

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 10, 2024

Findings Date: December 10, 2024

Project Analyst: Crystal Kearney

Co-Signer: Micheala Mitchell

Project ID #: F-12530-24

Facility: BMA Nations Ford

FID #: 970826

County: Mecklenburg

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

Project: Add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 28 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 three dialysis stations to BMA Nations Ford pursuant to Condition 2 of the facility need methodology for a total of no more than 28 stations upon project completion and Project ID# F-12469-24 (develop new 10 station facility) at Fresenius Kidney Care Huntersville (FKC Huntersville) 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 80.36% or 3.2 patients per station per week, based on 90 in-center dialysis patients and 28 certified dialysis stations (90 patients / 28 stations = 3.214,  $3.214 / 4 = 80.36\%$ ).

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 at BMA Nations Ford is up to three additional stations; thus, the applicant is eligible to apply to add up to three stations during the 2024 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than three new stations to the facility, which is consistent with the 2024 SMFP calculated facility need determination for up to twenty-eight 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*, on page 29 of the 2024 SMFP, states:

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

### **Promote Safety and Quality**

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 76- 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 67-70, 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 73 and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the application is consistent with Condition 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 three dialysis stations to BMA Nations Ford pursuant to Condition 2 of the facility need methodology for a total of no more than 28 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. 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 also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

| County         | BMA Nations Ford<br>Patient Origin    |               |   |               |
|----------------|---------------------------------------|---------------|---|---------------|
|                | Historical<br>Last Full FY<br>CY 2023 |               | Projected<br>2 <sup>nd</sup> Full FY<br>CY 2028 |               |
|                | # of IC Patients                      | % of Total    | # of IC Patients                                | % of Total    |
| Mecklenburg    | 93.0                                  | 97.9%         | 97.2  | 98.0%         |
| South Carolina | 2.0                                   | 2.1%          | 2.0   | 2.0%          |
| <b>Total</b>   | <b>95.0</b>                           | <b>100.0%</b> | <b>99.2</b>                                     | <b>100.0%</b> |

Source: Section C, pages 25-26

In Section C, pages 25-27, the applicant provides assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects origin for Mecklenburg County residents based on the facility’s historical patient origin. The applicant states that Mecklenburg County in-patient population has grown from 93 patients as of December 31, 2023, to 97 patients as of December 31, 2028, or 1.1% in one year.
- The applicant states the facility also served two in-center patients residing in South Carolina. These patients will continue dialysis at BMA Nations Ford as a function of patient choice. The applicant does not project any growth of this segment of the patient population.
- The applicant projects growth of the Mecklenburg County population using the Mecklenburg County Five Year Average Change Rate (5-Year AACR) of 1.1%. as published in the 2024 SMFP.

**Analysis of Need**

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

- The applicant proposes to develop new dialysis stations, filed in response to the facility need determination.
- The need the population has for this service is based on the individual patient’s need for dialysis care and treatment.

- The applicant projects that 98.1 in-center dialysis patients will be served by the facility by the end of the first Operating Year of the project. This equates to a utilization rate of 87.6%, or 3.51 patients per station per week 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 the need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant adequately demonstrates need based on the facility's historical growth in the patient population.

### **Projected Utilization**

In Section C, pages 29-30 and Section Q, pages 82-85, the applicant provides historical and projected utilization, as illustrated in the following tables.

