

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 21, 2018

Findings Date: November 21, 2018

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: L-11579-18

Facility: FMC South Rocky Mount

FID #: 130370

County: Nash

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

Project: Add three dialysis stations for a total of 19 dialysis stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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. (BMA), d/b/a Fresenius Medical Care South Rocky Mount (FMC South Rocky Mount) proposes to add three dialysis stations to the existing facility for a total of 19 dialysis stations upon project completion.

#### **Need Determination**

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of two dialysis stations in Nash County; thus the applicant cannot apply to add any additional stations based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations in its existing facility, based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for FMC South

Rocky Mount in the July 2018 SDR is 3.375 patients per station per week, or 84.38%, based on 54 in-center dialysis patients and 16 certified dialysis stations [ $54 / 16 = 3.375$ ;  $3.375 / 4 = 0.84375$  or 84.38%].

Application of the facility need methodology indicates up to nine additional stations are needed for this facility, as illustrated in the following the table.

**October 1 Review Table (July SDR)**

|  |   | <b>Part A</b> |
|--|---|---------------|
| Required SDR Utilization                                     |   | 80%           |
| FMC South Rocky Mount  |   |               |
| July 2018 SDR  |   |               |
| Facility Utilization Rate (as of 12/31 of the previous rate) |   | 84.38%        |
|  |   | <b>Part B</b> |
| # of Certified Stations (12/31/2017)                         |   | 16            |
| # of Pending Stations  |   | 0             |
| <b>Total Existing and Pending Stations</b>                   |   | <b>16</b>     |
| In-Center Patients as of 12/31/17 - (July 2018 SDR) (SDR2)   |   | 54            |
| In-Center Patients as of 6/30/17 - (January 2018 SDR) (SDR1) |   | 44            |
| <b>Step</b>  | <b>Description</b>  | <b>Result</b> |
| (i)  | Difference (SDR2 - SDR1)  | 10            |
|  | Multiply the difference by 2 for the projected net in-center change   | 20            |
|  | Divide the projected net in-center change for 1 year by the number of in-center patients from SDR1  | 0.4545        |
| (ii)   | Divide the result of Step (i) by 12   | 0.0379        |
| (iii)  | Multiply the result of Step (ii) by 12  | 0.4545        |
| (iv)   | Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2 | 78.5455       |
| (v)  | Divide the result of Step (iv) by 3.2 patients per station  | 24.5455       |
|  | and subtract the number of certified and pending stations to determine the number of stations needed  | <b>8.5455</b> |

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is nine stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add three new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2018 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 33 of the 2018 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 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.4(a), page 8; Section K.1(g), pages 43-44; Section N.1, page 53; Section O, pages 55-57; 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.4(b), page 9; Section C.3, page 16; Section L, pages 47-50; Section N.1, page 53; 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.4(c), page 10; Section F, pages 26-28; Section K, pages 42-43; Section N.1, page 53; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value 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 for the reasons stated above.

- (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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

FMC South Rocky Mount proposes to add three dialysis stations to the existing facility for a total of 19 dialysis stations upon project completion.

**Patient Origin**

On page 365, the 2018 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Nash County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 19, the applicant provides the historical patient origin for FMC South Rocky Mount patients as of June 30, 2018, as shown in the table below.

**Dialysis Patients as of (June 30, 2018)**

| <b>County of Residence</b> | <b>In-Center Dialysis Patients</b> | <b>Home Hemo Dialysis Patients</b> | <b>PD Dialysis Patients</b> |
|----------------------------|------------------------------------|------------------------------------|-----------------------------|
| Nash                       | 34                                 | 7                                  | 15                          |
| Edgecombe                  | 19                                 | 2                                  | 6                           |
| Franklin                   |                                    | 1                                  |                             |
| Halifax                    | 1                                  | 1                                  | 2                           |
| Northampton                |                                    | 1                                  |                             |
| Wilson                     | 3                                  |                                    |                             |
| <b>Total</b>               | <b>57</b>                          | <b>12</b>                          | <b>23</b>                   |

The following table illustrates projected patient origin for the first two years of operation following project completion, as provided in Section C, page 13.

