 82.8%]
- OY2: 133.9 patients per station per week or 83.7% [ $133.9 / 40 \text{ stations} = 3.35$ ;  $3.35 / 4 = .8369$  or 83.7%]

The projected utilization of 132.5 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center days per station per week required by 10 NCAC 14C. 2203(b).

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

- The applicant bases the projections of the future patient population to be served at the facility based on actual patient census as of December 31, 2023.
- The applicant projects growth of the Mecklenburg County patient population using the Mecklenburg County Five Year Average Annual Change Rate (5-Year AACR) of 1.1%, as published in the 2024 SMFP, Table 9B.

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

In Section C, pages 31-32, 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 our 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 32, 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>Percentage of Total Patients</b>
Low-income persons	26.6%
Racial and ethnic minorities	28.4%
Women	40.4%
Persons with Disabilities	20.2%
Persons 65 and Older	34.9%
Medicare beneficiaries	62.4%
Medicaid recipients	25.7%

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.

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.

### C

The applicant proposes to add no more than six dialysis stations to FMC of North Charlotte pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility).

In Section E, page 41, the applicant states that there are no alternative methods considered for meeting the need for this proposal for the following reasons:

- Failure to apply for additional stations at FMC of North Charlotte would result in higher utilization rates.
- Higher utilization rates would potentially disrupt patient admissions which, in turn, would push treatment times to later in the evening, which may not be convenient or accessible for patients.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

### Conclusion

The Agency reviewed the:

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

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

- 1. Bio-Medical Facilities of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**



2. Pursuant to Condition 2 of the facility need determination in the 2024 SMFP, the certificate holder shall develop no more than six additional dialysis stations for a total of no more than 40 stations at the FMC of North Charlotte upon completion of this project, and Project ID# F-12469-24.
  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 March 1, 2025.
  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 six dialysis stations to FMC of North Charlotte pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility).

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

In Section F, page 44, the applicant states that there are no start-up costs or initial operating costs associated with this project because it is an existing facility that is already operational.

In Section F, page 44, the applicant states there are no projected capital or working capital costs because it is a backfill for six stations approved to be relocated from FMC of North Charlotte to the new FKC Huntersville facility that was CON approved June 28, 2024.

### **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 89, the

applicant projects that operating expenses will exceed revenues in the first two full fiscal years following completion of the project, as shown in the table below:

<b>FMC of North Charlotte Projected Revenue and Operating Expenses</b>		
	<b>1<sup>st</sup> Full Fiscal Year CY2027</b>	<b>2<sup>nd</sup> Full Fiscal Year CY2028</b>
Treatments	19,509	19,710
Gross Patient Revenue	\$122,728,199	\$123,996,275
Net Patient Revenue	\$7,447,033	\$7,523,978
Average Net Revenue per Treatment	\$382	\$382
Total Operating Expenses	\$4,738,413	\$4,798,312
Average Operating Expense per Treatment	\$243	\$243
Net Income	\$2,708,620	\$2,725,666

Totals may not sum due to rounding.

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

Based on that review, the Agency concludes that the application is conforming to this criterion because there are no capital costs for the project because the applicant is backfilling six stations that are being transferred to another facility.

- (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 six dialysis stations to FMC of North Charlotte pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility).

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

According to Table 9A on pages 125- 126 of the 2024 SMFP, there are 25 existing facilities which provide dialysis services in Mecklenburg County. Information on all of these dialysis facilities is provided in the table below.

