

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 7, 2018

Findings Date: December 7, 2018

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: M-11574-18

Facility: Fayetteville Kidney Center

FID #: 944475

County: Cumberland

Applicant: Bio-Medical Applications of Fayetteville, Inc.

Project: Add six dialysis stations for a total of 56 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 Fayetteville, Inc., d/b/a Fayetteville Kidney Center (BMA Fayetteville) proposes to add six dialysis stations for a total of 56 stations upon project completion.

#### **Need Determination**

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of nine dialysis stations in Cumberland County. Therefore, the July 2018 SDR does not indicate a need for additional stations in Cumberland County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations. 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 BMA Fayetteville in the July 2018 SDR is 3.22 patients per station per week, or 80.50 percent, based on 161 in-center dialysis patients and fifty certified dialysis stations [ $161 / 50 = 3.22$ ;  $3.22 / 4 = 0.805$  or 80.50%].

Below is a table that illustrates the facility need for additional dialysis stations at BMA Fayetteville:

<b>July SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		80.50%
Certified Stations		50
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>50</b>
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		161
In-Center Patients as of 6/30/17 (January 2018 SDR) (SDR1)		140
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	21
	Multiply the difference by 2 for the projected net in-center change	42
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.3000
(ii)	Divide the result of Step (i) by 12	0.0250
(iii)	Multiply the result of Step (ii) by 12	0.3000
(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	209.3000
(v)	Divide the result of Step (iv) by 3.2 patients per station	65.4063
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>15.4063</b> <b>15</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is fifteen 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 six new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2018 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 33 of the 2018 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the*

*delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.4(a), pages 9-10; Section K.1(g), pages 46-47; Section N.1, page 56; Section O, pages 57-60; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.4(b), page 10; Section C.3, page 18; Section L, pages 50-54; Section N.1, page 56; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.4(c), page 11; Section F, pages 27-31; Section K, pages 45-47; Section N.1, page 56; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

### Conclusion

The Agency reviewed the:

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

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

- (2) Repealed effective July 1, 1987.

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

C

Bio-Medical Applications of Fayetteville, Inc., d/b/a Fayetteville Kidney Center (BMA Fayetteville) proposes to add six dialysis stations for a total of 56 stations upon project completion.

**Patient Origin**

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

In Section C.8, page 20, the applicant provides the historical patient origin for BMA Fayetteville as of June 2018, as shown in the table below.

**BMA Fayetteville  
Patient Origin, June 30, 2018**

<b>County of Residence</b>	<b># of In-Center Dialysis Patients</b>	<b># of Home Hemo (HH) Dialysis Patients</b>	<b># of Home Peritoneal (PD) Dialysis patients</b>
Cumberland	166	27	45
Harnett	0	1	1
Hoke	3	2	2
Robeson	2	0	2
Sampson	1	0	1
<b>Total</b>	<b>172</b>	<b>30</b>	<b>51</b>

Source: Section C.8, page 20

The following table illustrates projected patient origin for the first two years of operation following project completion, as provided in Section C, page 14.

<b>BMA Fayetteville Projected Patient Origin</b>								
	<b>Projected (Operating Year 1) CY2020</b>				<b>Projected (Operating Year 2) CY2021</b>			
<b>County</b>	<b>In-Center</b>	<b>HH</b>	<b>PD</b>	<b>% of Total</b>	<b>In-Center</b>	<b>HH</b>	<b>PD</b>	<b>% of Total</b>
<b>Cumberland</b>	183.1	29.3	48.8	96.3%	194.1	30.3	50.4	96.5%
<b>Harnett</b>	0.0	1.0	1.0	0.7%	0.0	1.0	1.0	0.7%
<b>Hoke</b>	0.0	2.0	2.0	1.5%	0.0	2.0	2.0	1.4%
<b>Robeson</b>	0.0	0.0	2.0	0.7%	0.0	0.0	2.0	0.7%
<b>Samson</b>	1.0	0.0	1.0	0.7%	1.0	0.0	1.0	0.7%
<b>Total</b>	184.0	32.0	54.0	100.0%	195.0	33.0	56.0	100.0%

Source: Section C.1, page 14

In Section C, pages 13-18, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section B.2, pages 6-8, the applicant states that the application is filed pursuant to the facility need methodology in the 2018 SMFP, utilizing the data from the July 2018 SDR. The applicant proposes to add six dialysis stations to the existing BMA Fayetteville facility, for a total of 56 dialysis stations upon project completion. In Section C, page 17, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 14-17, the applicant describes its need methodology and assumptions for projecting utilization of the proposed facility as follows:

- The applicant begins the projections by using the in-center patient census at BMA Fayetteville as of June 30, 2018.
- The applicant assumes that BMA Fayetteville will have higher in-center patient growth than the Cumberland County Five Year Average Annual Change Rate (AACR) of 3.3% as published in the July SDR, based on the significant growth at BMA Fayetteville in the last 12 months ending June 30, 2018 which was 22.86%. The applicant uses an annual growth rate of 6.0%. From June 30, 2017 to December 31, 2017, the number of in center patients increased from 140 patients to 161 patients; an increase of 15%. From December 31, 2017 to June 30, 2018, the in center patient census increased from 161 patients to 172 patients; an increase of 6.8%. Therefore, the applicant's use of a 6.0% annual growth rate is reasonable.
- The applicant assumes no growth for patients living outside of Cumberland County.
- The applicant subtracts 8 patients from the patient census of BMA Fayetteville as of December 31, 2018 because the applicant projects that 8 patients will transfer their care to FKC Rockfish upon completion of that project, Project ID # M-11502-18, which is expected to be December 31, 2018.

- Operating Year 1 (OY1) = January 1, 2020 – December 31, 2020 (CY2020)  
 Operating Year 2 (OY2) = January 1, 2021 – December 31, 2021 (CY2021)

Projected Utilization

In Section C, pages 15-17, the applicant provides its projected utilization methodology, based on its stated assumptions, as illustrated in the table below.

*In-Center*

<b>BMA Fayetteville In-Center Patients</b>	
Begin with Cumberland County patients dialyzing at the facility as of June 30, 2018	166
Project Cumberland County patient census forward six months to December 31, 2018 using one half the annual growth rate of 6.0%.	$166 \times 1.03 = 171.0$
Subtract the 8 patients projected to transfer to FKC Rockfish	$171.0 - 8 = 163.0$
Project Cumberland County patient census forward one year to December 31, 2019 using an annual growth rate of 6.0%.	$163.0 \times 1.06 = 172.8$
Add the 1 patient from Sampson County. This is the starting census for this project.	$172.8 + 1 = 173.8$
Project the Cumberland patient census forward one year to December 31, 2020 using an annual growth rate 6.0%.	$172.8 \times 1.06 = 183.1$
Add the 1 patient from Sampson County. This is the ending census for Operating Year 1	$183.1 + 1 = 184.1$
Project Cumberland County patient census forward one year to December 31, 2021 using an annual growth rate of 6.0%	$183.1 \times 1.06 = 194.1$
Add the 1 patient from Sampson County. This is the ending census for Operating Year 2	$194.1 + 1 = 195.1$

Source: Table in Section C, page 15

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2020) the facility is projected to serve 184 in-center patients and at the end of OY2 (CY2021) the facility is projected to serve 195 in-center patients.

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

- OY1: 3.2857 patients per station per week or 82.14% ( $184 \text{ patients} / 56 \text{ stations} = 3.2857/4 = 0.8214$  or 82.14%)
- OY2: 3.4821 patients per station per week or 87.05% ( $195 \text{ patients} / 56 \text{ stations} = 3.4821/4 = 0.8705$  or 87.05%)

The project utilization of 3.2857 patients per station per week at the end of OY1 is equal to or exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

*Home Peritoneal Dialysis (PD) and Home Hemodialysis (HH) Patients*

- The applicant begins its utilization projections by using its PD and HH patient census as of June 30, 2018.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Cumberland County which is 3.3% to project the Cumberland County patient population forward.
- The applicant projects a growth rate equal to the Cumberland County Five-Year AACR of 3.3%.
- The applicant assumes no growth for patients living outside Cumberland County.
- Operating Year 1 (OY1) = January 1, 2020 – December 31, 2020 (CY2020)  
 Operating Year 2 (OY2) = January 1, 2021 – December 31, 2021 (CY2021)

In Section C.1, pages 16-17, the applicant provides the calculations it used to arrive at the projected PD and HH patient census for OY1 and OY2, as summarized in the table below.