| FMC South Rocky Mount Projected Patient Origin |                              |                  |                  |               |                              |                  |                  |               |
|--|------------------------------|------------------|------------------|---------------|------------------------------|------------------|------------------|---------------|
| County   | Operating Year 1<br>(CY2020) |                  |                  |               | Operating Year 2<br>(CY2021) |                  |                  |               |
|  | # of IC Patients             | # of HH Patients | # of PD Patients | % of Total    | # of IC Patients             | # of HH Patients | # of PD Patients | % of Total    |
| Nash   | 42.2                         | 8.7              | 18.6             | 67.8%         | 45.4                         | 9.3              | 20.0             | 69.4%         |
| Edgecombe                                      | 16                           | 2                | 6                | 23.4%         | 16                           | 2                | 6                | 22.3%         |
| Franklin                                       | 0                            | 1                | 0                | 1.0%          | 0                            | 1                | 0                | 0.9%          |
| Halifax  | 1                            | 1                | 2                | 3.9%          | 1                            | 1                | 2                | 3.7%          |
| Northampton                                    | 0                            | 1                | 0                | 1.0%          | 0                            | 1                | 0                | 0.9%          |
| Wilson   | 3                            | 0                | 0                | 2.9%          | 3                            | 0                | 0                | 2.8%          |
| <b>Total</b>                                   | <b>62</b>                    | <b>13</b>        | <b>26</b>        | <b>100.0%</b> | <b>65</b>                    | <b>14</b>        | <b>28</b>        | <b>100.0%</b> |

Table may not foot due to rounding.

In Section C, pages 13-15, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section B.2, pages 5-7, the applicant states that the application is filed pursuant to the facility need methodology in the 2018 SMFP, utilizing data from the July 2018 SDR. The applicant proposes to add three dialysis stations to the existing FMC South Rocky Mount facility, for a total of 19 dialysis stations upon project completion. In Section C, page 16, the applicant explains why it believes the population projected to utilize the proposed services. On pages 13-14, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

- The applicant projects the first two full operating years of the project will be January 1, 2020– December 31, 2020 (CY2020) and January 1, 2021-December 31, 2021 (CY2021).
- The applicant projects growth of the Nash county residents at 7.5% which is the Nash County Five Year Average Annual Change Rate (AACR) per the July 2018 SDR.
- As of June 30, 2018, the current patient census of Nash county residents at FMC South Rocky Mount was 34 in-center patients.
- As of June 30, 2018, the patient census of non-Nash county residents at FMC South Rocky Mount was a total 23 in-center patients from other NC counties. BMA assumes that these patients will continue dialyzing at FMC South Rocky Mount however, no patient growth is projected for this segment of the patient population.
- BMA subtracts three patients from the Edgecombe County patient census of FMC South Rocky Mount as of December 31, 2018 because BMA projects that these patients will transfer their care to FKC Boice-Willis facility upon completion of that project.

Projected Utilization

In Section C, pages 14-15, the applicant provides its utilization methodology, based on its stated assumptions, as illustrated in the following table.

| <b>FMC South Rocky Mount In-Center Patients</b>  |                            |
|--|----------------------------|
| Begin with Nash County patients dialyzing at FMC South Rocky Mount as of June 30, 2018.  | 34                         |
| Project Nash County patient census forward by six months to December 31, 2018 using Five-Year AACR for Nash County.                                | $34 \times 1.0375 = 36.6$  |
| Project Nash County patient census forward one year to December 31, 2019 using Five-Year AACR for Nash County.                                     | $36.6 \times 1.075 = 39.3$ |
| Add the 20 patients from Sampson County (3 Edgecombe County patients not included with this number). This is the starting census for this project. | $39.3 + 20 = 59.3$         |
| Project Nash County patient census forward one year to December 31, 2020 using Five-Year AACR for Nash County.                                     | $39.3 \times 1.075 = 42.2$ |
| Add the 20 patients currently dialyzing at the facility, residing in other counties. This is the ending census for Operating Year 1 (CY2020).      | $42.2 + 20 = 62.2$         |
| Project Nash County patient census forward one year to December 31, 2021 using Five-Year AACR for Nash County.                                     | $42.2 \times 1.075 = 45.4$ |
| Add the 20 patients currently dialyzing at the facility, residing in other counties. This is the ending census for Operating Year 2 (CY2021).      | $45.4 + 20 = 65.4$         |

Source: Table in Section C, page14

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2020) the facility is projected to serve 62 in-center patients and at the end of OY2 (CY2021) the facility is projected to serve 65 in-center patients.

