

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 29, 2016

Findings Date: November 29, 2016

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Project ID #: M-11219-16

Facility: Fayetteville Kidney Center

FID #: 944475

County: Cumberland

Applicant: Bio-Medical Applications of Fayetteville

Project: Relocate five dialysis stations from FMC West Fayetteville to Fayetteville Kidney Center for a total of 50 stations at Fayetteville Kidney Center upon completion of this project, Project ID# M-10191-13 (add three stations), Project ID# M-10304-14 (relocate Fayetteville Kidney Center to be known as BMA Fayetteville) and Project ID# M-10340-14 (add three stations)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

Biomedical Applications of Fayetteville, Inc. (BMA) d/b/a Fayetteville Kidney Center proposes to add five dialysis stations by relocating five stations from FMC West Fayetteville for a total of 50 certified dialysis stations upon completion of this project, Project ID# M-10191-13 (add three stations), Project ID# M-10304-14 (relocate Fayetteville Kidney Center to be known as BMA Fayetteville) and Project ID# M-10340-14 (add three stations). The applicant uses the facility names Fayetteville Kidney Center and BMA of Fayetteville interchangeably throughout this application.

## **Need Determination**

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Cumberland County. Therefore, the applicant is not eligible to apply for additional stations in its existing facility based on the county need methodology. The applicant is not eligible to apply for additional stations in its existing facility based on the facility need methodology. The applicant does not propose to add new dialysis stations to an existing facility. Therefore, neither of the two ESRD need methodologies in the 2016 SMFP are applicable to the review.

## **Policies**

Policy GEN-3 is not applicable to this review since there is no identified need for additional dialysis stations in Cumberland County based on the county need methodology, nor is there a need for new dialysis stations at Fayetteville Kidney Center based on the facility need methodology.

Policy ESRD-2 is applicable to this review. Policy ESRD-2 of the 2016 SMFP states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:*

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate five dialysis stations from FMC West Fayetteville to Fayetteville Kidney Center, both in Cumberland County. According to the July 2016 SDR, Table B, there is a deficit of 12 dialysis stations in Cumberland County. Therefore, after the proposed relocation of five dialysis stations from FMC West Fayetteville, there will still be a deficit of 12 dialysis stations in Cumberland County. The applicant adequately demonstrates that the proposal will not result in a greater deficit or a surplus in the number of dialysis stations in Cumberland County as a result of the proposed project. Therefore, the application is conforming to Policy ESRD-2.

**Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2. Therefore, the application is conforming to this criterion.

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

C

BMA d/b/a Fayetteville Kidney Center proposes to add five dialysis stations by relocating five stations from FMC West Fayetteville for a total of 50 certified dialysis stations upon completion of this project, and all of the following projects: Project ID# M-10191-13 (add three stations), Project ID# M-10304-14 (relocate Fayetteville Kidney Center to be known as BMA Fayetteville) and Project ID# M-10340-14 (add three stations).

**Patient Origin**

On page 369, the 2016 SMFP defines the service area for dialysis stations as “*the 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 25, the applicant provides the historical patient origin for Fayetteville Kidney Center in-center patients as of June 30, 2016, which is summarized in the following table:

<b>FAYETTVILLE KIDNEY CENTER</b>				
<b>County of Residence</b>	<b>In-Center Patients</b>	<b>Home Hemo Patients</b>	<b>PD Patients</b>	<b>Percent In-Center</b>
Cumberland	135	43	23	97.1%
Harnett	0	0	1	0.0%
Hoke	3	3	1	2.2%
Robeson	1	3	0	0.7%
Sampson	0	1	0	0.0%
<b>TOTAL</b>	<b>139</b>	<b>50</b>	<b>25</b>	<b>100.0%</b>

In Section C.1, page 19, the applicant provides the projected patient origin for Fayetteville Kidney Center for the first two years of operation following completion of the project as follows:

FAYETTEVILLE KIDNEY CENTER						
	OPERATING YEAR 1 FY2018		OPERATING YEAR 2 FY2019		COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER	
	IN-CENTER	HOME*	IN-CENTER	HOME*	YEAR 1	YEAR 2
Cumberland	159.9	73.1	168.2	76.9	97.6%	97.7%
Harnett	0	1	0	1	0.0%	0.0%
Hoke	3	4	3	4	1.8%	1.8%
Robeson	1	3	1	3	0.6%	0.5%
Sampson	0	1	0	1	0.0%	0.0%
<b>TOTAL</b>	163.9	82.1	172.2	85.9	100.0%	100.0%

\*The "Home" category includes hemo dialysis and peritoneal dialysis patients.

