

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 20, 2019

Findings Date: May 20, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: F-11671-19

Facility: Fresenius Medical Care Belmont

FID #: 050039

County: Gaston

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

Project: Add no more than three dialysis stations for a total of no more than 19 stations upon completion of this project and Project ID #F-11635-18 (relocate 3 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 Fresenius Medical Care Belmont (FMC Belmont and/or the facility) proposes to add three dialysis stations to the existing facility for a total of no more than 19 stations upon completion of this project and Project ID #F-11635-18 (relocate 3 stations to BMA Kings Mountain). FMC Belmont does not currently offer either a peritoneal dialysis (PD) program or a home hemodialysis (HH) program. The parent company of Bio-Medical Applications of North Carolina, Inc. is Fresenius Medical Care Holdings, Inc. (Fresenius).

#### Need Determination

The 2019 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 January 2019 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 Belmont in the January 2019 SDR is 3.4211 patients per station per week. This utilization rate was calculated based on 65 in-center dialysis patients and 19 certified dialysis stations as of June 30, 2018 (65 patients /19 stations = 3.4211 patients per station per week). Application of the facility need methodology indicates that 3 additional stations are needed for this facility, as illustrated in the following table.

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		85.53%
Certified Stations		19
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>19</b>
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		65
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		61
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.1311
(ii)	Divide the result of step (i) by 12	0.0109
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.0656
(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	69.2623
(v)	Divide the result of step (iv) by 3.2 patients per station	21.6445
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>3</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 3 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 2019 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 3 new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2019 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*, on page 31 of the 2019 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 9, 11-12, Section K.1(g), page 44, Section N, page 53, Section O, pages 54-57, 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 10, Section C.3, page 16, Section L, pages 47-50, Exhibit L-1 and Section N, page 53. 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 10-12, Section C, pages 14-16, Section F, pages 23-26, Section K, pages 42-44 and Section N.1, page 53. 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

The applicant proposes to add three dialysis stations to the existing facility, FMC Belmont, for a total of no more than 19 stations upon completion of this project and Project ID #F-11635-18 (relocate 3 stations to BMA Kings Mountain)

**Patient Origin**

On page 369, the 2019 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 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.

**FMC Belmont: Historical Utilization as of 12/31/18**

County	IC Patients
Gaston	54
Mecklenburg	12
Lincoln	4
Catawba	1
Other States	1
Total	72

Source: Table on page 18 of the application.

**FMC Belmont: Projected Utilization**

County	OY1 (CY2020)	OY2 (CY2021)	County Patients as a % of Total	
	IC Patients	IC Patients	OY1	OY2
Gaston	59.4	62.3	77.8%	78.6%
Mecklenburg	12.0	12.0	15.7%	15.1%
Lincoln	4.0	4.0	5.2%	5.0%
Catawba	1.0	1.0	1.3%	1.3%
Total	76.0	79.0	100.0%	100.0%

Source: Table on page 14 of the application.

In Section C, pages 14-16, 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 B.2, pages 6-7, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the July 2018 and January 2019 SDRs. The facility need methodology shows a need for three dialysis stations and the proposed project is for three additional dialysis stations at FMC Belmont.

In Section C, pages 15-16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 14-16, the applicant describes its need methodology assumptions for projecting utilization based on the proposed project as follows:

- The first full operating year will be January 1, 2020 – December 31, 2020 (CY2020).
- The second full operating year will be January 1, 2021 – December 31, 2021 (CY2021).
- The applicant projects future patient populations for the facility starting as of December 31, 2018 with the 72 patients dialyzing at FMC Belmont. The applicant documents that 54 of the 72 patients were residents of Gaston County, 17 patients were from other counties in North Carolina and 1 patient was a resident of another state.
- As of December 31, 2018 there was one patient from another state dialyzing at the facility. BMA does not project any patients from other states as part of FMC Belmont's future patient population.
- The applicant calculates projected utilization by growing Gaston County patients at 4.9%, the Five-Year Average Annual Change Rate (AACR) for Gaston County, as shown in Table D in the January 2019 Semi-Annual Dialysis Report (SDR).

The information is reasonable and adequately supported because the proposed project is consistent with the facility need methodology.

### *Projected Utilization*

In Section C.1, pages 14-18, 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 December 31, 2018, FMC Belmont had 72 in-center patients, consisting of 54 residents of Gaston County and 18 patients residing in other counties or states.
- One of the 18 non-Gaston County patients was reported as a resident of “Other States”. BMA does not include this patient in projected patient populations of the facility because BMA assumes this patient to be a transient patient who will be dialyzing at FMC Belmont for a brief period of time.
- 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 January 2019 Semi-Annual Dialysis Report (SDR).
- The applicant projects no growth for the remaining patients. BMA assumes the remaining 17 in-center patients who are not residents of Gaston County utilized the FMC Belmont facility by choice and will continue to dialyze at FMC Belmont.