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

- OY1: 3.2631 patients per station per week or 81.57% ( $62 \text{ patients} / 19 \text{ stations} = 3.2631/4 = 0.8157$  or 81.57%)
- OY2: 3.4210 patients per station per week or 85.52% ( $65 \text{ patients} / 19 \text{ stations} = 3.4210/4 = 0.8552$  or 85.52%)

The project utilization of 3.2631 patients per station per week at the end of OY1 is equal to or exceeds the minimum standards of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

*Home Peritoneal and Home Hemodialysis Dialysis Patients*

BMA states that PD and HH patient utilization is expected to increase at the Nash County Five Year AACR of 7.5%. The same methodology used to project in-center patient utilization was used to project PD and HH patient utilization.

In Section C, page 15, the applicant provides its utilization methodology, based on its stated assumptions, as illustrated in the following table.

|   | <b>HH</b>                | <b>PD</b>                  |
|---|--------------------------|----------------------------|
| Begin with Nash County patients dialyzing at FMC South Rocky Mount as of June 30, 2018.                             | 7                        | 15                         |
| Project Nash County patient census forward by six months to December 31, 2018 using Five-Year AACR for Nash County. | $7 \times 1.0375 = 7.5$  | $15 \times 1.0375 = 16.1$  |
| Project Nash County patient census forward one year to December 31, 2019 using Five-Year AACR for Nash County.      | $7.5 \times 1.075 = 8.1$ | $16.1 \times 1.075 = 17.3$ |
| Add the patients from other Counties. This is the starting census for this project.                                 | $8.1 + 5 = 13.1$         | $17.31 + 8 = 25.3$         |
| Project Nash County patient census forward one year to December 31, 2020 using Five-Year AACR for Nash County.      | $8.1 \times 1.075 = 8.7$ | $17.3 \times 1.075 = 18.6$ |
| Add the patients from other counties. This is the ending census for Operating Year 1 (CY2020).                      | $8.7 + 5 = 13.7$         | $18.6 + 8 = 26.6$          |
| Project Nash County patient census forward one year to December 31, 2021 using Five-Year AACR for Nash County.      | $8.7 \times 1.075 = 9.3$ | $18.6 \times 1.075 = 20.0$ |
| Add the patients from other counties. This is the ending census for Operating Year 2 (CY2021).                      | $9.3 + 5 = 14.3$         | $20.0 + 8 = 28.0$          |

Projected utilization is reasonable and adequately supported for the following reasons:

- FMC South Rocky Mount is currently operating at 83.38% capacity.
- The applicant projects future utilization based on historical utilization, adjusted for all approved transfer of patients.
- The applicant assumes a projected annual growth rate of 7.5 percent for Nash County patient census at FMC South Rocky Mount, which is equal to the Nash County Five Year AACR for as published in the July 2018 SDR.
- The applicant does not project growth for its patients who do not reside in Nash County.
- Projected utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

**Access**

In Section C.3, page 16, 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, ability to pay or any other fact that would classify.*

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

In Section L, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

| <b>FMC South Rocky Mount Projected Payor Mix CY 2021</b> |                         |                             |                      |                      |
|--|-------------------------|-----------------------------|----------------------|----------------------|
| <b>Payment Source</b>                                    | <b>% Total Patients</b> | <b>% In-Center Patients</b> | <b>% HH Patients</b> | <b>% PD Patients</b> |
| Private Pay  | 0.00%                   | 0.00%                       | 0.00%                | 0.00%                |
| Medicare   | 70.09%                  | 79.62%                      | 57.90%               | 57.90%               |
| Medicaid   | 0.93%                   | 0.38%                       | 0.00%                | 0.00%                |
| Commercial Insurance                                     | 14.02%                  | 7.92%                       | 24.83%               | 24.83%               |
| Medicare/Commercial                                      | 12.15%                  | 11.92%                      | 11.69%               | 11.69%               |
| Medicare/Medicaid  | 0.00%                   | 0.00%                       | 0.00%                | 0.00%                |
| Misc. (including VA)                                     | 2.80%                   | 0.16%                       | 5.59%                | 5.59%                |
| Other  | 0.00%                   | 0.00%                       | 0.00%                | 0.00%                |
| <b>Total</b>   | <b>100.0%</b>           | <b>100.0%</b>               | <b>100.0%</b>        | <b>100.0%</b>        |

The applicant states on page 48 that the future payor mix is based on FMC South Rocky Mount treatment volumes instead of the percent of patients. The applicant states it provided a more detailed analysis of which payor source is providing reimbursement. The projected payor mix is reasonable and adequately supported.

