

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: October 12, 2023

Findings Date: October 12, 2023

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: F-12408-23

Facility: BMA West Charlotte

FID #: 955792

County: Mecklenburg

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

Project: Add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion

### REVIEW CRITERIA

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or “BMA West Charlotte”), proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

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

Chapter 9 of the 2023 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9B, page 133, the county need methodology shows there is not a county need determination for additional dialysis stations in Mecklenburg County.

However, the applicant is eligible to apply for additional stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, if the utilization rate for the facility as reported in the 2023 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 76.72% or 3.1 patients per station per week, based on 89 in-center dialysis patients and 29 certified dialysis stations (89 patients/29 stations = 3.1;  $3.1 / 4 = 76.72\%$ ).

As shown in Table 9D, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 4 additional stations; thus, the applicant is eligible to apply to add up to 4 stations during the 2023 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 2 new stations to the facility, which is less than the 2023 calculated facility need determination for up to 4 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

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

Policy *GEN-3*, page 30 of the 2023 SMFP, states:

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

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 21; Section N, page 74-75; Section O, pages 77-80; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 22; Section C, pages 30- 31; Section L, pages 66-72; Section N, page 75; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23; Section F, pages 42-47; Section N, page 75; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

### Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with Condition 2 of the facility need methodology as applied from the 2023 SMFP.
- The applicant adequately demonstrates how BMA West Charlotte's projected volumes incorporate the concepts of safety and quality, equitable access, and maximum value for resources expended in meeting the facility need and is consistent with Policy GEN-3.

(2) Repealed effective July 1, 1987.

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

C

BMA West Charlotte proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

**Patient Origin**

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

The following table illustrates historical and projected patient origin.

County	BMA West Charlotte Patient Origin			
	Historical Last Full FY CY 2022		Projected 2 <sup>nd</sup> Full FY CY 2026	
	# of IC Patients	% of Total	# of IC Patients	% of Total
Mecklenburg	87.0	100.0%	95.3	100.0%
<b>Total</b>	<b>87.0</b>	<b>100.0%</b>	<b>95.3</b>	<b>100.0%</b>

Source: Section C, pages 25 - 26

The applicant does not currently provide home peritoneal dialysis and home hemodialysis and does not project to begin offering those services in this application.

In Section C, page 26-27, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s patient origin projections are reasonable and adequately supported because they are based the historical (CY2022) patient origin for the facility.

**Analysis of Need**

In Section C, page 28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

*“The need that this population has for the proposed services is a function of the individual patient’s need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the population to be served as 93.1 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates a utilization rate of 75.11%, or 3.0 patients per station and exceeds the minimum required by the performance standard.”*

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

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2023 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

- The applicant adequately demonstrates need based on the facility’s projected growth in the patient population.

Projected Utilization

In Section C, page 27, and Section Q, page 85, the applicant provides projected utilization, as illustrated in the following table.

<b>BMA West Charlotte</b>	<b>In-Center patients</b>
Begin with the Mecklenburg County patient population as of December 31, 2022.	87
Project the Mecklenburg County patient population forward for one year to December 31, 2023, using the Mecklenburg County Five-Year AACR.	$87.0 \times 1.023 = 89.0$
Project the Mecklenburg County patient population forward for one year to December 31, 2024, using the Mecklenburg County Five-Year AACR.	$89.0 \times 1.023 = 91.0$
Project the Mecklenburg County patient population forward for one year to December 31, 2025, using the Mecklenburg County Five-Year AACR. <b>This is the projected ending census or Operating Year 1.</b>	$91.0 \times 1.023 = 93.1$
Project the Mecklenburg County patient population forward for one year to December 31, 2026, using the Mecklenburg County Five-Year AACR. <b>This is the projected ending census for Operating Year 2.</b>	$93.1 \times 1.023 = 95.3$

In Section C, pages 26-27 and Section Q, page 85, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The 2023 SMFP, Table 9D indicates that BMA West Charlotte qualifies to apply for up to 4 additional dialysis stations pursuant to Condition 2 of the Facility Need Methodology. This is an application for two additional dialysis stations.
- The applicant begins its projections of the future patient population to be served, with the facility census as of December 31, 2022. This information was reported on the 2022 ESRD Data Collection Form submitted to DHSR Planning in February 2023.
- The applicant projects growth of the Mecklenburg County patient population using the Mecklenburg County Five Year Annual Change Rate (5-Year AACR) of 2.3% as published in the 2023 SMFP.
- The new stations are projected to be certified as of December 31, 2024.

