

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 30, 2018

Findings Date: November 30, 2018

Project Analyst: Gregory F. Yakaboski

Chief: Martha J. Frisone

Project ID #: F-11583-18

Facility: FMC Gastonia

FID #: 955615

County: Gaston

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

Project: Add four stations to the facility for a total of 37 stations upon completion of this project, Project I.D. # F-11266-16 (relocate 12 stations to develop the new FKC Gaston) and Project # F-11309-17 (add six stations)

### 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 and/or the applicant), d/b/a FMC Gastonia (FMC Gastonia and/or the facility) proposes to add four dialysis stations to the existing facility for a total of 37 dialysis stations upon completion of this project, Project I.D. # F-11266-16 (relocate 12 stations to develop the new FKC Gaston) and Project #F-11309-17 (add six stations). FMC Gastonia offers a home hemodialysis and peritoneal program.

#### **Need Determination**

The 2018 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 the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there

is no county need determination for Gaston County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC Gastonia in the July 2018 SDR is 3.6667 patients per station per week. This utilization rate was calculated based on 143 in-center dialysis patients and 39 certified dialysis stations as of December 31, 2017 (143 patients /39 stations = 3.6667 patients per station per week). Application of the facility need methodology indicates that 4 additional stations are needed for this facility, as illustrated in the following table.

| <b>OCTOBER 1 REVIEW-JULY SDR</b>                         |   |               |
|--|---|---------------|
| Required SDR Utilization                                 |   | 80%           |
| Center Utilization Rate as of 12/31/17                   |   | 91.7%         |
| Certified Stations                                       |   | 39            |
| Pending Stations   |   | 6             |
| <b>Total Existing and Pending Stations</b>               |   | <b>45</b>     |
| In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2) |   | 143           |
| In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)   |   | 136           |
| <b>Step</b>  | <b>Description</b>  | <b>Result</b> |
| (i)  | Difference (SDR2 - SDR1)  | 7             |
|  | Multiply the difference by 2 for the projected net in-center change   | 14            |
|  | Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17  | 0.1029        |
| (ii)   | Divide the result of Step (i) by 12   | 0.0086        |
| (iii)  | Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)  | 0.1029        |
| (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 | 157.7206      |
| (v)  | Divide the result of Step (iv) by 3.2 patients per station  | 49.2877       |
|  | and subtract the number of certified and pending stations to determine the number of stations needed  | 4.2877        |

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 4 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2018 SDR. 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 4 new stations and, therefore, 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 233 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.”*

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 8, 10-11, Section K.1(g), page 44, Section N, page 54, Section O, pages 56-59, and Exhibits O-1 and O-2. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 9, Section C.3, pages 16-17, Section L, pages 48-52, and Exhibit L-1 and Section N, page 54. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 10-11, Section C, pages 13-16, Section F, pages 24-32, Section K, pages 42-47 and Section N.1, page 54. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

### **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.

(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

BMA proposes to add four dialysis stations to the existing FMC Gastonia facility for a total of 37 dialysis stations upon completion of this project, Project I.D. # F-11266-16 (relocate 12 stations to develop the new FKC Gaston) and Project #F-11309-17 (add six stations). FMC Gastonia offers a home hemodialysis and peritoneal program.

**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 for this facility consists of Gaston County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin for in-center (IC) patients, home hemodialysis (HH) patients and peritoneal (PD) patients.

**FMC Gastonia: Dialysis Patients as of 6/30/18**

| COUNTY         | IC  | HH | PD |
|----------------|-----|----|----|
| Gaston         | 137 | 18 | 8  |
| Cabarrus       | 1   | 0  | 0  |
| Cleveland      | 1   | 7  | 1  |
| Lincoln        | 1   | 0  | 4  |
| Mecklenburg    | 6   | 1  | 0  |
| South Carolina | 1   | 3  | 1  |
| Totals         | 147 | 29 | 14 |

Source: Table on page 19 of the application.