**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 identifies the population to be served.
  - The applicant adequately explains why the population to be served needs the services proposed in this application.
  - Projected utilization is reasonable and adequately supported.
  - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payer mix) and adequately supports its assumptions.
- (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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

FMC South Rocky Mount proposes to add three dialysis stations to the existing facility for a total of 19 dialysis stations upon project completion.

In Section E, pages 23-24, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo-The applicant states that with the projected patient population greater than 80% utilization at the end of Operating Year 1, failure to develop additional capacity at the facility will result in higher utilization rates at the facility and potentially restrict patient admissions.

- Relocate Stations from BMA Rocky Mount-The applicant states that BMA Rocky Mount is well utilized and its utilization is increasing. The applicant states it is not appropriate to relocate stations when the utilization is increasing.
- Relocate Stations from FMC Spring Hope -The applicant states that FMC Spring Hope has had steady growth each year since 2013 despite a recent decline in the facility census. The applicant states, based on the historical growth it is not appropriate to relocate stations from the facility.

In Section E.2, Page 24, the applicant states that its proposal is the most effective alternative because it is the most efficient alternative to the meet the needs of patients choosing to dialyze at BMA in Nash County.

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 provided 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. d/b/a Fresenius Medical Care South Rocky Mount shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the July 2018 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care South Rocky Mount shall develop no more than three additional dialysis stations for a total of no more than 19 certified stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care South Rocky Mount shall install plumbing and electrical wiring through the walls for no more than three dialysis stations, which shall include any isolation stations.**
- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care South Rocky Mount 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

FMC South Rocky Mount proposes to add three dialysis stations to the existing facility for a total of 19 dialysis stations upon project completion.

**Capital and Working Capital Costs**

In Section F.1, page 26, the applicant projects the total capital cost to be \$11,250, with \$2,250 to be used for water treatment equipment and \$9,000 for other equipment. In Sections F.10 and F.11, page 29, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

**Availability of Funds**

In Section F.2, page 27, the applicant states that it will fund the entire capital cost of the proposed project with accumulated reserves as show in the table below.

**Sources of Capital Cost Financing**

| Type                         | Bio-Medical Application of North Carolina, Inc. | Total     |
|------------------------------|---|-----------|
| Loans                        | \$  | \$        |
| Accumulated reserves or OE * | \$11,250  | \$11,250  |
| Bonds                        | \$  | \$        |
| Other (Specify)              | \$  | \$        |
| <b>Total Financing</b>       | \$11,250  | \$11, 250 |

\* OE = Owner's Equity

Exhibit F-1 contains a letter from Senior Vice President and Treasurer of Fresenius Medical Care Holding, Inc., parent company of Bio-Medical Application of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-2 contains a copy of the Consolidated Financial Statement from Fresenius Medical Care Holding, Inc., for year ending December 31, 2017. Bio-Medical Application of North Carolina, Inc. had adequate cash and assets to fund the capital cost of the proposed project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

| <b>Projected Revenues and Operating Expenses</b> |                                     |                                     |
|--|-------------------------------------|-------------------------------------|
| <b>FMC South Rocky Mount</b>                     | <b>Operating Year 1<br/>CY 2020</b> | <b>Operating Year 2<br/>CY 2021</b> |
| Total Treatments                                 | 8,892                               | 9,336                               |
| Total Gross Revenues (Charges)                   | \$58,507,948                        | \$61,459,068                        |
| Total Net Revenue                                | \$5,075,783                         | \$5,332,402                         |
| Average Net Revenue per Treatment                | \$570.83                            | \$571.17                            |
| Total Operating Expenses (Costs)                 | \$3,383,561                         | \$3,509,574                         |
| Average Operating Expense per Treatment          | \$380.52                            | \$375.92                            |
| <b>Net Income/Profit</b>                         | <b>1,692,222</b>                    | <b>\$1,822,828</b>                  |

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) 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 cost is based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

FMC South Rocky Mount proposes to add three dialysis stations to the existing facility for a total of 19 dialysis stations upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Nash County. Facilities may serve residents of counties not included in their service area.