The applicant provides the assumptions and methodology used to project in-center patient origin on pages 19-21. The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C.2, page 22, the applicant describes the need for the proposed project as follows:

*“BMA has begun projections of the patient population to be served with the existing patients of BMA Fayetteville and a projection of 10 patients who will transfer their care to the BMA Fayetteville facility. Letters of support from 20 patients who will transfer their care are included in Exhibit C-1. Within this application, BMA has projected a patient population of 163.9 rounded down to 163 in-center patients, to be dialyzing at the Fayetteville Kidney Center facility at the end of the first year. Utilization by 163 patients on 50 dialysis stations is calculated to be 3.22 patients per station, or 81.5% utilization.*

*This application is for relocation of existing in-center dialysis stations to BMA Fayetteville. Thus, this application will not impact the home dialysis patient population of BMA Fayetteville.*

*The patient population projected to utilize the Fayetteville Kidney Center facility indeed has a need for the stations at this location. The need of this population for the proposed services is a function of the individual patient need for dialysis care and treatment.”*

**Projected Utilization**

The applicant projects that Operating Years One and Two for the proposed project will be FY2018 and FY2019, respectively. In Section C, page 20, the applicant describes its methodology for projecting utilization as follows:

<b>FAYETTEVILLE KIDNEY CENTER OY1 &amp; OY2 FY2018 &amp; FY2019</b>	
<b>In-center Methodology:</b>	
BMA begins with the facility census of Cumberland County patients as of July 1, 2016.	135
BMA projects this census forward one year to June 30, 2016.	$(135 \times .052) + 135 = 142.0$
BMA adds the 10 patients residing in Cumberland County and expected to transfer their care to the facility upon project completion.	$142.0 + 10 = 152.0$
Add the four patients from Hoke and Robeson Counties. This is the starting census for Operating Year 1.	$152.0 + 4 = 156.0$
BMA projects this Cumberland County patient population forward for 12 months to June 30, 2017.	$(152.0 \times .052) + 152.0 = 159.9$
Add the four patients from Hoke and Robeson Counties. This is the ending census for Operating Year 1.	$159.9 + 4 = 164.0$
BMA projects this Cumberland County patient population forward for 12 months to June 30, 2018.	$(159.9 \times .052) + 160.0 = 168.2$
Add the four patients from Hoke and Robeson Counties. This is the ending census for Operating Year 2.	$168.2 + 4 = 172.32$

In Section C, pages 19-20, the applicant states its in-center assumptions as follows:

1. *BMA assumes that the Fayetteville Kidney Center patient population of Cumberland County residents is increasing at a rate equal to the Cumberland County Five Year Average Annual Change Rate [AACR]. That rate is 5.2% as published in the July 2016 SDR.*
2. *BMA has included 20 [21] patient letters of support for this project. These 20 [21] patients are dialyzing at another related facility in Cumberland County. Based upon the patient support letters, BMA is projecting that 10 patients will transfer to the relocated Fayetteville Kidney Center once the project is completed and stations certified. In projections of future patient populations BMA will reflect these transfers to be effective December 31, 2016. BMA notes that the relocated facility is projected to be certified by year end 2016.”*

The following chart identifies the patients’ current dialysis facility and zip code of residence.