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

Begin January 1, 2019 with the 54 Gaston County patients.	54
Project the Gaston County in-center patients forward to December 31, 2019, using the Five Year AACR for Gaston County.	$54 \times 1.049 = 56.646$
Project this Gaston County patient population forward one year to December 31, 2020 using the Five Year AACR for Gaston County.	$56.646 \times 1.049 = 59.421$
Add the 17 patients who reside outside Gaston County. <b>This is the projected ending census for Operating Year 1 (CY2020).</b>	$59.421 + 17 = \mathbf{76.421}$
Project this Gaston County patient population forward one year to December 31, 2021 using the Five Year AACR for Gaston County.	$59.421 \times 1.049 = 62.332$
Add the 17 patients who reside outside Gaston County. <b>This is the projected ending census for Operating Year 1 (CY2021).</b>	$62.332 + 17 = \mathbf{79.332}$

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 76 and 79 in-center patients, respectively.

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

- OY1: 4.0 patients per station per week, or 100.0% ( $76 \text{ patients} / 19 \text{ stations} = 4.0 / 4 = 1.00$  or 100.0%).
- OY2: 4.1579 patients per station per week, or 103.9% ( $79 \text{ patients} / 19 \text{ stations} = 4.1579/4 = 1.039$  or 103.9%).

The projected utilization of 4.0 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 54 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 January 2019 SDR.
- The non-Gaston County patients are existing patients and no growth is projected.
- The existing patient dialyzing at the facility as of December 31, 2018, who is a resident of another state, is not included in the projected future dialysis patients.

**Access**

In Section C, page 16, the applicant states,

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

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.

**CY2021**

<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicaid	4.50%
Medicare	65.59%
Medicare/Commercial	13.14%
Miscellaneous (incl. VA)	6.70%
Commercial Insurance	9.51%
Self Pay/Indigent/Charity	0.56%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 48 of the application.

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 a service, eliminate a service or relocate a facility. 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

In Section E, page 22, 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 projected utilization at the end of OY1 is 100.0%. Not developing additional capacity at FMC Belmont will potentially restrict patient access and result in utilization rates of over 100.0%.

*Relocate Stations from another BMA Facility in Gaston County-* BMA's other operational facilities in Gaston County are well utilized with no excess stations available. This is not an effective alternative as the other two operational facilities are over 80% utilization and the other operational facility, FMC South Gaston, is operating at 79.46% as reported in the January 2019 SDR.

*Apply for fewer than three stations-* The applicant states that developing fewer than three additional stations is not an effective alternative based on the projected patient census. Fewer stations would not meet the projected patient need.

On page 22, the applicant states that its proposal is the most effective alternative because

- The projected population to be served has a demonstrated need for the proposed additional stations.
- The facility need methodology shows a need for 3 additional dialysis stations at the facility based on projected utilization and the proposed project is for 3 stations.
- There is no capital cost for the proposed project.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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. 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 January 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than 3 additional dialysis stations for a total of no more than 19 certified stations at FMC Belmont upon completion of this project, Project I.D. # F-11635-18 (relocate 3 stations to BMA Kings Mountain), 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

The applicant proposes to add three dialysis stations to the existing facility, FMC Belmont, for a total of 19 dialysis stations upon completion of this project and Project I.D. #F-11635-18 (relocate three stations to BMA Kings Mountain).

**Capital and Working Capital Costs**

In Section F, pages 23 and 25-26, the applicant states that the proposed project does not involve any capital expenditures or working capital costs.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section R, 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	11,115	11,411
Total Gross Revenues (Charges)	\$44,326,620	\$45,507,068
Total Net Revenue	\$3,484,197	\$3,576,984
Average Net Revenue per Treatment	\$313	\$313
Total Operating Expenses (Costs)	\$3,089,611	\$3,170,401
Average Operating Expense per Treatment	\$278	\$277
Net Income	\$394,586	\$406,583

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

The applicant proposes to add three dialysis stations to the existing facility, FMC Belmont, for a total of 19 dialysis stations upon completion of this project and Project I.D. #F-11635-18 (relocate three stations to BMA Kings Mountain).

On page 369, the 2019 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 Gaston County. Facilities may also serve residents of counties not included in their service area.

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

<b>Facility Name</b>	<b>Provider</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Percent Utilization</b>
BMA Kings Mountain	FMC	Kings Mountain	18	83.33%
FMC Belmont	FMC	Belmont	19	85.53%
FMC Gastonia	FMC	Gastonia	39	94.23%
FMC South Gaston	FMC	Gastonia	28	79.46%
FMC North Gaston*	FMC	Dallas	0	0.00%

Source: January 2019 SDR, Table B

\*Received CON approval but facility (12 stations) is not operational yet.