| <b>BMA Nations Ford<br/>Projected Utilization<br/>In-Center Patients</b>  |                            |
|---|----------------------------|
| Begin with the Mecklenburg County patient population as of December 31, 2023.   | 93.0                       |
| Project the Mecklenburg County patient population forward for one year to December 31, 2024, using 1.1% growth rate commensurate with the Mecklenburg County 5-Year AACR.   | $93.0 \times 1.011 = 94.0$ |
| Add the patients from South Carolina. This is the projected ending census for Interim Year 1.   | $94.0 + 2.0 = 96.0$        |
| Project the Mecklenburg County patient population forward for one year to December 31, 2025, using a 1.1% growth rate commensurate with the Mecklenburg County 5-Year AACR. | $94.0 \times 1.011 + 95.1$ |
| Add the patients from South Carolina. This is the projected ending census for Interim Year 2.   | $95.1 + 2.0 = 97.1$        |
| Project the Mecklenburg County patient population forward for one year to December 31, 2026, using a 1.1% growth rate commensurate with the Mecklenburg County 5-Year AACR. | $95.1 \times 1.011 = 96.1$ |
| Subtract the patient projected to transfer to the new FKC Huntersville facility upon certification on December 31, 2026.  | $96.1 - 1 = 95.1$          |
| Add the patients from South Carolina. This is the projected ending census for Interim Year 3.   | $95.1 + 2.0 = 97.1$        |
| Project the Mecklenburg County patient population forward for one year to December 31, 2027, using a 1.1% growth rate commensurate with the Mecklenburg County 5-Year AACR. | $95.1 \times 1.011 = 96.1$ |
| Add the patients from South Carolina. <b>This is the projected ending census for Operating Year 1.</b>  | $96.1 + 2.0 = 98.1$        |
| Project the Mecklenburg County patient population forward for one year to December 31, 2028, using a 1.1% growth rate commensurate with the Mecklenburg County 5-Year AACR. | $96.1 \times 1.011 = 97.2$ |
| Add the patients from South Carolina. <b>This is the projected ending census for Operating Year 2.</b>  | $97.0 + 2.0 = 99.2$        |

Section Q, page 84

| BMA Nations Ford   | Operating Year 1 | Operating Year 2 |
|--------------------|------------------|------------------|
| In-Center Patients | 98.1             | 99.2             |

Section Q, page 85

In Section C, pages 26-29, the applicant provides the assumptions and methodology used to project utilization, which is summarized below

**In-Center Assumptions:**

- The applicant begins projections of the future in-center patient population to be served with the facility census as of December 31, 2023.
- The applicant will project growth of the Mecklenburg County patient population using the Mecklenburg County Five Year Average Annual Change Rate (5-Year AACR) of 1.1%.

- As of December 31, 2023, the facility also served two in-center patients residing in South Carolina.
- South Carolina is contiguous to Mecklenburg County; thus, it is reasonable to conclude that in-center patients residing in this county would continue dialysis at BMA Nations Ford as a function of patient choice. These patients are assumed to continue dialysis with the facility; however, the applicant does not project any growth for this segment of the patient population. These patients will be added to projections at appropriate points in time.
- At the end of Operating Year 1, BMA Nations Ford is projected to serve 98.1 in-center patients and at the end of Operating Year 2, the facility is projected to serve 99.2 in-center patients on 28 stations.

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

- The applicant projects to serve 95 patients on 28 stations, which is 3.39 patients per station per week (98 patients / 28 stations = 3.5), by the end of the first full operating year.
- The applicant projects to serve 96 patients on 28 stations, which is 3.4 patients per station per week (99 patients / 28 stations = 3.54), by the end of the second full operating year.
- This meets the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

In Section C, page 31, the applicant states:

*“The applicant and its parent organization, Fresenius Medical Care, has a long history of providing dialysis services to the underserved populations of North Carolina. ... 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.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

| Medically Underserved Groups | Percentage of Total Patients |
|------------------------------|------------------------------|
| Low-income persons           | 57.3%                        |
| Racial and ethnic minorities | 85.4%                        |
| Women                        | 40.2%                        |
| Persons with disabilities    | 12.2%                        |
| Persons 65 and older         | 31.7%                        |
| Medicare beneficiaries       | 73.2%                        |
| Medicaid recipients          | 34.1%                        |

Source: Section C, page 33

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services, based on the following:

- The applicant provides a statement saying it will provide services to all residents of the service area, including underserved groups.
- BMA Nations Ford is an existing dialysis facility in Mecklenburg County that currently provides dialysis services to underserved groups.

### **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 service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.



C

The applicant proposes to add no more than three dialysis stations to BMA Nations Ford pursuant to Condition 2 of the facility need methodology for a total of no more than 28 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 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.