Operating Year 1 is the period from January 1-December 31, 2025  
Operating Year 2 is the period from January 1 – December 31, 2026

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

	Operating Year 1	Operating Year 2
In-center	93.1	95.3

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

- OY1: 3 patients per station per week or 75% (93.1 patients /31 stations = 3; 3/4 = 0.75 or 75%)
- OY2: 3 patients per station per week or 77% (95.3 patients/31 stations = 3.07; 3.07/4 = 0.7675 or 77%).

The projected utilization of 3 patients per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C.2203(b).

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

- Utilization projections were based at historical patient census at the facility and the Mecklenburg County 5- Year AACR.
- The applicant’s proposal to add two dialysis stations will meet the need of the projected growth of the facility’s patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

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

In Section C, pages 30 - 31, the applicant states:

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

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

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

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

<b>Medically Underserved Group</b>	<b>Percentage of Total Patients</b>
Low-income persons	4.5%
Racial and ethnic minorities	97.7%
Women	35.2%
Person with disabilities	5.7%
Persons 65 and older	18.2%
Medicare beneficiaries	69.3%
Medicaid recipients	4.5%

**Source:** Section C, page 31

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.

### **Conclusion**

The Agency reviewed the:

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or 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

BMA West Charlotte proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

In Section E, page 40, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- The applicant could have chosen not to file for additional stations at BMA West Charlotte. Failure to apply for additional stations at BMA West Charlotte would ultimately result in higher utilization rates. The applicant has demonstrated that the projected utilization for the end of Operating Year 1 is 3.00 patients per station; the projected utilization for the end of Operating Year 2 is 3.07 patients per station.
- The applicant could have chosen to file for less than two additional stations. An application for fewer than two stations would have the same effect as not applying: higher utilization rates as the facility patient census increases.
- The applicant could have chosen to file for more as may as four additional stations. An application for more than two stations is not cost effective. The facility does not have the physical space for more than 31 dialysis stations. Even though the facility qualifies to apply for as many as four dialysis stations, there is no room for more than two additional dialysis stations.

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2023 SMFP, the certificate holder shall develop no more than two additional dialysis stations for a total of no more than 31 stations at BMA West Charlotte.**



3. **Progress Reports**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
  - b. The certificate holder shall complete all sections of the Progress Report form.
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
  - d. The first progress report shall be due on April 1, 2024.
4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA West Charlotte proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

**Capital and Working Capital Costs**

In Section F, page 42, the applicant projects the total capital cost of the project, as shown in the table below.

Non-Medical Equipment	\$1,500
Furniture	\$6,000
<b>Total</b>	<b>\$7,500</b>

Source: Form F1.a, page 87 of the application

In Section Q, page 87, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the applicant's experience with similar projects.

On page 44, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project because BMA West Charlotte is an existing facility.

**Availability of Funds**

In Section F, page 44, the applicant states that the capital cost will be funded as shown in the table below.

<b>Source of Financing for Working Capital</b>	<b>Total</b>
Loans	\$0
Accumulated reserves or OE *	\$7,500
Bonds	\$0
Other (Specify)	\$0
<b>Total Financing</b>	<b>\$7,500</b>

\* OE = Owner's Equity

Exhibit F-2 contains a letter dated July 17, 2023, from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, authorizing the use of accumulated reserves for the capital needs of the project. The letter in Exhibit F-2 also states that the 2022 Consolidated Balance Sheet reflects more than \$446 million in cash, and total assets exceeding \$25 billion.

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

**Financial Feasibility**

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, in Section Q, 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>BMA West Charlotte</b>	<b>1<sup>st</sup> FFY CY 2025</b>	<b>2<sup>nd</sup> FFY CY 2026</b>
Total Treatments (Form C)	13,630	13,944
Total Gross Revenues (Charges)	\$85,746,778	\$87,718,953
Total Net Revenue	\$4,114,279	\$4,208,907
Average Net Revenue per Treatment	\$302	\$302
Total Operating Expenses (Costs)	\$4,494,519	\$4,566,309
Average Operating Expense per Treatment	\$330	\$327
Net Income	\$(380,240)	\$(357,402)

In Section Q, page 91, the applicant states,

*“Fresenius Medical Care is aware that the BMA West Charlotte facility is currently operating in a financial loss position. Adding capacity and increasing our patient census will help in our efforts to return the facility to a profitable status. In the meantime, our parent company, Fresenius Medical Care Holdings, Inc. is prepared to*

*absorb the financial losses of the BMA West Charlotte facility. Exhibit F-3 includes the Fresenius Medical Care Holdings, Inc. ad Subsidiaries Consolidated Financial Statements for Quarter One of 2023, which will show that Fresenius Medical Care Holdings, Inc. has the financial means to absorb the financial losses of the BMA West Charlotte facility until it returns to a profitable status.”*

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3, and F.4.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposals and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

### C

BMA West Charlotte proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

The 2023 SMFP, page 113, defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located.* Thus, the service area for this facility

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

The table below lists the existing and approved facilities, certified station, and utilization of dialysis facilities for Fresenius Medical Care related facilities in Mecklenburg County as of December 31, 2022. There are twenty-two kidney disease treatment centers providing dialysis services in Mecklenburg County.