<b>BMA Fayetteville PD and HH patients</b>		
	<b>PD</b>	<b>HH</b>
Begin with Cumberland County patients dialyzing at the facility as of June 30, 2018	45	27
Project Cumberland County patient census forward six months to December 31, 2018 using the Five-Year AACR of 3.3% for Cumberland County.	$45 \times 1.0165 = 45.7$	$27 \times 1.0165 = 27.4$
Project Cumberland County patient census forward one year to December 31, 2019	$45.7 \times 1.033 = 47.3$	$27.4 \times 1.033 = 28.4$
Add the patients from other Counties. This is the starting census for this project.	$47.3 + 6 = 53.3$	$28.4 + 3 = 31.4$
Project the Cumberland patient census forward one year to December 31, 2020	$47.3 \times 1.033 = 48.8$	$28.4 \times 1.033 = 29.3$
Add the patients from other Counties. This is the ending census for Operating Year 1	$48.8 + 6 = 54.8$	$29.3 + 3 = 32.3$
Project Cumberland County patient census forward one year to December 31, 2021	$48.8 \times 1.033 = 50.1$	$29.3 \times 1.033 = 30.3$
Add the patients from other Counties. This is the ending census for Operating Year 2	$50.4 + 6 = 56.4$	$30.3 + 3 = 33.3$

Source: Tables in Section C, pages 16-17

Projected utilization for all patients at BMA Fayetteville is reasonable and adequately supported for the following reasons:

- The applicant begins its utilization projections with the existing in-patient, PD, and HH census for Cumberland County for BMA Fayetteville.
- The applicant assumes that BMA Fayetteville will have higher in-center patient growth than the Cumberland County Five Year Average Annual Change Rate (AACR) of 3.3% as published in the July SDR, based on the significant growth at BMA Fayetteville in the last 12 months ending June 30, 2018.
- The applicant uses the Five Year AACR for Cumberland County as published in the July 2018 SDR to project growth of PD and HH patients dialyzing at BMA Fayetteville.
- The applicant does not project growth for its patients who do not reside in Cumberland County.
- The applicant adequately demonstrates the need for six additional dialysis stations at BMA Fayetteville pursuant to the facility need methodology in the 2018 SMFP. Projected utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

### Access

In Section C.3, page 18, the applicant states:

*“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally undeserved persons.*

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

In Section L, page 51, 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.



**BMA Fayetteville  
Projected Payor Mix  
CY2020**

<b>Payment Source</b>	<b>% Total Patients</b>	<b>% of In-Center Patients</b>	<b>% of HH Patients</b>	<b>% of PD Patients</b>
Self- Pay/Indigent/Charity	1.10%	1.04%	0.53%	0.53%
Medicare	65.50%	64.16%	69.60%	69.60%
Medicaid	3.60%	5.28%	0.35%	0.35%
Commercial Insurance	8.70%	6.09%	15.10%	15.10%
Medicare/Commercial	16.0%	19.33%	6.92%	6.92%
Misc. (including VA)	5.10%	4.11%	7.51%	7.51%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

The applicant states on page 51 that the future payor mix is based on BMA Fayetteville's facility performance for the previous 12 months ending June 30, 2018. The projected payor mix is reasonable and adequately supported.

**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 a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

BMA Fayetteville proposes to add six dialysis stations for a total of 56 stations upon project completion.

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

- Maintain the Status Quo. The applicant states this option ignores the growing number of patients choosing to dialysis at BMA Fayetteville. The applicant states this would result in the facility reaching a 100% utilization and changing patients to a third shift.
- Relocate Stations from other BMA Facilities in Cumberland County. The applicant states all BMA facilities are well-utilized.

On page 24, the applicant states that its proposal is the most effective alternative because additional dialysis stations are needed in Cumberland County and BMA Fayetteville is the only facility that can accommodate additional stations. The applicant states that the only facility in Cumberland County that could relocate stations is FMC South Ramsey since its utilization is less than 80%. However, since the facility is at 78.43% utilization, the applicant believes relocating stations from FMC South Ramsey would not be appropriate.

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 applicant utilizes the facility need methodology to show the need for additional stations.
- The applicant's projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- The applicant adequately demonstrates that maintaining the status quo or relocating stations are not the most effective alternatives to meet the need for additional dialysis stations at BMA Fayetteville.

### **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 Fayetteville, Inc., d/b/a Fayetteville Kidney Center shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the July 2018 SDR, Bio-Medical Applications of Fayetteville, Inc., d/b/a Fayetteville Kidney Center shall develop no more than six additional dialysis stations for a total of no more than 56 certified stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
  - 3. Bio-Medical Applications of Fayetteville, Inc., d/b/a Fayetteville Kidney Center shall install plumbing and electrical wiring through the walls for no more than fifty-six dialysis stations, which shall include any isolation stations.**
  - 4. Bio-Medical Applications of Fayetteville, Inc., d/b/a Fayetteville Kidney Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA Fayetteville proposes to add six dialysis stations for a total of 56 stations upon project completion.