- Failure to apply for additional stations at BMA Nations Ford would ultimately result in higher utilization rates. The applicant has demonstrated that the projected utilization for the end of Operating Year 1 is 3.51 patients per station; the projected utilization for the end of Operating Year 2 is 3.54 patients per station. These utilization rates are calculated based on 28 dialysis stations.
- The applicant states that if it chose not to apply for additional stations, utilization on 25 dialysis stations would be projected to be 3.93 patients per station at the end of Operating Year 1, and 3.97 patients per year at the end of Operating Year 2.
- Failure to apply for additional stations would lead to higher utilization rates, potentially interrupt patient admissions to the facility, potentially require an evening shift which may not be convenient or accessible for the patients and would be the least effective alternative.

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

- The applicant's proposal is in response to a facility need pursuant to Condition 2 of the facility need methodology, as reported in the 2024 SMFP.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

**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 methodology in the 2024 SMFP, the certificate holder shall develop no more than three additional dialysis stations for a total of no more than 28 stations at BMA Nations Ford upon project completion.**
  - 3. Progress Reports**
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. The certificate holder shall complete all sections of the Progress Report form.**
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. The first progress report shall be due on 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 three dialysis stations to BMA Nations Ford pursuant to Condition 2 of the facility need methodology for a total of no more than 28 dialysis stations upon completion of this project and Project ID# F-12469-24 (develop new 10 station facility).

**Capital and Working Capital Costs**

In Section F, page 42, the applicant states that BMA has not proposed a capital cost to complete this project. The applicant states that this application is a backfill for these stations approved

to be relocated from BMA Nations Ford to the new Fresenius Kidney Care Huntersville (FKC Huntersville) facility.

In Section F page 43, the applicant states that dialysis machines are leased and space exists. The applicant states BMA will install machines in space previously utilized for dialysis. The applicant provides a letter of commitment from the VP of Corporate Tax for Fresenius Medical Care in Exhibit F.2. This letter further indicates that BMA requires no capital expenditure to develop this project.

In Section F, page 44, the applicant states that there will be no start-up costs or initial operating expenses because this is an existing operational facility.

### **Availability of Funds**

BMA has not projected a capital expenditure for this project. Exhibit F-2 contains a letter dated July 15, 2024, from the Vice President of Corporate Tax – North America of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, stating its commitment to fund the project through its cash reserves should any needs arise. The letter states that the 2023 Consolidated Balance Sheet for Fresenius Medical Care Holdings, Inc. shows more than \$711 million in cash and total assets exceeding \$26 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information 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, F.3, and F.4, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

| BMA Nations Ford                        | 1 <sup>st</sup> Full FY<br>CY 2027 | 2 <sup>nd</sup> Full FY<br>CY 2028 |
|---|------------------------------------|------------------------------------|
| Total Treatments                        | 14,449                             | 14,604                             |
| Total Gross Revenues (Charges)          | \$6,291                            | \$6,291                            |
| Total Net Revenue                       | \$4,625,174                        | \$4,675,008                        |
| Average Net Revenue per Treatment       | \$320.11                           | \$320.12                           |
| Total Operating Expenses (Costs)        | \$3,860,889                        | \$3,914,511                        |
| Average Operating Expense per Treatment | \$267.21                           | \$268.04                           |
| Net Income                              | \$764,285                          | \$760,498                          |

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- The applicant provided a letter from an appropriate company official indicating that no capital expenditure is necessary to develop the project and providing information about the applicants' cash and assets should any capital needs be required.

- 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 availability of sufficient funds for the operating needs of the proposal and the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above. or 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

The applicant proposes to add no more than three dialysis stations to BMA Nations Ford pursuant to Condition 2 of the facility need methodology for a total of no more than 28 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 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 also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Mecklenburg County as of December 31, 2023, as reported in the 2024 SMFP.