Fresenius Medical Care Facilities	Certified Stations as of 12/31/22	# of IC Patients as of 12/31/22	Utilization by percent as of 12/31/22
BMA West Charlotte	29	87	75.00%
BMA Beatties Ford	41	90	54.88%
BMA Nations Ford	28	90	80.36%
BMA East Charlotte	32	105	82.03%
FMC Charlotte	48	88	45.83%
FMC Matthews	21	80	95.24%
FMC North Charlotte	40	135	85.00%
FKC Mallard Creek	12	20	41.67%
FKC Regal Oaks	17	56	82.35%
FKC Southeast Mecklenburg	17	49	72.06%
FMC Aldersgate	16	51	79.69%
FMC Southwest Charlotte	26	67	64.42%
Brookside Dialysis	11	40	90.91%
Charlotte Dialysis	33	79	64.42%
Charlotte East Dialysis	34	102	90.91%
DSI Charlotte Latrobe Dialysis	24	70	59.85%
DSI Glenwater Dialysis	42	88	75.00%
Huntersville Dialysis	27	65	72.92%
Mint Hill Dialysis	21	56	52.38%
North Charlotte Dialysis Center	33	94	60.19%
South Charlotte Dialysis	27	72	66.67%
Sugar Creek Dialysis	0	0	00.00%

Source: 2023 SMFP, Table 9A, pages 124-125

In Section G, page 51, 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:

*“The need addressed by this applicant is not specific to Mecklenburg County as a whole. The stations are needed by the patient population projected to be served by facility. The applicant is not projecting to serve patients currently being served in another facility or served by another provider. These stations are needed to support the growing patient census at the BMA West Charlotte facility.”*

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

- The applicant proposes to increase the number of dialysis stations in Mecklenburg County based on Condition 2 of the facility need determination in the 2023 SMFP.
- The applicant adequately demonstrates that the proposed dialysis station is 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**

BMA West Charlotte proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

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

<b>BMA West Charlotte</b>	<b>Current Staff</b>	<b>2025</b>	<b>2026</b>
	<b>as of 06/7/23</b>	<b>1<sup>st</sup> Full FY</b>	<b>2<sup>nd</sup> Full FY</b>
Administrator (FMC Clinical Manager)	1.00	1.00	1.00
(Registered Nurses) RNs	4.00	4.00	4.00
Technicians (PCT)	10.00	10.00	10.00
Medical Records	1.00	1.00	1.00
Dieticians	0.50	0.50	0.50
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Other (FMC Director of Operations)	0.14	0.14	0.14
Other (FMC Chief Technician)	0.14	0.14	0.14
Other (FMC In-Service)	0.14	0.14	0.14
<b>TOTAL</b>	<b>18.92</b>	<b>18.92</b>	<b>18.92</b>

Source: Section Q, Form H, pages 98-99.

The assumptions and methodology used to project staffing are provided in Section Q, page 100. Adequate operating expenses for the health manpower and management positions

proposed by the applicant are budgeted in F.4 in Section Q, page 95. In Section H, pages 52-53, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- BMA West Charlotte is an existing facility in Mecklenburg County that has demonstrated its ability to attract qualified staff by offering a wide range of personnel benefits and maintain competitive salaries.
- In response to the pandemic's impact on staffing, Fresenius Medical Care, parent company to BMA, has implemented initiatives such as, sign-on and retention bonuses, increased starting salaries, corporate review of salary scales, intensified recruiting efforts, and comprehensive offerings of Total Rewards to aid in benefiting the employee and their families.
- New employees are required to complete a 10-week training program that includes safety precautions in addition to clinical training.

### **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

BMA West Charlotte proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

### **Ancillary and Support Services**

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 54-59, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

## **Coordination**

In Section I, page 59, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on its 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 66, the applicant provides the historical payor mix during CY 2022 for the proposed services, as shown in the table below.