Facility Name	Certified Stations as of 12/31/2022	Patients as of 12/31/2022	Utilization by Percent as of 12/31/2022
BMA Beatties Ford	43	90	54.88%
BMA Nations Ford	28	90	80.36%
BMA of East Charlotte	32	105	82.03%
BMA West Charlotte	29	87	75.00%
Brookshire Dialysis	20	11	90.91%
Charlotte Dialysis	33	79	59.85%
Charlotte East Dialysis	34	102	75.00%
DSI Charlotte Latrobe Dialysis	24	70	72.92%
DSI Glenwater Dialysis	42	88	52.38%
FMC Charlotte	48	88	45.83%
FMC Matthews	21	80	95.24%
FMC of North Charlotte	40	136	85.00%
Fresenius Kidney Care Mallard Creek	12	20	41.67%
Fresenius Kidney Care Regal Oaks	17	56	82.35%
Fresenius Kidney Care Southeast Mecklenburg	17	49	72.06%
Fresenius Medical Care Aldersgate	16	51	79.69%
Fresenius Medical Care Southwest Charlotte	26	67	64.42%
Huntersville Dialysis	27	65	60.19%
Mint Hill Dialysis	21	56	66.67%
North Charlotte Dialysis Center	33	94	71.21%
South Charlotte Dialysis	27	72	66.67%
Sugar Creek Dialysis	21	39	46.43%

Source: Table 9A, Chapter 9, 2024 SMFP, pages 125-126

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

*“This application is to add six dialysis stations to an existing dialysis facility based upon the performance and demonstrated need at the FMC of North Charlotte facility. This application is a backfill for six stations approved to be relocated from FMC of North Charlotte to the new Fresenius Kidney Care Huntersville (FKC Huntersville) facility that was CON approved on June 28, 2024”.*

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 FMC of North Charlotte County based on Condition 2 of the facility need determination in the 2024 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Mecklenburg County.

### **Conclusion**

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to add no more than six dialysis stations to FMC of North Charlotte pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility).

In Section Q, Form H, page 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 as of 6/18/2024	Projected FTE Staff 1 <sup>st</sup> Full FY 2027 (PY1)	Projected FTE Staff 2nd Full FY 2028 (PY2)
Administrator (FMC Clinic Manager)	1.00	1.00	1.00
Registered Nurses (RNs)	5.00	5.00	5.00
Technicians (PCT)	8.00	12.00	12.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Administration/Clerical	1.00	1.00	1.00
Other (FMC Director of Operations)	0.11	0.11	0.11
Other (FMC Chief Technician)	0.11	0.11	0.11
Other (FMC in-Service)	0.11	0.11	0.11
<b>Total</b>	<b>18.33</b>	<b>22.33</b>	<b>22.33</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H, pages 51-52, 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 at the facility.
- The applicant has existing policies regarding recruitment, qualifications for staff, training, and continuing education.

**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 six dialysis stations to FMC of North Charlotte pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility).

**Ancillary and Support Services**

In Section I, page 53, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 53-58, 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.

**Coordination**

In Section I, page 58, 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 established relationships with other physicians and hospitals in the area and its agreements for lab services, hospital affiliation and transplant.

**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.

- (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 65, the applicant provides the historical payor mix for CY2023 as shown in the table below.

FMC of North Charlotte Last Full FY 01/01/2023-12/31/2023		
Payment Source	In-Center	
	# Patients	% Patients
Self-Pay	17.2	12.91%
Insurance*	13.9	10.42%
Medicare*	91.3	68.66%
Medicaid*	7.7	5.75%
Other misc. including VA	3.0	2.26%
<b>Total</b>	<b>133.1</b>	<b>100.00%</b>

In Section L, page 67, the applicant provides the following population comparison of the service area for the last full operating year.

FMC North Charlotte	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	40.4%	51.6%
Male	59.6%	48.4%
Unknown		
64 and Younger	65.1%	87.8%
65 and Older	34.9%	12.2%
American Indian		0.9%
Asian		6.7%
Black or African-American	89.9%	33.2%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian	10.1%	56.4%
Other Race		17.1%
Declined / Unavailable		

Sources: \*BMA Internal Data, US Census Bureau

### Conclusion

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 68, the applicant states it has no such obligation.

In Section L, page 68, the applicant states that during the 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against FMC of North Charlotte.