| COUNTY         | OPERATING YEAR 1<br>CY2020 |      |      | OPERATING YEAR 2<br>CY2021 |      |      | COUNTY PATIENTS AS<br>% OF TOTAL |        |
|----------------|----------------------------|------|------|----------------------------|------|------|----------------------------------|--------|
|                | IC                         | HH   | PD   | IC                         | HH   | PD   | OY 1                             | OY 2   |
| Gaston         | 128.7                      | 18.2 | 6.9  | 135.1                      | 19.0 | 7.2  | 85.1%                            | 85.7%  |
| Cabarrus       | 1.0                        | 0.0  | 0.0  | 1.0                        | 0.0  | 0.0  | 0.6%                             | 0.5%   |
| Cleveland      | 1.0                        | 7.0  | 1.0  | 1.0                        | 7.0  | 1.0  | 5.0%                             | 4.8%   |
| Lincoln        | 1.0                        | 0.0  | 4.0  | 1.0                        | 0.0  | 4.0  | 2.8%                             | 2.7%   |
| Mecklenburg    | 6.0                        | 1.0  | 0.0  | 6.0                        | 1.0  | 0.0  | 3.9%                             | 3.7%   |
| South Carolina | 1.0                        | 3.0  | 1.0  | 1.0                        | 3.0  | 1.0  | 2.8%                             | 2.7%   |
| Totals         | 138.9                      | 29.0 | 12.0 | 145.0                      | 30.0 | 13.0 | 100.0%                           | 100.0% |

Source: Table on page 13 of the application.

In Section C, pages 13-16, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C, pages 13-16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 13-14, the applicant states:

- The first two full operating years (OYs) of the project will be  

OY1: January 1, 2020 – December 31, 2020 (CY2020), and  
OY2: January 1, 2021 – December 31, 2021 (CY2021).
- 143 patients were receiving in-center dialysis treatments at FMC Gastonia as of December 31, 2017. The facility was at 91.67% utilization with 39 certified stations.
- At no growth, upon completion Project I.D. # F-11266-16 (relocate 12 stations to develop the new FKC Gaston and 24 in-center patients) and Project #F-11309-17 (add six stations), FMC Gastonia will have 119 patients and 33 stations for a utilization of 90.15% [ $119 / 33 = 3.606 / 4 = 0.9015$  or 90.15%]

In Section B.2, pages 5-6, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the January and July 2018 SDR. The facility need methodology shows a need for 4 dialysis stations and the proposed project is for 4 dialysis stations.

The information is reasonable and adequately supported.

### **Projected Utilization**

#### *In-Center Patients*

In Section C.1, pages 13 – 14, the applicant describes its assumptions and the methodology used to project utilization of IC patients, which are summarized as follows:

- Operating Year 1 = Calendar Year 2020 (CY2020)
- Operating Year 2 = Calendar Year 2021 (CY2021)
- As of June 30, 2018, FMC Gastonia had 147 in-center patients, consisting of 137 residents of Gaston County and 10 patients residing in other counties.
- Utilization by Gaston County residents is projected to grow at 4.9%, the Five-Year Average Annual Change Rate (AACR) for Gaston County, as shown in Table D in the July 2018 Semi-Annual Dialysis Report (SDR).

- The applicant projects no growth for the remaining patients. BMA assumes the remaining ten in-center patients who are not residents of Gaston County utilized the FMC Gastonia facility by choice and will continue to dialyze at FMC Gastonia
- Twenty-four Gaston County in-center patients will transfer their care from FMC Gastonia as of June 30, 2019 to FKC North Gaston.

The following table illustrates application of these assumptions and the methodology used.

|  |                                 |
|--|---------------------------------|
| Begin June 30, 2018 with the 137 Gaston County patients  | 137                             |
| Project the Gaston County in-center patients forward to June 30, 2019, using the Five Year AACR for Gaston County.                         | $137 \times 1.049 = 143.713$    |
| Subtract the 24 patients projected to transfer their care to the new FKC North Gaston facility (Project ID# F-11266-16)                    | $143.713 - 24 = 119.713$        |
| Project the Gaston County in-center patients forward 6 months to December 31, 2019, using one half of the Five Year AACR for Gaston County | $119.713 \times 1.0245 = 122.7$ |
| Project this Gaston County patient population forward one year to December 31, 2020 using the Five Year AACR for Gaston County             | $122.7 \times 1.049 = 128.7$    |
| Add the 10 patients who reside outside Gaston County. <b>This is the projected ending census for Operating Year 1 (CY2020).</b>            | $128.7 + 10 = \mathbf{138.7}$   |
| Project this Gaston County patient population forward one year to December 31, 2021 using the Five Year AACR for Gaston County             | $128.7 \times 1.049 = 135$      |
| Add the 10 patients who reside outside Gaston County. <b>This is the projected ending census for Operating Year 1 (CY2021).</b>            | $135 + 10 = \mathbf{145}$       |

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2020) and OY2 (CY2021) the facility is projected to serve 138 and 145 in-center patients, respectively.