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

In Section F.1, page 27, the applicant projects the total capital cost of the project to be \$22,500, with \$4,500 for water treatment equipment and \$18,000 for equipment/furniture.

In Section F.1, page 27, the applicant provides the assumptions used to project the capital cost. In Sections F.10 and F.11, page 30, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

### **Availability of Funds**

In Section F.2, page 28, the applicant states that the capital cost will be funded as shown in the table below.

#### **Sources of Capital Cost Financing**

<b>Type</b>	<b>Bio-Medical Applications of North Carolina, Inc.</b>	<b>Total</b>
Loans	\$0	\$0
Accumulated reserves or OE *	\$22,500	\$22,500
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$22,500</b>	<b>\$22,500</b>

\* OE = Owner's Equity

Source: Section F, page 28

In Section F.2, page 28, the applicant states that it will fund the entire capital cost of the proposed project with accumulated reserves. Exhibit F-1 contains a letter from the applicant on behalf of the Senior Vice President and Treasurer, Fresenius Medical Care Holdings, Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-2 contains a Consolidated Financial Statement from Fresenius Medical Care Holdings, Inc., which showed that as of December 31, 2017 Fresenius Medical Care Holdings, Inc. had \$569,818,000 in cash and equivalents, \$19,822,127,000 in total assets and \$10,542,494,000 in net assets (total assets less total liabilities).

### **Financial Feasibility**

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

<b>Projected Revenues and Operating Expenses</b>		
<b>BMA Fayetteville</b>	<b>Operating Year 1 CY 2020</b>	<b>Operating Year 2 CY 2021</b>
Total Treatments	38,976	40,903
Total Gross Revenues (Charges)	\$153,084,353	\$160,725,510
Total Net Revenue	\$13,452,866	\$14,082,112
Average Net Revenue per Treatment	\$345	\$344
Total Operating Expenses (Costs)	\$10,021,388	\$10,330,528
Average Operating Expense per Treatment	\$257	\$253
<b>Net Income/Profit</b>	<b>\$3,431,478</b>	<b>\$3,751,584</b>

However, the applicant’s revenues in Form C differ from the total revenue reported in Form B, resulting in a difference of over \$1.2 million in OY1 and OY2. Despite this inconsistency, the projected revenues will still exceed operating expenses in OY1 and OY2. Therefore, the assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

**C**

BMA Fayetteville proposes to add six dialysis stations for a total of 56 stations upon project completion.

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

The applicant operates six facilities in Cumberland County. This includes two proposed facilities. Fresenius Medical Care is the only provider of dialysis services in Cumberland County. The applicant states the facilities are geographically dispersed and in close proximity to the larger number of dialysis patients in Cumberland County.

Facility Name	Provider Name	Location	# of Stations	Utilization
Fayetteville Kidney Center	Fresenius Medical Care	Fayetteville	50	80.50%
FMC North Ramsey	Fresenius Medical Care	Fayetteville	40	81.88%
FMC South Ramsey	Fresenius Medical Care	Fayetteville	51	78.43%
FMC of Roseboro	Fresenius Medical Care	Fayetteville	40	103.13%
FKC Hope Mills	Fresenius Medical Care	Fayetteville	0	NA
FKC Rockfish	Fresenius Medical Care	Fayetteville	0	NA

Source: Section G, page 35

In Section G, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cumberland County. The applicant states:

*“As Fresenius is the only provider of dialysis services in Cumberland County, Fresenius is aware of patients it serves, with the goal to routinely evaluate where more dialysis patients are residing and thus, where more dialysis stations are needed.”*

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 or approved dialysis stations.

- There is a facility need determination, as calculated using the methodology in the July 2018 SDR, for the proposed 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 H.1, page 37, the applicant provides current and projected staffing in full time equivalents (FTEs) for Cumberland County. The applicant does not project to change BMA Fayetteville's current staffing levels upon project completion.