| <b>Mecklenburg County Dialysis Facilities<br/>           Certified Stations and Utilization as of December 31, 2023</b> |  |   |                    |
|---|--|---|--------------------|
| <b>BMA Nations Ford</b>   | <b># of<br/>           Certified<br/>           Stations</b> | <b># of In-Center<br/>           Patients</b> | <b>Utilization</b> |
| BMA Beatties Ford   | 43   | 87  | 50.58%             |
| BMA Nations Ford  | 28   | 95  | 84.82%             |
| BMA of East Charlotte   | 32   | 118   | 92.19%             |
| BMA West Charlotte  | 29   | 77  | 66.38%             |
| FMC Charlotte   | 48   | 85  | 44.27%             |
| FMC Matthews  | 21   | 91  | 108.33%            |
| FMC of North Carolina   | 40   | 133   | 83.13%             |
| Fresenius Kidney Care Mallard Creek   | 12   | 39  | 81.25%             |
| Fresenius Kidney Care Regal Oaks  | 17   | 60  | 88.24%             |
| Fresenius Kidney Care Southeast Mecklenburg   | 17   | 52  | 81.25%             |
| Fresenius Medical Care Aldersgate   | 16   | 52  | 81.25%             |
| Fresenius Medical Care Southwest Charlotte  | 26   | 71  | 68.27%             |
| Brookshire Dialysis   | 20   | 46  | 57.50%             |
| Charlotte Dialysis  | 33   | 98  | 74.24%             |
| Charlotte East Dialysis   | 34   | 91  | 66.91%             |
| Huntersville Dialysis   | 27   | 78  | 72.22%             |
| Mint Hill Dialysis  | 21   | 49  | 58.33%             |
| North Charlotte Dialysis Center   | 33   | 83  | 62.88%             |
| South Charlotte Dialysis Center   | 27   | 74  | 68.52%             |
| DSI Charlotte Latrobe Dialysis  | 24   | 63  | 65.63%             |
| DSI Glenwater Dialysis  | 42   | 92  | 54.76%             |
| <b>Total</b>  | <b>590</b>   | <b>1,634</b>                                  | <b>69.24%</b>      |

Source: Table 9A on page 125-126 of the 2024 SMFP and Section G, page 48

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 three dialysis stations to an existing dialysis facility based upon the performance and demonstrated need at the BMA Nations Ford facility. This application is backfill for three stations approved to be relocated from BMA Nations Ford 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 would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved dialysis stations in the service area.
- There is a facility need determination in the 2024 SMFP for eight dialysis stations at BMA Nations Ford.

**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.

- (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 three dialysis stations to BMA Nations Ford pursuant to Condition 2 of the facility need methodology for a total of no more than 28 dialysis stations upon completion of this project and Project ID# F-12469-24 (develop new 10 station facility).

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.

| BMA Nations Ford                 | Current Staff     | Projected FTE Staff             |                                 |
|----------------------------------|-------------------|---------------------------------|---------------------------------|
|                                  | Interim Year 2026 | 1 <sup>st</sup> Full FY CY 2027 | 2 <sup>nd</sup> Full FY CY 2028 |
| Administrator                    | 1.00              | 1.00                            | 1.00                            |
| Registered Nurses (RNs)          | 3.00              | 3.00                            | 3.00                            |
| Licensed Practical Nurses (LPNs) | 1.00              | 1.00                            | 1.00                            |
| Technicians (PCT)                | 10.00             | 10.00                           | 10.00                           |
| Dieticians                       | 1.00              | 1.00                            | 1.00                            |
| Social Worker                    | 1.00              | 1.00                            | 1.00                            |
| Maintenance                      | 1.00              | 1.00                            | 1.00                            |
| Administrative/Clerical          | 1.00              | 1.00                            | 1.00                            |
| FMC Director of Operations       | 0.11              | 0.11                            | 0.11                            |
| FMC Chief Technician             | 0.11              | 0.11                            | 0.11                            |
| FMC In-Service                   | 0.11              | 0.11                            | 0.11                            |
| <b>TOTAL</b>                     | <b>19.33</b>      | <b>19.33</b>                    | <b>19.33</b>                    |

The assumptions and methodology used to project staffing are provided in Section Q, page 98. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in 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 applicant states that the facility is able to offer a wide range of personnel benefits and maintain competitive salaries to attract qualified staff.
- Each new employee is required to successfully complete a 10-week training program. The In-Service Coordinator will provide training and orientation to new employees.
- The In-Service Coordinator is responsible for the training of other direct care employees.

### **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 three dialysis stations to BMA Nations Ford pursuant to Condition 2 of the facility need methodology for a total of no more than 28 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 because it currently provides the necessary services as an existing, operational facility and states it will continue to do so.