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

- OY1: 3.7297 patients per station per week, or 93.24% ( $138 \text{ patients} / 37 \text{ stations} = 3.7297 / 4 = 0.9324$  or 93.24%).
- OY2: 3.919 patients per station per week, or 97.97% ( $145 \text{ patients} / 37 \text{ stations} = 3.9189/4 = 0.9797$  or 97.97%).

The projected utilization of 3.7297 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant starts with the 137 existing Gaston County patients.

- The Gaston County patients are projected to increase based on 4.9% per year which is the Five Year AACR for Gaston County as reported in Table D of the July 2018 SDR.
- The non-Gaston County patients are existing patients and no growth is projected.

*HH Patient Utilization*

The following table illustrates application of these assumptions and the methodology used to project HH patient utilization.

|  |                             |
|--|-----------------------------|
| Begin June 30, 2018 with the 18 Gaston County patients   | 18                          |
| Project the Gaston County in-center patients forward to June 30, 2019, using the Five Year AACR for Gaston County.                         | $18 \times 1.049 = 18.9$    |
| Subtract the 2 patients projected to transfer their care to the new FKC North Gaston facility (Project ID# F-11266-16)                     | $18.9 - 2 = 16.9$           |
| Project the Gaston County in-center patients forward 6 months to December 31, 2019, using one half of the Five Year AACR for Gaston County | $16.9 \times 1.0245 = 17.3$ |
| Project the Gaston County patient population forward one year to December 31, 2020 using the Five Year AACR for Gaston County              | $17.3 \times 1.049 = 18.2$  |
| Add the 11 patients who reside outside Gaston County. <b>This is the projected ending census for Operating Year 1 (CY2020).</b>            | $18.2 + 11 = 29.2$          |
| Project the Gaston County patient population forward one year to December 31, 2021 using the Five Year AACR for Gaston County              | $18.2 \times 1.049 = 19$    |
| Add the 11 patients who reside outside Gaston County. <b>This is the projected ending census for Operating Year 1 (CY2021).</b>            | $19 + 11 = 30$              |

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

- The applicant starts with the 18 existing Gaston County HH patients.
- The applicant accounts for both the HH patients projected to transfer their care to FKC North Gaston and the non-Gaston County PD patients.
- The Gaston County patients are projected to increase based on the five-year AACR for Gaston County of 4.9% as reported in Table D of the July 2018 SDR.

*PD Patient Utilization*

The following table illustrates application of the assumptions and the methodology used to project PD patient utilization.

|  |                           |
|--|---------------------------|
| Begin June 30, 2018 with the 8 Gaston County patients  | 8                         |
| Project the Gaston County in-center patients forward to June 30, 2019, using the Five Year AACR for Gaston County.                         | $8 \times 1.049 = 8.4$    |
| Subtract the 2 patients projected to transfer their care to the new FKC North Gaston facility (Project ID# F-11266-16)                     | $8.4 - 2 = 6.4$           |
| Project the Gaston County in-center patients forward 6 months to December 31, 2019, using one half of the Five Year AACR for Gaston County | $6.4 \times 1.0245 = 6.6$ |
| Project this Gaston County patient population forward one year to December 31, 2020 using the Five Year AACR for Gaston County             | $6.6 \times 1.049 = 6.9$  |
| Add the 6 patients who reside outside Gaston County. <b>This is the projected ending census for Operating Year 1 (CY2020).</b>             | $6.9 + 6 = 12.9$          |
| Project this Gaston County patient population forward one year to December 31, 2021 using the Five Year AACR for Gaston County             | $6.9 \times 1.049 = 7.2$  |
| Add the 6 patients who reside outside Gaston County. <b>This is the projected ending census for Operating Year 1 (CY2021).</b>             | $7.2 + 6 = 13.2$          |

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

- The applicant starts with the 8 existing Gaston County PD patients.
- The applicant accounts for both the PD patients projected to transfer their care to FKC North Gaston and the non-Gaston County PD patients.
- The Gaston County patients are projected to increase based on the five-year AACR for Gaston County of 4.9% as reported in Table D of the July 2018 SDR.

**Access**

In Section C.3, page 16, 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, ability to pay or any other factor that would classify a patient as underserved.*” In Section L.1, page 49, 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.

