

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 30, 2020

Findings Date: January 30, 2020

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: J-11769-19

Facility: FMC Dialysis Services of Briggs Avenue

FID #: 990969

County: Durham

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

Project: Add no more than four dialysis stations for a total of no more than 29 stations upon completion of this project, and Project ID #J-11736-19 (relocate four stations to FKC Eno River)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Dialysis Services of Briggs Avenue proposes to add no more than four dialysis stations for a total of no more than 29 stations upon completion of this project, and Project ID #J-11736-19 (relocate four stations to FKC Eno River)

#### **Need Determination**

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 14 dialysis stations in Durham County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for

the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for FMC Dialysis Services of Briggs Avenue in the July 2019 SDR is 3.62 patients per station per week, or 90.52 percent, based on 105 in-center dialysis patients and 29 certified dialysis stations [ $105 / 29 = 3.6207$ ;  $3.6207 / 4 = 0.9052$  or 90.52%].

Below is a table that illustrates the facility need for additional dialysis stations at FMC Dialysis Services of Briggs Avenue.

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

		<b>Part A</b>
Required SDR Utilization		80%
FMC Dialysis Services of Briggs Avenue		
July 2019 SDR		
Facility Utilization Rate (as of 12/31 of the previous year)		90.52%
		<b>Part B</b>
# of Certified Stations		29
# of Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>29</b>
In-Center Patients as of 12/31/18 - (July 2019 SDR) (SDR2)		105
In-Center Patients as of 6/30/18 - (Jan. 2019 SDR) (SDR1)		97
<b>Step</b>	<b>Description</b>	<b>Result</b>
	Difference (SDR2 - SDR1)	8
(i)	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients from SDR1	0.1649
(ii)	Divide the result of Step (i) by 12	0.0137
(iii)	Multiply the result of Step (ii) by 12	0.1649
(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	122.3196
(v)	Divide the result of Step (iv) by 3.2 patients per station	38.2249
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>9.2249</b>

Source: Table on page 9 of the application.

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

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 11-13; Section N.2, page 52; Section O, pages 54-57, and referenced exhibits. The information provided by the applicant is reasonable and 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, pages 11-13; Section C.7, pages 20-21; Section L, pages 46-49; Sections N.2 and N.3, pages 52-53, and referenced exhibits. The information provided by the applicant is reasonable and 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, pages 12-13; Section F, pages 28-31; Section K, pages 42-43; Section N.2, pages 51-52; Section Q, pages 65-80; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal would maximize healthcare value.

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

### **Conclusion**

The Agency reviewed the:

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

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

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than four dialysis stations for a total of no more than 29 stations upon completion of this project, and Project ID #J-11736-19 (relocate four stations to FKC Eno River).

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

The following table illustrates current and projected patient origin for in-center patients served by FMC Dialysis Services of Briggs Avenue.

<b>FMC Dialysis Services of Briggs Avenue In-Center Patients</b>				
<b>County</b>	<b>Historical (1/1/2018-12/31/2018)</b>		<b>Projected OY2 (1/1/22-12/31/22)</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Durham	102	97.1%	102.5	98.1%
Orange	2	1.9%	0	0.0%
Person	1	1.0%	0	0.0%
Chatham	0	0.0%	2	1.9%
<b>Total</b>	<b>105</b>	<b>100.0%</b>	<b>104.5</b>	<b>100.0%</b>

Source: Section C, page 16

In Section C, pages, 17-18, 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 18-19, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 18-19, the applicant states:

*“Failure to receive dialysis care will ultimately lead to the patient’s demise. The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. BMA has identified the population to be served as 104.5 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project.”*

The information is reasonable and adequately supported for the following reasons:

- The applicant demonstrates a facility need of nine additional stations based on the facility need methodology, as published in the July 2019 SDR. The applicant is proposing to add four stations.
- The facility was operating at 90.52% as of 12/31/18 and failure to add additional stations could restrict admissions.