The applicant operates three existing and approved facilities in Nash County. DaVita is the only other provider in Nash County. The Nash County facilities are shown below.

| <b>Facility Name</b>      | <b>Provider</b> | <b>Location</b> | <b># of Stations</b> | <b>Utilization</b> |
|---------------------------|-----------------|-----------------|----------------------|--------------------|
| FMC of Spring Hope        | FMC             | Spring Hope     | 16                   | 78.13%             |
| FMC South Rocky Mount     | FMC             | Rocky Mount     | 16                   | 84.38%             |
| Rocky Mount Kidney Center | FMC             | Rocky Mount     | 40                   | 81.25%             |
| Nash County Dialysis      | DaVita          | Rocky Mount     | 12                   | 00.00%             |

Source: July 2018 SDR, Table B

In Section G, page 34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Nash County. The applicant states:

*“BMA proposes to add three stations to FMC South Rocky Mount. This application is based upon the patient referrals to BMA and admissions in BMA facilities. The above table demonstrates that all three of the BMA facilities in Nash County are well utilized.*

*BMA is not proposing an unnecessary duplication of existing services. The Facility Need Methodology demonstrated that the facility qualifies to apply for up to nine additional stations. This application is for only three stations. BMA has provided projections of a patient population to be served which warrants additions of three stations at FMC South Rocky Mount.”*

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a facility need determination, as calculated using the methodology in the July 2018 SDR, for the proposed additional dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved additional dialysis stations.

### **Conclusion**

The Agency reviewed the:

- Application

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

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

In Section H.1, page 35, the applicant provides current and projected staffing in full time equivalents (FTEs) for FMC South Rocky Mount. The applicant does not project any changes in its FTE staff for FMC South Rocky Mount associated with the proposed project. The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, Section R. In Section I.3, page 39, the applicant identifies the current medical director for the facility. Exhibit I-5 of the application contains a letter from the medical director expressing his intention to continue serving in that capacity for FMC South Rocky Mount.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 for the reasons stated 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

In Section I, page 38, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

| <b>FMC South Rocky Mount – Ancillary and Support Services</b> |   |
|---|---|
| <b>Services</b>   | <b>Provider</b>   |
| In-center dialysis/maintenance                                | On site   |
| Self-care training (in-center)                                | On site   |
| Home training   |   |
| HH  | On site   |
| PD  | On site   |
| Accessible follow-up program                                  | On site/Asheville Kidney Center   |
| Psychological counseling                                      | Eastpointe Behavioral Health of Rock Mount, Coastal Plains Hospital   |
| Isolation – hepatitis   | On site   |
| Nutritional counseling  | On site   |
| Social Work services  | On site   |
| Acute dialysis in an acute care setting                       | UNC Nash Hospital   |
| Emergency care  | BMA Staff   |
| Blood bank services   | UNC Nash Hospital   |
| Diagnostic and evaluation services                            | UNC Nash Hospital   |
| X-ray services  | UNC Nash Hospital   |
| Laboratory services   | Spectra   |
| Pediatric nephrology  | Vidant Health   |
| Vascular surgery  | Boice Willis Surgery; Dr. David Seaman in Rocky Mont; Dr. Carl Hiasch, Trauma Surgery, Greenville           |
| Transplantation services                                      | Duke UMC  |
| Vocational rehabilitation & counseling                        | Nash County Vocational Rehab Services   |
| Transportation  | Private Medical Transport; Rocky Mount Transient Transportation; K&L Transportation; Nash Ambulance Service |

In Section I, pages 39-40, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1 through I-4.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, 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 51, the applicant provides the historical payor mix during CY 2016 for its existing services, as shown in the table below.

| Payment Source            | % Total Patients |
|---------------------------|------------------|
| Self-Pay/Indigent/Charity | 0.0%             |
| Medicare                  | 73.92%           |
| Medicaid                  | -0.08%           |
| Commercial Insurance      | 13.75%           |
| Medicare/Commercial       | 11.13%           |
| Medicare/Medicaid         | 0.0%             |
| Misc. (including VA)      | 1.28%            |
| Other                     | 0.0%             |
| <b>Total</b>              | <b>100.0%</b>    |

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

| Percent of Population |               |               |                               |                        |                              |  |
|-----------------------|---------------|---------------|-------------------------------|------------------------|------------------------------|--|
| County                | % 65+         | % Female      | % Racial and Ethnic Minority* | % Persons in Poverty** | % < Age 65 with a Disability | % < Age 65 without Health Insurance ** |
| 2017 Estimate         | 2017 Estimate | 2017 Estimate | 2017 Estimate                 | 2017 Estimate          | 2017 Estimate                | 2017 Estimate                          |
| Nash                  | 18%           | 52%           | 50%                           | 17%                    | 11%                          | 12%                                    |
| Statewide             | 16%           | 51%           | 37%                           | 15%                    | 10%                          | 12%                                    |