Facility	28304	28305	28306	28348	28371	Total
North Ramsey	3	1	1	2	1	8
South Ramsey			7	2		9
West Fayetteville				4		4
<b>Total</b>	<b>3</b>	<b>1</b>	<b>8</b>	<b>8</b>	<b>1</b>	<b>21</b>

3. *“The July 2016 SDR reports the Fayetteville Kidney Center facility census on December 31, 2015 was 137 in-center patients. The ESRD Data Collection Form for the period ended June 20, 2016, filed with DHSR/Healthcare Planning and Certificate of Need Section in August 2016, indicates the Fayetteville Kidney Center facility census was 139 in-center patients. Projections of future populations to be served will begin with the more current information, 139 patients.*
4. *Of the 139 in-center patients at Fayetteville Kidney Center as of June 30, 2016, four patients resided in other counties. BMA assumes the four patients from Hoke and Robeson Counties, dialyzing with Fayetteville Kidney Center, are at the facility by patient choice. BMA will not demonstrate any growth of this segment of the patient population, but will add these four patients at appropriate points in time.*
5. *BMA plans this project for completion by June 30, 2017.*

*Last Full Operating Year: January 1 – December 31, 2015*  
*Interim Year 1: January 1 – December 31, 2016*  
*Interim Year 2: January 1 – December 31, 2017*  
*Operating Year 1: July 1, 2017 – June 30, 2018*  
*Operating Year 2: July 1, 2018 – June 30, 2019”*

The applicant will continue to provide home hemo and peritoneal dialysis training and support at the Fayetteville Kidney Center.

The applicant projects to serve 163 in-center patients or 3.3 patients per station ( $163/50 = 3.3$ ) by the end of Operating Year 1 and 172 in-center patients or 3.4 patients per station ( $172/50 = 3.4$ ) by the end of Operating Year 2 for the proposed 50-station facility. This satisfies the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The applicant projects 28 home hemodialysis patients and 57 peritoneal patients in the second year of operation. In this application, the applicant assumes a projected annual rate of growth of 5.2% for the Cumberland County dialysis patient census, which is consistent with the Cumberland County Five Year Average Annual Change Rate (2011-2015 – Source: July 2016 SDR). The applicant states it rounds calculations of patients down to the whole patient. Exhibit C-1 contains copies of letters, dated August 2015, from 21 patients who are currently receiving dialysis services at other Fresenius facilities and who are expressing support for the proposed project and their intention to consider utilizing the Fayetteville Kidney Center facility. All of the 21 patient letters of support in Exhibit C-1 identify themselves as residents of Cumberland County. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

### **Access**

In Section L.1(a), pages 61-62, the applicant states that each of BMA's 104 facilities in 42 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. Form C, pages 88-89, shows the applicants project over 81% of the projected in-center patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

### **Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for five additional stations at Fayetteville Kidney Center, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (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.

### C

The applicant proposes to relocate five existing dialysis stations from the FMC West Fayetteville facility also in Cumberland County, to Fayetteville Kidney Center, for a total of 50 stations upon completion of this project, Project ID# M-10191-13 (add three stations), Project ID# M-10304-14 (relocate Fayetteville Kidney Center which will become BMA Fayetteville) and Project ID# M-10340-14 (add three stations).

In Section D.1, on pages 30-33, the applicant discusses how it will continue to meet the needs of dialysis patients at FMC West Fayetteville after the relocation of stations to the Fayetteville Kidney Center facility.

### **FMC West Fayetteville Dialysis**

On pages 30-31 of the application, the applicant provides the assumptions used to project Fayetteville Kidney Center's utilization on June 30, 2017. The assumptions are stated below:

- *“BMA is proposing to relocate five stations from FMC West Fayetteville to the BMA Fayetteville facility. Projections of future patient populations to be served will begin with the FMC West Fayetteville census on June 30, 2016.*

- *FMC West Fayetteville is not certified to provide home dialysis. The facility was serving the following number of in-center patients as of June 30, 2016 (information from the ESRD Data Collection Forms, submitted to DHSR / Healthcare Planning and Certificate of Need in August 2016).*

<b>FMC West Fayetteville Patient Origin</b>	<b>June 30, 2016 Patient Census</b>
<i>Cumberland</i>	<i>142</i>
<i>Hoke</i>	<i>9</i>
<i>Robeson</i>	<i>4</i>
<i>Sampson</i>	<i>1</i>
<b>TOTAL</b>	<b>156</b>