### **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.

- (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 68, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>FMC of North Charlotte 2<sup>nd</sup> Full FY 01/01/2028-12/31/2028</b>		
	<b>In-Center</b>	
<b>Payment Source</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	17.3	12.91%
Insurance*	14.0	10.42%
Medicare*	91.9	68.66%
Medicaid*	7.7	5.75%
Other misc. including VA	3.0	2.26%
<b>Total</b>	<b>133.9</b>	<b>100.00%</b>

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 12.91% of in-center services will be self-pay; 68.66% of in-center services will be covered by Medicare, and 5.75% of in-center services will be covered by Medicaid.

On pages 68-69, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix at FMC of North Charlotte.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 70, and in Exhibit L-4, the applicant adequately describes the range of means by which patients will have access to the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than six dialysis stations to FMC of North Charlotte pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility).

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant provides a copy of a letter sent to Central Piedmont Community College offering the facility as a training site for nursing students.
- The applicant states it intends to serve as a host for health-related education and training programs.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 six dialysis stations to FMC of North Charlotte pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility).

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

According to Table 9A on pages 125- 126 of the 2024 SMFP, there are 25 existing facilities which provide dialysis services in Mecklenburg County. Information on all four of these dialysis facilities is provided in the table below.

Facility Name	Certified Stations as of 12/31/2022	Patients as of 12/31/2022	Utilization by Percent as of 12/31/2022
BMA Beatties Ford	43	90	54.88%
BMA Nations Ford	28	90	80.36%
BMA of East Charlotte	32	105	82.03%
BMA West Charlotte	29	87	75.00%
Brookshire Dialysis	20	11	90.91%
Charlotte Dialysis	33	79	59.85%
Charlotte East Dialysis	34	102	75.00%
DSI Charlotte Latrobe Dialysis	24	70	72.92%
DSI Glenwater Dialysis	42	88	52.38%
FMC Charlotte	48	88	45.83%
FMC Matthews	21	80	95.24%
FMC of North Charlotte	40	136	85.00%
Fresenius Kidney Care Mallard Creek	12	20	41.67%
Fresenius Kidney Care Regal Oaks	17	56	82.35%
Fresenius Kidney Care Southeast Mecklenburg	17	49	72.06%
Fresenius Medical Care Aldersgate	16	51	79.69%
Fresenius Medical Care Southwest Charlotte	26	67	64.42%
Huntersville Dialysis	27	65	60.19%
Mint Hill Dialysis	21	56	66.67%
North Charlotte Dialysis Center	33	94	71.21%
South Charlotte Dialysis	27	72	66.67%
Sugar Creek Dialysis	21	39	46.43%

Source: Table 9A, Chapter 9, 2024 SMFP, pages 125-126

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 73, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 74, the applicant states:

*“This is a proposal to add six dialysis stations to the FMC of North Charlotte County facility. The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval of this application will allow the facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”*

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

Regarding the impact of the proposal on quality, in Section N, page 74, the applicant states:

*“Quality of care is always in the forefront at Fresenius Medical Care-related facilities. Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 74, the applicant states:

*“All Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. .... Each of those 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 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 C and L of the application and any exhibits.

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services 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 publicly available during the review and used by the Agency

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

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

### C

The applicant proposes to add no more than six dialysis stations to FMC of North Charlotte pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis stations upon completion of this project and Project ID #F-12469-24 (develop new 10-station facility).

In Section Q, Form O, pages 100-104, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. On page 15, the applicant identifies a total of 132 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy

violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 132 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 CAC 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- FMC of North Charlotte is an existing facility. Therefore, this Rule is not applicable to this review.

*(b) An applicant proposing to increase the number of dialysis stations in:*

- (1) an existing dialysis facility; or*
- (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*

-C- In Section C, page 33, and on Form C in Section Q, the applicant projects to serve 132.5 patients on 40 stations, or a rate of 3.31 in-center patients per station per week (132.5 patients / 40 stations = 3.31, 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 26-28, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.