In Section G, pages 31-32, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis stations in Union County. The applicant states:

- BMA is not duplicating existing capacity but rather taking a proactive step to ensure adequate access to care for the patients who choose to dialyze at FMC Belmont.
- Based on the data in the January 2019 SDR (as of June 30, 2018) utilization across all BMA facilities in Gaston County was 3.58 patients per station. All of the operational facilities were operating at basically 80% or above. The lowest utilization was FMC South Gaston at 79.46%.
- Based on the data in ESRD Data Collection Forms (as of December 31, 2018) utilization across all BMA facilities in Gaston County was 3.6442 patients per stations. All of the operational facilities were operating at basically 80% or above. The lowest utilization was BMA Kings Mountain at 76.79%.

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

- Based on the facility need methodology in the January 2019 SDR there is a need for three additional dialysis stations.
- The applicant adequately demonstrates that the proposed three dialysis stations are needed in addition to the existing or approved dialysis stations at FMC Belmont.

**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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.

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

Position	Current FTE Staff	Projected FTE Staff
	(CY2018)	2nd Full Fiscal Year (CY2021)
RNs	3.00	4.00
PCT	8.00	9.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Clinical Manager	1.00	1.00
Admin (FMC Dir. Ops)	0.15	0.15
In-Service	0.15	0.15
Clerical	1.00	1.00
Chief Tech	0.15	0.15
Equipment Tech	0.35	0.35
<b>TOTAL</b>	<b>14.80</b>	<b>16.80</b>

The assumptions and methodology used to project staffing are provided in Sections H and R. 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 Section H.3 and H.4, page 34, respectively, 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 current medical director. In Exhibit I-5, the applicant provides a letter from the 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 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 BELMONT DIALYSIS Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	On-Site
Self-care training (in-center)	Referral to BMA Gastonia
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	Referral to BMA Gastonia
Psychological counseling	Referral to CaroMont Regional Medical Center
Isolation – hepatitis	On-Site
Nutritional counseling	On-Site
Social Work services	On-Site
Acute dialysis in an acute care setting	CaroMont Regional Medical Center
Emergency care	BMA/ 911/ Hospital
Blood bank services	CaroMont Regional Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	SPECTRA
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Caramont Heart and Vascular; Gastonia Surgical Associates; Metrolina Vascular Access Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehabilitation Services
Transportation	Access of Gaston County

Source: Table on page 37 of the application.

On page 37, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1 and I-3.

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 Exhibit I-1 through I-5.

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 make more than minor renovations to 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 CY2018 for the proposed services, as shown in the table below.

**FMC Belmont Payor Mix  
 CY2018**

Payor Category	Percent of Total Patients
Medicaid	4.50%
Medicare	65.59%
Medicare/Commercial	13.14%
Miscellaneous (incl. VA)	6.70%
Commercial Insurance	9.51%
Self Pay/Indigent/Charity	0.56%
<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%
Lincoln	18%	50%	15%	13%	12%	11%
Catawba	17%	51%	25%	13%	10%	13%
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
- 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, 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 50, 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:

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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.

**CY2021**

<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicaid	4.50%
Medicare	65.59%
Medicare/Commercial	13.14%
Miscellaneous (incl. VA)	6.70%
Commercial Insurance	9.51%
Self Pay/Indigent/Charity	0.56%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 48 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.56% of total services will be provided to self-pay/indigent/charity patients, 78.73% to Medicare patients and 4.50% to Medicaid patients.

On page 48, 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 its most recent historical payor mix.

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, page 50, 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 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

The applicant proposes to add three dialysis stations to the existing facility, FMC Belmont, for a total of no more than 19 stations upon completion of this project and Project ID #F-11635-18 (relocate 3 stations).

On page 369, the 2019 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 Gaston County. Facilities may also serve residents of counties not included in their service area.

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

<b>Facility Name</b>	<b>Provider</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Percent Utilization</b>
BMA Kings Mountain	FMC	Kings Mountain	18	83.33%
FMC Belmont	FMC	Belmont	19	85.53%
FMC Gastonia	FMC	Gastonia	39	94.23%
FMC South Gaston	FMC	Gastonia	28	79.46%
FMC North Gaston*	FMC	Dallas	0	0.00%

Source: January 2019 SDR, Table B

\*Received CON approval but facility (12 stations) is not operational yet.

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:

*“BMA does not expect this proposal to have effect on the competitive climate in Gaston County. At this time BMA is the only provider of dialysis services in Gaston County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Belmont 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 January 2019 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 57, 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 57, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to (immediate jeopardy) 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

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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- The applicant is not proposing to establish a new ESRD 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, pages 14-16, the applicant provides the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project. The applicant projects to serve 76 patients on 19 stations, which is 4.0 patients per station per week ( $76 \text{ patients} / 19 \text{ stations} = 4.0$ ), by the end of OY1. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

-C- In Section C.1, pages 14-16, the applicant provides the assumptions and methodology used to project utilization of the facility.