**Projected Payor Mix**

| Payor Category             | FMC Gastonia<br>Percent of Total Treatments |
|----------------------------|---|
| Medicaid                   | 4.79%                                       |
| Medicare                   | 68.62%                                      |
| Self Pay/ Indigent/Charity | 1.06%                                       |
| Medicare/Commercial        | 12.23%                                      |
| Commercial Insurance       | 11.17%                                      |
| Miscellaneous (incl. VA)   | 2.13%                                       |
| <b>Total</b>               | <b>100.00%</b>                              |

Source: Table, page 49 of the application.

On page 49, the applicant states the projected payor mix is based on the payor mix during the last year of operation. The projected payor mix is reasonable and adequately supported.

### **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 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 (payor 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 or eliminate a service, nor does the applicant propose to 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

BMA proposes to add four dialysis stations to the existing FMC Gastonia facility for a total of 37 dialysis stations upon completion of this project, Project I.D. # F-11266-16 (relocate 12 stations to develop the new FKC Gaston) and Project #F-11309-17 (add six stations). FMC Gastonia offers a home hemodialysis and peritoneal program.

In Section E, page 23, 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 maintaining the status quo is not an effective alternative because of the growth rate at the facility.

*Relocate Stations from another BMA Facility*- BMA's other operational facilities in Gaston County are well utilized with no excess stations available.

*Apply for fewer than four stations*- Projected utilization at FMC Gastonia exceeds 3.2 patients per station. Applying for less than four stations would leave FMC Gastonia with an insufficient number of stations.

On page 23, the applicant states that its proposal is the most effective alternative because the proposed project will address both the issues of growth and access to the facility for no capital expenditure.

### **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. 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. shall develop no more than 4 additional dialysis stations for a total of no more than 37 certified stations at FMC Gastonia upon completion of this project, Project I.D. # F-11266-16 (relocate 12 stations to develop the new FKC Gaston) and Project #F-11309-17 (add six stations), which shall include any home hemodialysis training or isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to add four dialysis stations to the existing FMC Gastonia facility for a total of 37 dialysis stations upon completion of this project, Project I.D. # F-11266-16 (relocate 12 stations to develop the new FKC Gaston) and Project #F-11309-17 (add six stations). FMC Gastonia offers a home hemodialysis and peritoneal program.

**Capital and Working Capital Costs**

In Section F, pages 24 and 28, the applicant states that the proposed project does not involve any capital expenditures or initial operating expenses.

**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 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>1<sup>st</sup> Full Fiscal Year</b> | <b>2<sup>nd</sup> Full Fiscal Year</b> |
|---|--|--|
| Total Treatments*                       | 25,934                                 | 27,119                                 |
| Total Gross Revenues (Charges)          | \$103,424,792                          | \$108,150,572                          |
| Total Net Revenue                       | \$9,080,549                            | \$9,498,639                            |
| Average Net Revenue per treatment       | \$350.14                               | \$350.26                               |
| Total Operating Expenses (Costs)        | \$8,279,799                            | \$8,550,307                            |
| Average Operating Expense per treatment | \$319.26                               | \$315.29                               |
| Net Income                              | \$800,750                              | \$948,332                              |

\*Source: Form C

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 because the applicant adequately demonstrates sufficient funds for the operating needs of the

proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

BMA proposes to add four dialysis stations to the existing FMC Gastonia facility for a total of 37 dialysis stations upon completion of this project, Project I.D. # F-11266-16 (relocate 12 stations to develop the new FKC Gaston) and Project #F-11309-17 (add six stations). FMC Gastonia offers a home hemodialysis and peritoneal program.

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 for this facility consists of Gaston County. Facilities may also serve residents of counties not included in their service area.

BMA operates all five of the dialysis facilities in Gaston County, as shown below:

| GASTON COUNTY DIALYSIS FACILITIES    |       |                |   |                            |
|--------------------------------------|-------|----------------|---|----------------------------|
| Facility                             | Owner | Location       | Number of Certified Stations as of 12/31/17 | Utilization as of 12/31/17 |
| FMC Gastonia*                        | BMA   | Gastonia       | 39  | 91.67%                     |
| FMC South Gaston                     | BMA   | Gastonia       | 28  | 79.46%                     |
| FMC Belmont                          | BMA   | Belmont        | 19  | 80.26%                     |
| BMA Kings Mountain                   | BMA   | Kings Mountain | 18  | 90.28%                     |
| Fresenius Kidney Care North Gaston** | BMA   | Dallas         | 0   | 0.00%                      |

Source: Table B, July 2018 SDR

\*A certificate of need was issued on July 4, 2017 for Project ID #F-11309-17 to add 6 dialysis stations to FMC Gastonia for a total of no more than 33 stations upon completion of that project and Project ID #F-11266-16 (relocate 12 dialysis stations from FMC Gastonia to develop the new FKC North Gaston facility).