- *BMA will project growth of the Cumberland County patients at the Cumberland County Five Year Average Annual Change Rate. No growth factor will be applied to patients residing in other counties and dialyzing at FMC West Fayetteville. Patients from other counties will be added at appropriate points in time.*
- *Within this application BMA includes letters of support from patients projecting to transfer their care to BMA Fayetteville upon completion of the project. BMA projects the four Robeson County and two Cumberland County patients to transfer their care to Fayetteville Kidney Center, as that facility will be closer to the patient residence location.*
- *Using a growth rate of 5.2%, the future patient populations of FMC West Fayetteville is calculated as follows:*

<b>FMC WEST FAYETTEVILLE</b>	
<i>BMA begins with the Cumberland County patient census as of June 30, 2016.</i>	<i>142</i>
<i>BMA projects this census forward for one year to June 30, 2017.</i>	<i><math>(142 \times .052) + 142 = 149.4</math></i>
<i>BMA subtracts 2 Cumberland County patients projected to transfer to BMA Fayetteville</i>	<i><math>149.4 - 2 = 147.4</math></i>
<i>BMA adds the nine patients from Hoke County and 1 patient from Sampson County. The 4 patients from Robeson County are projected to transfer to Fayetteville Kidney Center</i>	<i><math>147.4 + 10 = 157.4</math></i>
<i>Projected Census for June 30, 2017.</i>	<i>157.4</i>

- *Thus on June 1, [30] 2017, The FMC West Fayetteville census is projected to be 157.4, rounded to 157 patients. On this date, BMA proposes to net the facility station count downward to 35 stations; five stations are to be relocated.*
- *Utilization by 157 patients on 35 stations is equivalent to 112.14% or 4.49 patients per station.*



- *BMA recognizes that utilization rates exceeding 100% necessarily mean a third dialysis shift. BMA is also committed to adding dialysis stations to the FMC West Fayetteville facility as it may qualify for additional stations through Facility Need Methodology. The July 2016 SDR reports the facility utilization rate 94.38%. Therefore the facility does qualify for additional stations. The following calculations demonstrate the facility could apply for up to five dialysis stations in the October 2016 CON review cycle.”*

<b>OCTOBER 1 REVIEW- JULY SDR FMC WEST FAYETTEVILLE</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		94.4%
Certified Stations		40
Pending Stations		
<b>Total Existing and Pending Stations</b>		<b>40</b>
In-Center Patients as of 12/31/14 (July 2016 SDR) (SDR2)		151
In-Center Patients as of 6/30/14 (Jan 2016 SDR) (SDR1)		154
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	-3
	Multiply the difference by 2 for the projected net in-center change	-6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	-0.0390
(ii)	Divide the result of Step (i) by 12	-0.0032
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	-0.0390
(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	145.1169
(v)	Divide the result of Step (iv) by 3.2 patients per station	45.3490
	and subtract the number of certified and pending stations to determine the number of stations needed	5.3490

BMA filed a CON application on September 15, 2016 (Project ID# M-11225-16) to add five dialysis stations to FMC West Fayetteville, as it states on pages 32-33 of this application. If approved, the facility will become certified for 40 in-center dialysis stations. The applicant further states,

*“Utilization on 40 stations by 157 patients is equivalent to 3.93 patients per station, or 98.125% utilization. While this is a high utilization rate, BMA notes that failure to prepare for the six patients to transfer their care to BMA Fayetteville would actually result in a utilization rate exceeding four patients per station, forcing the facility to a third, or evening shift.*

*This application will ensure access to care in a convention [sic] setting for those patients who have been admitted at a facility other than BMA Fayetteville. BMA expects that no patients will be denied service by the proposed relocation (and decertification) of stations at FMC West Fayetteville.”*

## **Conclusion**

The applicant demonstrates that the needs of the population presently served at FMC West Fayetteville will continue to be adequately met following the proposed relocation of five dialysis stations to Fayetteville Kidney Center and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