Source: <http://www.census.gov/quickfacts/table/US/PST045217>; Latest Data 7/1/17 as of 7/17/18

\*Excludes "White alone, not Hispanic or Latino"

\*\* "Estimates are not comparable to other geographical levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g. V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar

to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 Annual Report (pages 25-26<sup>1</sup>) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

### **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 handicapped persons 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, the applicant states in Section L, page 49, that it has no obligation by any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 50, the applicant states that during the last five years 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:

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<sup>1</sup><https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- 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 48, 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>FMC South Rocky Mount Projected Payor Mix CY 2021</b> |                         |                             |                      |                      |
|--|-------------------------|-----------------------------|----------------------|----------------------|
| <b>Payment Source</b>                                    | <b>% Total Patients</b> | <b>% In-Center Patients</b> | <b>% HH Patients</b> | <b>% PD Patients</b> |
| Self-Pay/Indigent/Charity                                | 0.0%                    | 0.0%                        | 0.0%                 | 0.0%                 |
| Medicare   | 70.09%                  | 79.62%                      | 57.90%               | 57.90%               |
| Medicaid   | 0.93%                   | 0.38%                       | 0.0%                 | 0.0%                 |
| Commercial Insurance                                     | 14.02%                  | 7.92%                       | 24.83%               | 24.83%               |
| Medicare/Commercial                                      | 12.15%                  | 11.92%                      | 11.69%               | 11.69%               |
| Medicare/Medicaid  | 2.80%                   | 0.0%                        | 0.0%                 | 0.0%                 |
| Misc. (including VA)                                     | 0.0%                    | 0.16%                       | 5.59%                | 5.59%                |
| Other  | 0.0%                    | 0.0%                        | 0.0%                 | 0.0%                 |
| <b>Total</b>   | <b>100.0%</b>           | <b>100.0%</b>               | <b>100.0%</b>        | <b>100.0%</b>        |

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 86% of all patients will have some or all of their services covered by Medicare and/or Medicaid.

On page 48, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix.
- The applicant's proposed patient origin is based on historical patient origin of the facility.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 50, 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

In Section M, page 52, 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.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

FMC South Rocky Mount proposes to add three dialysis stations to the existing facility for a total of 19 dialysis stations upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Nash County. Facilities may serve residents of counties not included in their service area.

The applicant operates three existing and approved facilities in Nash County. DaVita is the only other provider in Nash County. The Nash County facilities are shown below.

| <b>Facility Name</b>      | <b>Provider</b> | <b>Location</b> | <b># of Stations</b> | <b>Utilization</b> |
|---------------------------|-----------------|-----------------|----------------------|--------------------|
| FMC of Spring Hope        | FMC             | Spring Hope     | 16                   | 78.13%             |
| FMC South Rocky Mount     | FMC             | Rocky Mount     | 16                   | 84.38%             |
| Rocky Mount Kidney Center | FMC             | Rocky Mount     | 40                   | 81.25%             |
| Nash County Dialysis      | DaVita          | Rocky Mount     | 12                   | 00.00%             |

In Section N, page 53, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 53, the applicant states:

*“FMC South Rocky Mount does not expect this proposal to have any effect on the competitive climate in Nash County. The existing operational dialysis facilities in Nash County are operated by Fresenius Medical Care, parent to FMC South Rock Mount. BMA does not project to serve dialysis patients currently being served by another provider in a contiguous county.*

*BMA does recognize that DaVita has a Certificate of Need to develop their Nash County Dialysis facility. That project had not yet been certified. Thus, there is no impact to the facility. Once the DaVita facility is opened, they will have the own referring physicians.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

In Exhibit A-4, 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 114 of this type of facility located in North Carolina.

In Section O, page 58, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities. Supporting documentation is provided in Exhibit O-2. The applicant states that all of

the problems have been corrected. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 114 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

### C

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

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

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year 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- FMC South Rocky Mount is an existing facility.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C, page 14, the applicant projects that FMC South Rocky Mount will serve 62 in-patients on 19 stations, or a rate of 3.3 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 shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section C, pages 13-15, 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.