#### Projected Utilization

In Section Q, pages 66-67, the applicant provides its projected utilization, as illustrated in the following table.

<b>FMC Dialysis Services of Briggs Avenue</b>	<b>In-Center Dialysis Patients</b>
BMA begins with the Durham County patient population as of June 30, 2019.	100
Project the Durham County patient population forward for six months to December 31, 2019 using half of the Five-Year Average Annual Growth Rate (AACR) of 4.6%.	$100 \times 1.023 = 102.3$
Project the Durham County patient population forward for one year to December 31, 2020 using the County's Five-Year AACR.	$102.6 \times 1.046 = 107.0$
Subtract the patients projected to transfer to FKC Eno River.	$107.0 - 9 = 98.0$
Add the Chatham County patients. This is the projected starting census for this project.	$98.0 + 2 = 100$
Project the Durham County patient population forward for one year to December 31, 2021 using the County's Five-Year AACR.	$98.0 \times 1.046 = 102.5$
Add the Chatham County patients. This is the ending census for Operating Year 1.	$102.5 + 2 = 104.5$
Project the Durham County patient population forward for one year to December 31, 2022 using the County's Five-Year AACR.	$102 \times 1.046 = 107.2$
Add the Chatham County patients. This is the ending census for Operating Year 2.	$107.2 + 2 = 109.2$

Source: Section Q, page 67

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2021) the facility is projected to serve 104 in-center patients and at the end of OY2 (CY2022) the facility is projected to serve 109 in-center patients.

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

- OY1: 3.59 patients per station per week or 89.7% ( $104 \text{ patients} / 29 \text{ stations} = 3.5862/4 = 0.897$  or 89.7%)
- OY2: 3.76 patients per station per week or 94.0% ( $109 \text{ patients} / 29 \text{ stations} = 3.76/4 = 0.940$  or 94.0%)

The project utilization of 3.59 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).

- The applicant begins the projections by using the in-center patient census at FMC Dialysis Services of Briggs Avenue as of June 30, 2019, based on ESRD Data collection forms submitted to the Agency August 2019.

- The applicant projects the Durham County patient population will increase based on the Five-Year Average Annual Change Rate of 4.6%, as published in the July 2019 SDR.
- As of June 30, 2019, FMC Dialysis Services of Briggs Avenue was serving two patients from Chatham County. The applicant does not project any increase in this population but projects that by choice they will continue to dialyze at this facility.
- As of June 30, 2019, the facility was serving a patient from Caldwell County and the state of Tennessee. The applicant does not project these patients to continue to dialyze at the facility.
- BMA has previously projected that nine patients would transfer their care to the new FKC Eno River upon certification. BMA projects that these nine patients will transfer to FKC Eno River as of December 31, 2020.
- The project is scheduled for completion on December 31, 2020.
- Operating Year 1 (OY1) = January 1, 2021 – December 31, 2021 (CY2021)
- Operating Year 2 (OY2) = January 1, 2022 – December 31, 2022 (CY2021)

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

- The applicant demonstrates a facility need of nine additional stations based on the facility need methodology, as published in the July 2019 SDR. The applicant is proposing to add four stations.
- The applicant projects future utilization based on historical utilization.
- The applicant assumes a projected annual growth rate of 4.6 percent for Durham County patient census at FMC Dialysis Services of Briggs Avenue which is equal to the Durham County Five-Year AACR as published in the July 2019 SDR.
- The applicant demonstrated that the existing and approved stations are inadequate to serve the current and projected patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

### Access

In Section C, page 20, the applicant states all of Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved population in North Carolina.

In Section L.3, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>FMC Dialysis Services of Briggs Avenue Projected Payor Mix Project Year 2, CY 2022</b>		
<b>Payment Source</b>	<b># of In-Center Patients</b>	<b>% of Total</b>
Self-Pay	0.72	0.66%
Insurance*	11.12	10.18%
Medicare*	73.28	67.08%
Medicaid*	7.70	7.05%
Other: Medicare Commercial	12.14	11.12%
Misc. (including VA)	4.27	3.91%
<b>Total</b>	<b>109.23</b>	<b>100.00%</b>

\* Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 78% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 7% to Medicaid patients.

**Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the 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 or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add no more than four dialysis stations for a total of no more than 29 stations upon completion of this project and Project ID #J-11736-19 (relocate four stations to FKC Eno River).

In Section E, pages 26-27, the applicant describes the alternatives it considered and explains why the alternatives not chosen are 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 state this was not effective due to the growth in patient population in the area of the facility. The applicant states that failure to add stations will result in higher utilization rates and fewer opportunities for admission.
- Apply for Fewer than Four Stations-The applicant states this was not an effective alternative since the facility need methodology indicates a need for nine stations. The applicant states that fewer stations would result in higher utilization rates.
- Relocated Stations from Another facility Owned by BMA in Durham County-The applicant states that this would not be an effective alternative because out of the four facilities in Durham owned by the applicant, there is only one operating below 80 percent utilization. As of December 31, 2018, FMC West Pettigrew's utilization rate was 77.08 percent. However, by June 30, 2019, it increased to 78.13 percent. The applicant states it would not be appropriate to relocate stations from this facility.

In Section E.2, Page 27, the applicant states that its proposal is the most effective alternative because the project will meet the facility need, as demonstrated in the application, and the project does not require any capital cost.

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 facility is operating at over 90% capacity as of the July 2019 SDR.
- The applicant utilizes the facility need methodology to show the need for additional stations.
- 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

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion and 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 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than four additional dialysis stations for a total of no more than 29 certified stations at FMC Dialysis Services of Briggs Avenue upon completion of this project, and Project ID #J-11736-19 (relocate four stations to FKC Eno River), 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 no more than four dialysis stations for a total of no more than 29 stations upon completion of this project, and Project ID #J-11736-19 (relocate four stations to FKC Eno River).

### **Capital and Working Capital Costs**

In Section F.1, page 28, the applicant states there is no capital cost for the proposed project. The applicant is adding dialysis stations to an existing facility and the space designated for the stations already exists.

The applicant states there are no start-up or initial operating costs because FMC Dialysis Services of Briggs Avenue is an operational facility.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section Q, Form F.2, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

<b>Projected Revenues and Operating Expenses</b>		
<b>FMC Dialysis Services of Briggs Avenue</b>	<b>Operating Year 1 CY 2021</b>	<b>Operating Year 2 CY 2022</b>
Total Treatments	15,134.47	15,817.04
Total Gross Revenues (Charges)	\$95,210,952	\$99,504,997
Total Net Revenue	\$4,847,220	\$5,065,831
Average Net Revenue per Treatment	\$320.28	\$320.28
Total Operating Expenses (Costs)	\$3,858,230	\$3,982,710
Average Operating Expenses per Treatment	\$254.94	\$251.80
<b>Net Income/Profit</b>	<b>\$988,990</b>	<b>\$1,083,121</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q 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. 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.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 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 no more than four dialysis stations for a total of no more than 29 stations upon completion of this project, and Project ID #J-11736-19 (relocate four stations to FKC Eno River).

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 Durham County. Facilities may serve residents of counties not included in their service area.

The applicant has five facilities in Durham County, four of which are operational. The average utilization for all four operational facilities is 87.41%, or 3.50 patients per station according to the July 2019 SDR.

Facility Name	Certified stations as of 12/31/2018	# of In-Center Patients as of 12/31/2018	Utilization by percent as of 12/31/2018	Patients per Station
FMC Dialysis Services of Briggs Avenue	29	105	90.52%	3.6207
FMC Dialysis Services West Pettigrew	24	74	77.08%	3.0833
Freedom Lake Dialysis Center	26	94	90.38%	3.6154
FKC Eno River	0	0	0%	0
FMC South Durham Dialysis	18	66	91.67%	3.6667
Bull City Dialysis	16	44	68.75%	2.7500
Downtown Durham Dialysis	0	0	0%	0
Durham Dialysis	25	98	98.00%	3.9200
Durham Regional Dialysis	10	14	35.00%	1.4000
Durham West Dialysis	27	79	73.15%	2.9259
Hope Valley Dialysis	0	0	0%	0
RTP Dialysis	10	21	52.50%	2.1000
Southpoint Dialysis	16	69	107.81%	4.3125
<b>Total</b>	<b>201</b>	<b>664</b>		