### **Coordination**

In Section I, page 58, the applicant describes its existing relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because it has longstanding

relationships with local and social service providers and has agreements in place with other ESRD-related service providers.

### **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 during CY 2023 for the proposed services, as shown in the table below.

| BMA Nations Ford<br>Historical Payor Mix<br>01/01/2023-12/31/2023 |                    |                |                   |             |                     |             |
|---|--------------------|----------------|-------------------|-------------|---------------------|-------------|
| Payor Source  | In-center Dialysis |                | Home Hemodialysis |             | Peritoneal Dialysis |             |
|   | # of Patients      | % of Total     | # of Patients     | % of Total  | # of Patients       | % of Total  |
| Self-Pay  | 15.3               | 16.13%         | 0.0               | 0.0%        | 0.0                 | 0.0%        |
| Insurance*  | 7.0                | 7.37%          | 0.0               | 0.0%        | 0.0                 | 0.0%        |
| Medicare*   | 63.2               | 66.52%         | 0.0               | 0.0%        | 0.0                 | 0.0%        |
| Medicaid*   | 8.0                | 8.41%          | 0.0               | 0.0%        | 0.0                 | 0.0%        |
| Other Misc. including VA  | 1.5                | 1.57%          | 0.0               | 0.0%        | 0.0                 | 0.0%        |
| <b>Total</b>  | <b>95.0</b>        | <b>100.00%</b> | <b>0.0</b>        | <b>0.0%</b> | <b>0.0</b>          | <b>0.0%</b> |

\*Including any managed care plans.

In Section L, page 67, the applicant provides the following comparison.

| BMA Nations Ford                    | Last Full Operating Year                                      |  |
|-------------------------------------|---|--|
|                                     | Percentage of Total Patients Served (All modalities combined) | Percentage of the Population Service Area where the Stations will be Located or Services Offered |
| Female                              | 40.2%   | 51.6%  |
| Male                                | 59.8%   | 48.4%  |
| Unknown                             | 0.0%  | 0.0%   |
| 64 or Younger                       | 68.3%   | 87.8%  |
| 65 or Older                         | 31.7%   | 12.2%  |
| American Indian                     | 0.0%  | 0.9%   |
| Asian                               | 1.2%  | 6.7%   |
| Black or African American           | 61.0%   | 33.2%  |
| Native Hawaiian or Pacific Islander | 0.0%  | 0.1%   |
| White or Caucasian                  | 11.0%   | 56.4%  |
| Other Race                          | 26.8%   | 17.1%  |
| Declined / Unavailable              | 0.0%  | 0.0%   |

^ All patients (in-center, home hemodialysis, and peritoneal dialysis).

\* 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>.

**Conclusion**

The Agency reviewed the:

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

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

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

C

In Section L, page 68, the applicant states that the facility is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

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 the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

**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 for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

| BMA Nations Ford<br>Projected Payor Mix<br>01/01/2028-12/31/2028 (2 <sup>nd</sup> Full FY) |                    |               |                   |             |                     |             |
|--|--------------------|---------------|-------------------|-------------|---------------------|-------------|
| Payor Source   | In-center Dialysis |               | Home Hemodialysis |             | Peritoneal Dialysis |             |
|  | # of Patients      | % of Total    | # of Patients     | % of Total  | # of Patients       | % of Total  |
| Self-Pay   | 16.0               | 16.13%        | 0.0               | 0.0%        | 0.0                 | 0.0%        |
| Insurance*   | 7.3                | 7.37%         | 0.0               | 0.0%        | 0.0                 | 0.0%        |
| Medicare*  | 66.0               | 66.52%        | 0.0               | 0.0%        | 0.0                 | 0.0%        |
| Medicaid*  | 8.3                | 8.41%         | 0.0               | 0.0%        | 0.0                 | 0.0%        |
| Other Misc. including VA   | 1.6                | 1.57%         | 0.0               | 0.0%        | 0.0                 | 0.0%        |
| <b>Total</b>   | <b>99.2</b>        | <b>100.0%</b> | <b>0.0</b>        | <b>0.0%</b> | <b>0.0</b>          | <b>0.0%</b> |

\*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 16.13% of total in-center will be provided to self-pay patients, 66.52% of total in-center dialysis to Medicare patients and 8.41% of total in-center dialysis services will be provided to Medicaid patients. Neither home hemodialysis nor peritoneal dialysis services are provided at this facility.