\*\*A certificate of need was issued on April 29, 2017 for Project ID #F-11266-16 to develop a new 12-station dialysis facility to be known as Fresenius Kidney Care North Gaston by relocating 12 dialysis stations from FMC Gastonia and offer PD & HH training.

As shown in the table above, all of the operational dialysis facilities operated at utilization rates of 79.46% or higher.

In Section G.2, page 33, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Gaston County. The applicant states:

*“The Gaston County ESRD patient population is increasing at a rate of 4.9%, meaning that new dialysis stations and new facilities will be needed. While this proposal will not*

*create a new facility, it does increase the number of dialysis stations within the county. ... The dialysis facilities in Gaston County are well utilized. ... BMA is not creating unnecessary duplication of existing or approved health services.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services because the applicant adequately demonstrates that the proposed addition of four dialysis stations at FMC Gastonia is needed in addition to the existing 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 34, the applicant provides the current staffing for the facility, and states that FMC Gastonia is not projected to add any full time equivalent (FTE) positions as a result of this proposal. The applicant states the facility currently staffs 45.3 FTE positions and will have a staff of 45.3 FTEs upon project completion. In addition, the applicant provides projected direct care staff in OY 2 in Section H.7, page 36.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, page 35, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-1 and H-2, the applicant provides supporting documentation. In Section I.3, page 38, the applicant identifies the medical director. In Exhibit I-5, the applicant provides a letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services.

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.1, page 37, the applicant identifies the ancillary and support services necessary for the proposed services, as shown in the table below.

| <b>FMC GASTONIA<br/>Ancillary and Support Services</b>    |   |
|---|---|
| <b>Services</b>   | <b>Provider</b>   |
| In-center dialysis/maintenance                            | FMC Gastonia  |
| Self-care training (in-center)                            | FMC Gastonia  |
| Home training<br>HH<br>PD<br>Accessible follow-up program | FMC Gastonia  |
| Psychological counseling                                  | Gaston County Behavioral Health   |
| Isolation – hepatitis                                     | FMC Gastonia  |
| Nutritional counseling                                    | FMC Gastonia  |
| Social Work services                                      | FMC Gastonia  |
| Acute dialysis in an acute care setting                   | CaroMont Regional Medical Center  |
| Emergency care  | Ambulance Transport to Hospital: All BMA staff trained to respond and fully stocked crash cart available. |
| Blood bank services                                       | CaroMont Regional Medical Center-Referral   |
| Diagnostic and evaluation services                        | CaroMont Regional Medical Center-Referral   |
| X-ray services  | CaroMont Regional Medical Center-Referral   |
| Laboratory services                                       | Spectra   |
| Pediatric nephrology                                      | Carolinas Medical Center- Referral  |
| Vascular surgery  | Foothills Dialysis Access Center; Gastonia Surgical Associates; Southeast Surgical Associates             |
| Transplantation services                                  | Carolinas Medical Center-Referral   |
| Vocational rehabilitation & counseling                    | Division of Vocational Rehabilitation Services  |
| Transportation  | TGC (Transportation of Gaston County)   |

On page 37, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.

In Section I, pages 38-40, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-3 and 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.

- (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 nor 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.7, page 51, the applicant provides the historical payor mix during calendar year 2017 at FMC Gastonia, as shown in the table below.

**Historical Payor Mix CY2017: FMC Gastonia**

| <b>PAYOR CATEGORY</b>     | <b>% OF TOTAL TREATMENTS</b> |
|---------------------------|------------------------------|
| Medicaid                  | 3.77%                        |
| Medicare                  | 69.46%                       |
| Medicare/Commercial       | 11.00%                       |
| Self Pay/Indigent/Charity | 0.02%                        |
| Commercial Insurance      | 14.19%                       |
| Miscellaneous (Incl. VA)  | 1.56%                        |
| <b>Total</b>              | <b>100.00%</b>               |

Source: Table on page 51 of the application.