Source: July 2019 SDR, Fresenius related facilities’ ESRD data collection forms

In Section G, page 34-35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. The applicant states in reference to data from the June 30, 2019 ESRD Data Collection Forms:

*“All of the BMA facilities in Durham County are well utilized. The overall utilization by 334 dialysis patients on 99 certified dialysis stations is 3.4433 patients per station.*

...

*The July 2019 SDR does report a surplus of 14 dialysis stations in Durham County. The SDR also reports that the Durham County ESRD census for December 31, 2018 was 670, and that this census was increasing at a rate of 4.2%.*

...

*BMA is applying for four stations. Approval of this application [sic] not cause unnecessary duplication of services but will ensure an adequate inventory of dialysis stations exists for the ESRD patient population of the county.”*

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing and approved dialysis stations.

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reason 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 Q, the applicant provides current and projected staffing in full time equivalents (FTEs) for the proposed services as illustrated in the following table. The applicant states that the Medical Director is not an FTE of the facility, and thus is not reflected in the staffing chart.

<b>FMC Dialysis Services of Briggs Avenue Staffing</b>		
<b>Position</b>	<b>Current # FTEs</b>	<b>Projected # FTEs</b>
	<b>As of June 30, 2019</b>	<b>OY2 (CY2022)</b>
Administrator	1.00	1.00
Registered Nurse	5.00	5.00
Patient Care Technician	11.50	12.25
Dietitian	0.75	0.75
Social Worker	1.00	1.00
Maintenance	0.50	0.50
Administration	1.00	1.00
FMC Director of Operations	0.20	0.20
Other: In-Service	0.15	0.15
Chief Tech	0.15	0.15
<b>Total</b>	<b>21.25</b>	<b>22.00</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 82. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form H, which is found in Section Q. In Section H, page 37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 38, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-3 and H-3.2, the applicant provides supporting documentation.

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, pages, 39-40, 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 Dialysis Services of Briggs Avenue Necessary Ancillary and Support Services</b>		
<b>Services</b>	<b>Provider</b>	
Self-care training (in-center)	Referral to FMC West Pettigrew	
Home training: HH PD Accessible follow-up program		
Isolation – hepatitis		On site
Nutritional counseling		On site
Social Work services	On site	
Laboratory Services	On Site	
Vascular surgery	Referral to Carolina Vascular; Duke Regional Vascular	
Pediatric nephrology	Referral to Duke UMC or UNC HealthCare	
Acute dialysis in an acute care setting	Duke Regional Hospital	
Transplantation services	Duke UMC	
Emergency care	Duke Regional Hospital	
Blood bank services	Duke Regional Hospital	
Diagnostic and evaluation services	Duke Regional Hospital	
X-ray services	Duke Regional Hospital	
Psychological Counseling	Behavioral Health Services of Durham	
Vocational rehabilitation & counseling	Vocational Rehab Services of Durham	
Transportation	Access, H2Go, and nursing home transportation	

Source: Section I, page 40

In Section I, page 40, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

NA

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:



- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 47, the applicant provides the historical payor mix during Calendar Year 2018 (CY 2018) for its existing services, as shown in the table below.

<b>FMC Dialysis Services of Briggs Avenue Historical Payor Mix CY 2018</b>	
<b>Payment Source</b>	<b>% Total Patients</b>
Self-Pay	0.66%
Insurance*	10.18%
Medicare*	67.08%
Medicaid*	7.05%
Other: Medicare Commercial	11.12%
Misc. (including VA)	3.91%
<b>Total</b>	<b>100.00%</b>

\*Including any managed care plans

In Section L.1(a), page 46, the applicant provides a comparison of the demographical information on FMC Dialysis Services of Briggs Avenue patients and the service area population during CY2018, as summarized below.