<b>BMA West Charlotte Historical Payor Mix 01/01/2022-12/31/2022</b>		
<b>Payor Source</b>	<b>In-Center Dialysis</b>	
	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	3.2	3.72%
Insurance*	2.2	2.50%
Medicare*	76.5	87.88%
Medicaid*	4.2	4.84%
Other-VA	0.9	1.07%
<b>Total</b>	<b>87.0</b>	<b>100.0%</b>

\*Including any managed care plans.  
 Source: Section L, page 66

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

<b>BMA West Charlotte</b>	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY</b>	<b>Percentage of the Population of the Service Area</b>
Female	35.2%	51.7%
Male	64.8%	48.3%
Unknown		
64 and Younger	81.8%	88.1%
65 and Older	18.2%	11.9%
American Indian	0.0%	0.9%
Asian	1.1%	6.5%
Black or African-American	90.9%	33.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	2.3%	56.6%
Other Race	5.7%	16.7%
Declined / Unavailable		

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

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 69, the applicant states:

*“The facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.”*

In Section L, page 69, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 69, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

<b>BMA West Charlotte Projected Payor Mix 01/01/2026-12/31/2026</b>		
<b>Payor Source</b>	<b>In-Center Dialysis</b>	
	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	3.5	3.72%
Insurance*	2.4	2.50%
Medicare*	83.7	87.88%
Medicaid*	4.6	4.84%
Other-VA	1.0	1.07
<b>Total</b>	<b>95.3</b>	<b>100.0%</b>

\*Including any managed care plans.

Source: Section L, page 69

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 3.72% of total IC dialysis services will be provided to self-pay patients, 87.88% of total IC dialysis services to Medicare patients and 4.84% of total IC dialysis services to Medicaid patients.

On pages 69-70, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical (CY2022) payor mix at BMA West Charlotte.

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 based on the reasons stated above.

- (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

BMA West Charlotte proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

In Section M, page 73, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. 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 facility has a history of allowing health-related education and training programs visit the facility to observe the operation of the unit while patients receive treatment.
- The applicant provides a copy of a letter sent to Central Piedmont Community College encouraging the school to include BMA West Charlotte facility in their clinical rotations for nursing students.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

demonstrate that its application is for a service on which competition will not have a favorable impact.

C

BMA West Charlotte proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

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

The table below lists the existing and approved facilities, certified station, and utilization of dialysis facilities for Fresenius Medical Care related facilities in Mecklenburg County as of December 31, 2022. There are twenty-two kidney disease treatment centers providing dialysis services in Mecklenburg County.

<b>Fresenius Medical Care Facilities</b>	<b>Certified Stations as of 12/31/22</b>	<b># of IC Patients as of 12/31/22</b>	<b>Utilization by percent as of 12/31/22</b>
BMA West Charlotte	29	87	75.00%
BMA Beatties Ford	41	90	54.88%
BMA Nations Ford	28	90	80.36%
BMA East Charlotte	32	105	82.03%
FMC Charlotte	48	88	45.83%
FMC Matthews	21	80	95.24%
FMC North Charlotte	40	135	85.00%
FKC Mallard Creek	12	20	41.67%
FKC Regal Oaks	17	56	82.35%
FKC Southeast Mecklenburg	17	49	72.06%
FMC Aldersgate	16	51	79.69%
FMC Southwest Charlotte	26	67	64.42%
Brookside Dialysis	11	40	90.91%
Charlotte Dialysis	33	79	64.42%
Charlotte East Dialysis	34	102	90.91%
DSI Charlotte Latrobe Dialysis	24	70	59.85%
DSI Glenwater Dialysis	42	88	75.00%
Huntersville Dialysis	27	65	72.92%
Mint Hill Dialysis	21	56	52.38%
North Charlotte Dialysis Center	33	94	60.19%
South Charlotte Dialysis	27	72	66.67%
Sugar Creek Dialysis	0	0	00.00%

Source: 2023 SMFP, Table 9A, pages 124-125

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

*“The applicant does not expect this proposal to have any effect on the competitive climate in Mecklenburg County...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 BMA West Charlotte.”*

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

*“Approval of this application will allow the facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”*

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

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

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

See also Sections B, 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 75, the applicant states:

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

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

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

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

- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

BMA West Charlotte proposes to add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

In Section Q, pages 101-105, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 109 of this type of facility located in North Carolina.

In Section O, page 82, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of these facilities. After reviewing and considering information provided at all 109 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.  
  
G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

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

*(a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- BMA West Charlotte is an existing facility. The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.

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

*(1) an existing dialysis facility; or*

*(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

*shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*

-C- In Section C, page 27 and on Form C in Section Q, page 88, the applicant projects to serve 93 patients on 31 stations, which is 3.0 patients per station per week ( $93 \text{ patients} / 31 \text{ stations} = 3.0$ ), by the end of OY1 and 95 patients on 21 stations, which is 3.1 patients per station per week ( $95 \text{ patients} / 31 \text{ stations} = 3.4$ ). by the end of OY2. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

*(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C, pages 27, and Section Q, pages 88, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.