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

### CA

In Section E, pages 34-35, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because the needs would not be met of patients residing near Fayetteville Kidney Center, but dialyzing at another Cumberland County facility, as there is a lack of access at Fayetteville Kidney Center. Therefore, this alternative was rejected.
- Apply to relocate stations from the FMC South Ramsey dialysis facility - Utilization is reported in the July 2016 SDR as 70.10%. However, the applicant states, “*the FMC South Ramsey dialysis facility is generally utilized to support transient patients visiting the Fayetteville area and is just minutes from Ft. Bragg and downtown Fayetteville.*” The applicant further states it believes it is important to maintain capacity at FMC South Ramsey to support the transient patient populations. Therefore, this alternative was rejected.
- Apply to relocate stations from the FMC North Ramsey dialysis facility - Current utilization is only 76.88%. However, the applicant states that the facility reported a census of 140 patients as of June 30, 2016, on the ESRD Data Collection Form. This is a utilization rate of 3.5 patients per station, or 87.5%. The application states that FMC North Ramsey will qualify for additional stations in the April 2017 CON review cycle. Therefore, this alternative was rejected.
- Apply to develop a fifth ESRD facility in Cumberland County - The applicant states that it may be applying to develop another facility in the future, but that is not the most expedient alternative at this time. Therefore, this alternative was rejected.

After considering the above alternatives, the applicant states that it has chosen the most efficient and cost effective alternative to meet the needs of its patients.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and 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. **Bio-Medical Applications of Fayetteville, Inc. shall relocate no more than five dialysis stations from FMC West Fayetteville to Fayetteville Kidney Center for a total of no more than 50 certified stations which shall include any home hemodialysis training or isolation stations, following completion of this project and all of the following projects: Project ID# M-10191-13 (add three stations), Project ID# M-10304-14 (relocate Fayetteville Kidney Center to be known as BMA Fayetteville) and Project ID# M-10340-14 (add three 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 five additional dialysis stations, for a total of no more than 50 dialysis stations, which shall include any isolation or home hemodialysis stations.**
  4. **Bio-Medical Applications of Fayetteville, Inc. shall take the necessary steps to decertify five dialysis stations at FMC West Fayetteville for a total of no more than 35 dialysis stations at FMC West Fayetteville upon project completion.**
  5. **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 Healthcare Planning and Certificate of Need Section 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, BMA of Fayetteville, Inc. d/b/a Fayetteville Kidney Center, proposes to relocate five dialysis stations from FMC West Fayetteville.

**Capital and Working Capital Costs**

In Section F.1, page 37, the applicant projects \$18,750 in capital costs to develop the proposed project. In Sections F.10-F.12, pages 40-41, the applicant states that no start-up expenses and initial operating expenses are required because Fayetteville Kidney Center is an existing facility.

**Availability of Funds**

In Section F.13, page 41, the applicant states it will finance the capital costs with accumulated reserves of Fresenius Medical Care Holdings, Inc. (FMCH).

Exhibit F-1 contains a letter dated August 15, 2016, from the Senior Vice President and Treasurer for FMCH, the parent company of BMA, which authorizes and commits cash reserves for the project capital costs of \$18,750, as well as, “*any additional funds as may be necessary for development of this project.*” Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$249.3 million in cash and cash equivalents as of December 31, 2015, \$19.3 in total assets and \$10.1 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

In Section R, the applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statements (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown below in the table.

<b>FAYETTEVILLE KIDNEY CENTER</b>		
	<b>FY2018</b>	<b>FY2019</b>
Total Net Revenue	\$12,779,992	\$13,424,364
Total Operating Expenses	\$10,448,763	\$10,896,296
<b>Net Income</b>	<b>\$2,331,229</b>	<b>\$2,528,068</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R, the financial section of the application, for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (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, BMA proposes to add five dialysis stations by relocating five stations from FMC West Fayetteville for a total of 50 certified dialysis stations upon completion of this project, Project ID# M-10191-13 (add three stations), Project ID# M-10304-14 (relocate Fayetteville Kidney Center to be known as BMA Fayetteville and Project ID# M-10340-14 (add three stations).

On page 369, the 2016 SMFP defines the service area for dialysis stations as “*the 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 currently operates four dialysis centers in Cumberland County. There is no other provider of ESRD facilities in Cumberland County, as shown below in the table.