On page 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 based on the following:

- The applicant projects payor mix based upon BMA Nations Ford's recent history of actual treatment volumes of the facility.
- Patients are calculated as partial patients based on multiple payor sources applied to one patient during a fiscal year.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the 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, pages 69-70, 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 three dialysis stations to BMA Nations Ford pursuant to Condition 2 of the facility need methodology for a total of no more

than 28 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 a letter to Central Piedmont Community College encouraging the school to include the dialysis facility in their clinical rotations for nursing students.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

### C

The applicant proposes to add no more than three dialysis stations to BMA Nations Ford pursuant to Condition 2 of the facility need methodology for a total of no more than 28 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.

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

| <b>Mecklenburg County Dialysis Facilities<br/>Certified Stations and Utilization as of December 31, 2023</b> |                                |                                |                    |
|--|--------------------------------|--------------------------------|--------------------|
| <b>BMA Nations Ford</b>  | <b># of Certified Stations</b> | <b># of In-Center Patients</b> | <b>Utilization</b> |
| BMA Beatties Ford  | 43                             | 87                             | 50.58%             |
| BMA Nations Ford   | 28                             | 95                             | 84.82%             |
| BMA of East Charlotte  | 32                             | 118                            | 92.19%             |
| BMA West Charlotte   | 29                             | 77                             | 66.38%             |
| FMC Charlotte  | 48                             | 85                             | 44.27%             |
| FMC Matthews   | 21                             | 91                             | 108.33%            |
| FMC of North Carolina  | 40                             | 133                            | 83.13%             |
| Fresenius Kidney Care Mallard Creek  | 12                             | 39                             | 81.25%             |
| Fresenius Kidney Care Regal Oaks   | 17                             | 60                             | 88.24%             |
| Fresenius Kidney Care Southeast Mecklenburg  | 17                             | 52                             | 81.25%             |
| Fresenius Medical Care Aldersgate  | 16                             | 52                             | 81.25%             |
| Fresenius Medical Care Southwest Charlotte   | 26                             | 71                             | 68.27%             |
| Brookshire Dialysis  | 20                             | 46                             | 57.50%             |
| Charlotte Dialysis   | 33                             | 98                             | 74.24%             |
| Charlotte East Dialysis  | 34                             | 91                             | 66.91%             |
| Huntersville Dialysis  | 27                             | 78                             | 72.22%             |
| Mint Hill Dialysis   | 21                             | 49                             | 58.33%             |
| North Charlotte Dialysis Center  | 33                             | 83                             | 62.88%             |
| South Charlotte Dialysis Center  | 27                             | 74                             | 68.52%             |
| DSI Charlotte Latrobe Dialysis   | 24                             | 63                             | 65.63%             |
| DSI Glenwater Dialysis   | 42                             | 92                             | 54.76%             |
| <b>Total</b>   | <b>590</b>                     | <b>1,634</b>                   | <b>69.24%</b>      |

Source: Table 9A on page 125-126 of the 2024 SMFP and Section G, page 48

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 project to serve dialysis patients currently being served by another provider.”*

*“With this application, the applicant seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at BMA Nations Ford.”*

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

*“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.”*

See also Section B, 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 care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment. Our organizational mission statement captures this sentiment very well:*

*‘We deliver the superior care that improves the quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.’”*

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

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

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

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

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

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

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section Q, Form O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 125 of this type of facility located in North Carolina.

In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of the Fresenius Medical Care related facilities in North Carolina. After reviewing and considering information provided by the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C



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

**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 Nations Ford 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 29, and Section Q, page 82, the applicant projects that BMA Nations Ford will serve 98.1 in-center patients on 28 stations, or a rate of 3.51 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant 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 and does not plan to begin offering those services in this application. 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 or peritoneal dialysis stations and does not plan to begin offering those services in this application. 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 25-29, and Section Q, pages 82-85, 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.