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                         |
| Gaston                | 16%           | 52%           | 28%                           | 16%                    | 12%                          | 12%                                   |
| Mecklenburg           | 11%           | 52%           | 53%                           | 12%                    | 6%                           | 12%                                   |
| Cleveland             | 18%           | 52%           | 27%                           | 21%                    | 12%                          | 12%                                   |
| Cabarrus              | 13%           | 51%           | 34%                           | 11%                    | 7%                           | 10%                                   |
| Lincoln               | 18%           | 50%           | 15%                           | 13%                    | 12%                          | 11%                                   |
| 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 geographic 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 2016 Annual 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 2016 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.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities

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

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, in Section L.3 (e), page 50, the applicant states:

*“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status.”*

In Section L.6, page 51, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facilities.

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 49, 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.

| PAYOR CATEGORY            | % OF TOTAL TREATMENTS |
|---------------------------|-----------------------|
| Medicaid                  | 4.79%                 |
| Medicare                  | 68.62%                |
| Medicare/Commercial       | 12.23%                |
| Self Pay/Indigent/Charity | 1.06%                 |
| Commercial Insurance      | 11.17%                |
| Miscellaneous (Incl. VA)  | 2.13%                 |
| <b>Total</b>              | <b>100.0%</b>         |

Source: Table on page 49 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.06% of total services will be provided to self-pay/indigent/charity patients, 80.85% to Medicare patients and 4.79% to Medicaid patients.

On page 49, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for FMC Gastonia during July 1, 2017 to June 30, 2018.

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.4, pages 50-51, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 53, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The 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

BMA proposes to add four dialysis stations to the existing FMC Gastonia facility for a total of 37 dialysis stations upon completion of this project, Project I.D. # F-11266-16 (relocate 12 stations to develop the new FKC Gaston) and Project #F-11309-17 (add six stations). FMC Gastonia offers a home hemodialysis and peritoneal program.

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 for this facility consists of Gaston County. Facilities may also serve residents of counties not included in their service area.

BMA operates all five of the dialysis facilities in Gaston County, as shown below:

| GASTON COUNTY DIALYSIS FACILITIES    |       |                |   |                            |
|--------------------------------------|-------|----------------|---|----------------------------|
| Facility                             | Owner | Location       | Number of Certified Stations as of 12/31/17 | Utilization as of 12/31/17 |
| FMC Gastonia*                        | BMA   | Gastonia       | 39  | 91.67%                     |
| FMC South Gaston                     | BMA   | Gastonia       | 28  | 79.46%                     |
| FMC Belmont                          | BMA   | Belmont        | 19  | 80.26%                     |
| BMA Kings Mountain                   | BMA   | Kings Mountain | 18  | 90.28%                     |
| Fresenius Kidney Care North Gaston** | BMA   | Dallas         | 0   | 0.00%                      |

Source: Table B, July 2018 SDR

\*A certificate of need was issued on July 4, 2017 for Project ID #F-11309-17 to add 6 dialysis stations to FMC Gastonia for a total of no more than 33 stations upon completion of that project and Project ID #F-11266-16 (relocate 12 dialysis stations from FMC Gastonia to develop the new FKC North Gaston facility).

\*\*A certificate of need was issued on April 29, 2017 for Project ID #F-11266-16 to develop a new 12-station dialysis facility to be known as Fresenius Kidney Care North Gaston by relocating 12 dialysis stations from FMC Gastonia and offer PD & HH training.

In Section N, page 54, 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 54, the applicant states:

*“The applicant does not expect this proposal to have effect on the competitive climate in Gaston County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Gastonia facility begins with patients currently served by BMA within the county, and a growth of that patient population consistent with the Gaston County five year annual change rate of 4.9% as published within the July 2018 SDR.”*

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 Section O.3, page 59, the applicant identifies the dialysis facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of more than 100 Fresenius related dialysis facilities located in North Carolina. (See Exhibit A-4.)

In Section O.3, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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

**SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

**10A 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- The applicant is not proposing to establish a new End Stage Renal Disease 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.1, pages 13-14, the applicant projects to serve 138 in-center patients by the end of OY1 (CY2020) for a utilization rate of 93.24% or 3.7297 patients per station per week (138 patients / 37 stations =  $3.7297 / 4 = 0.9324$  or 93.24%). 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 13-16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.