<b>CUMBERLAND COUNTY DIALYSIS FACILITIES EXISTING &amp; APPROVED CERTIFIED STATIONS &amp; UTILIZATION as of DECEMBER 31, 2015</b>				
<b>Dialysis Facility</b>	<b>Certified Stations 12/31/15</b>	<b># In-center Patients</b>	<b>Percent Utilization</b>	<b>Patients/ Station</b>
<b>BMA Owned/Operated Facilities</b>				
Fayetteville Kidney Center*	39	137	87.82%	3.5128
FMC Dialysis Services North Ramsey	40	123	76.88%	3.0750
FMC Dialysis Services South Ramsey	51	143	70.10%	2.8039
FMC Services of West Fayetteville	40	151	94.38%	3.7750
BMA of Fayetteville**	0	0	0.00%	0.0000%

Source: 2016 SMFP. \* add 3 stations. CON issued/Not certified. \*\* Proposed new site. 45 stations CON issued/Not certified (former Fayetteville Kidney Center).

As shown in the table above, two of the four BMA Cumberland County dialysis facilities are operating above 80% utilization (3.2 patients per station), and two of the four facilities are operating at or above 70% utilization (2.8 patients per station). Furthermore, BMA of Fayetteville will be a relocated facility and has not yet been certified.

The applicant provides reasonable projections for the patient population it proposes to serve in Section C, pages 19-23 of the application. The growth projections are based on a projected 5.2% average annual growth rate in Cumberland County residents. At the end of the first operating year following project completion, Fayetteville Kidney Center projects the in-center utilization will be 3.3 in-center patients per station (163 patients / 50 dialysis stations = 3.3), which is 80% of capacity. The applicant does not propose to increase or decrease the number of certified stations in the service area. The applicant adequately demonstrates the need to relocate five existing dialysis stations to Fayetteville Kidney Center from FMC West Fayetteville.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, the application is conforming to this criterion.

- (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 48, the applicant provides the current and proposed staffing for the facility. The applicant currently has 46.15 FTEs at the facility and does not propose any new staff as a result of this project. In Section H.3, page 49, the applicant describes its experience and process for recruiting and retaining staff. In Section I.3, page 53, the applicant identifies the medical director as Maureen Achuko, M.D., and Exhibit I-5 contains a copy of a letter from Dr. Achuko expressing her support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 52, the applicant includes a list of providers of the necessary ancillary and support services. Exhibits I-2, 3 and 4 contain documentation for laboratory, hospital and transplant services, respectively. Exhibit I-5 contains a letter from the medical director of the facility describing the facility's established relationships with other healthcare providers. The applicant discusses coordination with the existing health care system on pages 53-54. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, 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

- (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

(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

(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.1, page 61, the applicant states that BMA has a long history of providing dialysis services to the underserved populations of North Carolina. FMC, BMA's parent company, currently operates 104 facilities in 42 North Carolina Counties, including affiliations with RRI facilities. The applicant further states it is policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor which would classify a patient as underserved. On pages 61-62, the applicant states:

*“BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. For example, Medicare (includes Medicare*

*Advantage treatments) represented 81.38% of North Carolina dialysis treatments in BMA facilities in FY 2015; Medicaid treatments represented an additional 4.87% of treatments in BMA facilities for FY 2015.”*

In Section L.7, page 65, the applicant provides a table indicating that 88.89% of the patients who received treatments at Fayetteville Kidney Center in CY2015 had some or all of their services paid for by Medicare or Medicaid.

<b>FAYETTEVILLE KIDNEY CENTER</b>	
<b>HISTORICAL PAYOR SOURCE (CY2015)</b>	<b>PERCENT OF TOTAL IN-CENTER PATIENTS</b>
Self-Pay/Indigent/Charity	1.09%
Medicare	70.98%
Medicaid	5.20%
Commercial Insurance	5.46%
Medicare/Commercial	12.40%
Miscellaneous incl. VA	4.88%
<b>Total</b>	<b>100.00%</b>

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

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
Cumberland	11%	51%	55%	18%	11%	16%
Harnett	11%	51%	37%	21%	10%	19%
Hoke	8%	51%	59%	20%	11%	21%
Robeson	13%	52%	73%	33%	13%	25%
Sampson	16%	51%	48%	29%	14%	24%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

\*Excludes "White alone" who are "not Hispanic or Latino" \*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. 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., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:



<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (Southeastern *Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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

In Section L.3, page 63, 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 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.6, page 64, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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.1, page 62, the applicant projects that 88.89% of the patients who will receive in-center treatments at Fayetteville Kidney Center will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected (FY2019) payor sources for the facility for in-center patients:

<b>FAYETTEVILLE KIDNEY CENTER</b>	
<b>PROJECTED PAYOR SOURCE (PY2) (FY2019)</b>	<b>PERCENT OF TOTAL IN-CENTER PATIENTS</b>
Self-Pay/Indigent/Charity	1.09%
Medicare	70.98%
Medicaid	5.20%
Commercial Insurance	5.46%
Medicare/Commercial	12.40%
Miscellaneous incl. VA	4.88%
<b>Total</b>	<b>100.00%</b>

In Section L, pages 62-63, the applicant provides the assumptions used to project payor mix. The applicant's projected payment sources in Section L are consistent with the facility's projected (CY2019) payment sources in Section R, Form C, page 89, and as clarified by the applicant in information provided on November 16, 2016. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at Fayetteville Kidney Center. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 64, the applicant describes the range of means by which a person will have access to the dialysis services at Fayetteville Kidney Center, including referrals from nephrologists. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, 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 66, the applicant states that Fayetteville Kidney Center has established relationships with local community training programs. Exhibit M-1 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicant to offer the facility as a clinical training site. The information provided is reasonable and adequately supports a determination that 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, BMA proposes to add five dialysis stations by relocating five stations from FMC West Fayetteville for a total of 50 certified dialysis stations at Fayetteville Kidney Center upon completion of this project, Project ID# M-10191-13 (add three stations), Project ID# M-10304-14 (relocate Fayetteville Kidney Center to be known as BMA Fayetteville) and Project ID# M-10340-14 (add three stations).

On page 369, the 2016 SMFP defines the service area for dialysis stations as “*the 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 currently operates four dialysis centers in Cumberland County. There is no other provider of ESRD facilities in Cumberland County, as shown below in the table.

<b>CUMBERLAND COUNTY DIALYSIS FACILITIES            EXISTING &amp; APPROVED            CERTIFIED STATIONS &amp; UTILIZATION as of DECEMBER 31, 2015</b>				
<b>Dialysis Facility</b>	<b>Certified Stations 12/31/15</b>	<b># In-center Patients</b>	<b>Percent Utilization</b>	<b>Patients/ Station</b>
<b>BMA Owned/Operated Facilities</b>				
Fayetteville Kidney Center*	39	137	87.82%	3.5128
FMC Dialysis Services North Ramsey	40	123	76.88%	3.0750
FMC Dialysis Services South Ramsey	51	143	70.10%	2.8039
FMC Services of West Fayetteville	40	151	94.38%	3.7750
BMA of Fayetteville**	0	0	0.00%	0.0000

Source: 2016 SMFP. \* add 3 stations. CON issued/Not certified. \*\* Proposed new site. 45 stations CON issued/Not certified (former Fayetteville Kidney Center).

As shown in the table above, two of the four BMA Cumberland County dialysis facilities are operating above 80% utilization (3.2 patients per station), and two of the four facilities are operating at or above 70% utilization (2.8 patients per station). Furthermore, BMA of Fayetteville will be a relocated facility and has not yet been certified.

In Section N.1, page 67, the applicant discusses how any enhanced competition would have a positive impact on the cost-effectiveness, quality and access to the proposed services. 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 served by another provider in a contiguous county. The projected patient population for the Fayetteville Kidney Center facility begins with patients currently served by BMA, and a growth of that patient population using a five year average annual change rate of 5.2% for the Cumberland County patients.”*

See also Sections A, B, C, D, E, F, G, H, I, K, L, and O where the applicant discusses the impact of the project on cost-effectiveness, quality and/or access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section O-3, pages 72-74, the applicant identifies three kidney disease treatment centers located in North Carolina, owned and operated by the applicant, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. In Section O.3, page 74, the applicant states all three facilities are back in compliance with CMS Guidelines as of the date of submission of this application. Exhibit O-3 contains copies of letters documenting that the facilities were determined to be back in compliance by the Centers for Medicare and Medicaid Services and the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

## 10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant is not proposing to establish a new facility in this application.
- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C.1, page 13, the applicant projects to serve 163 in-center patients by the end of Operating Year 1, which is 3.3 patients per station ( $163 / 50 = 3.3$ ). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 19-21, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.