<b>FMC Dialysis Services of Briggs Avenue</b>	<b>Percentage of Total Patients Served during the Last Full OY</b>	<b>Percentage of the Population of the Service Area*</b>
Female	35.6%	52.3%
Male	64.4%	47.7%
Unknown	0.0%	0.0%
64 and Younger	65.3%	86.9%
65 and Older	34.7%	13.1%
American Indian	0.0%	0.9%
Asian	1.0%	5.5%
Black or African-American	79.2%	37.3%
Native Hawaiian or Pacific Islander	1.0%	0.1%
White or Caucasian	16.8%	42.6%
Other Race	1.0%	13.6%
Declined / Unavailable	0.0%	0.0%

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

**Conclusion**

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 47, the applicant states,

*“BMA does not have any obligations under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.”*

In Section L, page 48, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

<b>FMC Dialysis Services of Briggs Avenue Projected Payor Mix Project Year 2, CY 2022</b>		
<b>Payment Source</b>	<b># of In-Center Patients</b>	<b>% of Total</b>
Self-Pay	0.72	0.66%
Insurance*	11.12	10.18%
Medicare*	73.28	67.08%
Medicaid*	7.70	7.05%
Other: Medicare Commercial	12.14	11.12%
Misc. (including VA)	4.27	3.91%
<b>Total</b>	<b>109.23</b>	<b>100.00%</b>

\* Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 78% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 7% to Medicaid patients.

On pages 48-49, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix.
- Projected utilization is reasonable and adequately supported. 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.

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

C

In Section L, page 49, the applicant adequately describes the range of means by which patients will have access to the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 50, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

**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 no more than four dialysis stations for a total of no more than 29 stations upon completion of this project, and Project ID #J-11736-19 (relocate four stations to FKC Eno River).

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 Durham County. Facilities may serve residents of counties not included in their service area.

The applicant has five facilities in Durham County, four of which are operational.

Facility Name	Certified stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by percent as of 12/31/2018	Patients per Station
FMC Dialysis Services of Briggs Avenue	29	105	90.52%	3.6207
FMC Dialysis Services West Pettigrew	24	74	77.08%	3.0833
Freedom Lake Dialysis Center	26	94	90.38%	3.6154
FKC Eno River	0	0	0%	0
FMC South Durham Dialysis	18	66	91.67%	3.6667
Bull City Dialysis	16	44	68.75%	2.7500
Downtown Durham Dialysis	0	0	0%	0
Durham Dialysis	25	98	98.00%	3.9200
Durham Regional Dialysis	10	14	35.00%	1.4000
Durham West Dialysis	27	79	73.15%	2.9259
Hope Valley Dialysis	0	0	0%	0
RTP Dialysis	10	21	52.50%	2.1000
Southpoint Dialysis	16	69	107.81%	4.3125
<b>Total</b>	<b>201</b>	<b>664</b>		

Source: July 2019 SDR, Fresenius related facilities' ESRD data collection forms

In Section N, page 51, 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 51, the applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Durham County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Briggs Avenue facility begins with current patient population.”*

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 B, F, K, N and Q of the application and any exhibits).
- Quality services will be provided (see Sections B, K, N and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections, B, C, L, and N of the application and any exhibits).

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

In Section Q, Form A, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 127 of this type of facility located in North Carolina.

In Section O, page 57, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of *“Immediate Jeopardy”* occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 127 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

### C

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

**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- FMC Dialysis Services of Briggs Avenue is an existing facility.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C, pages 18-19, the applicant documents the need for the project and demonstrates that it will serve a total of 104.5 in-center patients on 29 stations at the end of the first operating year, which is 3.60 patients per station per week or a utilization rate of 90.00 percent. The discussion regarding analysis of need 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 17-18, and in Section Q, page 66-67, 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.