The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, page 37, the applicant states the facility operates with two clinical managers. One is dedicated to the in-center area, and the other is dedicated to home training. In Section I.3, page 42, the applicant identifies the current medical director for the facility. In Section H, page 38, 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.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 41, 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>BMA Fayetteville – Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	Bio-Medical Applications on site
Self-care training (in-center)	Bio-Medical Applications on site
Home training HH PD Accessible follow-up program	Bio-Medical Applications-Referral to FMC Fayetteville
Psychological counseling	Cumberland County Mental Health-Referral
Isolation – hepatitis	Bio-Medical Applications on site
Nutritional counseling	Bio-Medical Applications on site
Social Work services	Bio-Medical Applications on site
Acute dialysis in an acute care setting	Cape Fear Valley Hospital-Referral
Emergency care	Bio-Medical Applications, 911, Cape Fear
Blood bank services	Cape Fear Valley Hospital-referral
Diagnostic and evaluation services	Cape Fear Valley Hospital, Imaging Center, Valley Radiology-Referral
X-ray services	Cape Fear Valley Hospital, Imaging Center, Valley Radiology-Referral
Laboratory services	Spectra
Pediatric nephrology	UNC Pediatric Nephrology-Referral
Vascular surgery	Carolina Kidney Care Vascular Access Center, Village Surgical-Referral
Transplantation services	UNC/Pitt County Memorial Hospital
Vocational rehabilitation & counseling	Vocational Rehab Services of Fayetteville
Transportation	Cumberland County DSS, Fayetteville Area System Transit

Source: Section I, page 41

In Section I, pages 42-43, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-2, I-3 and I-4.

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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



NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. 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 54, the applicant provides the historical payor mix during CY 2017 for its existing services, as shown in the table below.

**BMA Fayetteville  
CY 2017**

<b>Payment Source</b>	<b>% Total Patients</b>
Self-Pay/Indigent/Charity	1.11%
Medicare	67.90%
Medicaid	4.11%
Commercial Insurance	8.77%
Medicare/Commercial	12.40%
Misc. (including VA)	5.72%
<b>Total</b>	<b>100.00%</b>

Source: Section L, page 54

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
Cumberland	12%	50%	55%	19%	12%	11%
Statewide	16%	51%	37%	15%	10%	12%

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

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

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

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

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

### Conclusion

The Agency reviewed the:

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

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

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

- (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 52, 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 accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”*

In Section L, page 53, 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 51, 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>Projected Payor Mix Project Year 2, CY 2021</b>	
<b>Payment Source</b>	<b>% Total Patients*</b>
Self-Pay/Indigent/Charity	1.10%
Medicare	65.50%
Medicaid	3.60%
Commercial Insurance	8.70%
Medicare/Commercial	16.00%
Misc. (including VA)	5.19%
<b>Total</b>	<b>100.00%</b>

\*Total may not foot due to rounding.

Source: Section L, page 51

As shown in the table above, during the second year of operation, the applicant projects that 82% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 3.6% to Medicaid patients.

On page 51, 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, pages 52-53, 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.1, page 55, 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-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

BMA Fayetteville proposes to add six dialysis stations for a total of 56 stations upon project completion.

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

The applicant operates six facilities in Cumberland County. This includes two proposed facilities. Fresenius Medical Care is the only provider of dialysis services in Cumberland County.

Facility Name	Provider Name	Location	# of Stations	Utilization
Fayetteville Kidney Center	Fresenius Medical Care	Fayetteville	50	80.50%
FMC North Ramsey	Fresenius Medical Care	Fayetteville	40	81.88%
FMC South Ramsey	Fresenius Medical Care	Fayetteville	51	78.43%
FMC of Roseboro	Fresenius Medical Care	Fayetteville	40	103.13%
FKC Hope Mills	Fresenius Medical Care	Fayetteville	0	NA
FKC Rockfish	Fresenius Medical Care	Fayetteville	0	NA

Source: Section G, page 35

In Section N, page 56, 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 56, the applicant states:

*“Fayetteville Kidney Center does not expect this proposal to have effect on the competitive climate in Cumberland County. All of the dialysis facilities in Cumberland County are operated by Fresenius Medical Care, parent to Fayetteville Kidney Center. BMA does not project to serve dialysis patients currently being serviced by another provider in a contiguous county.*

*The facility also has added value stemming from the strength of our relationship with Carolina Kidney Care nephrology practice.....the practice brings together a*

*collaborative effort of 10 very qualified nephrologists to provide care for the patients choosing to dialyze at Fayetteville Kidney Center.*

*BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.”*

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

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

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

## C

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 114 of this type of facility located in North Carolina.

In Section O, page 60, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care 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 114 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.



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

C

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

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

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- BMA Fayetteville 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.2, page 17, the applicant projects that BMA Fayetteville will serve 184 in-center patients on 56 stations, or a rate of 3.3 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 14-16, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.