

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 20, 2013

PROJECT ANALYST: Gregory F. Yakaboski
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: M-10191-13 / Bio-Medical Applications of Fayetteville, Inc, d/b/a Fayetteville Kidney Center / Add three dialysis stations for a total of 42 stations upon project completion / Cumberland County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department 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.

NC

Bio-Medical Applications of Fayetteville, Inc, d/b/a Fayetteville Kidney Center ("Fayetteville Kidney Center or BMA Fayetteville") whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add three dialysis stations to its existing facility for a total of 42 certified dialysis stations upon completion of the proposed project. The 2013 State Medical Facilities Plan (2013 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 6 dialysis stations in Cumberland County. The applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported for the Fayetteville Kidney Center in the July 2013 SDR is 3.49 patients per station. This utilization rate was calculated based on 136 in-center dialysis patients and 39 certified dialysis stations (136 patients / 39 stations = 3.49 patients per station).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/12		87.2%
Certified Stations		39
Pending Stations		0
Total Existing and Pending Stations		39
In-Center Patients as of 12/31/12 (SDR2)		136
In-Center Patients as of 6/30/12 (SDR1)		112
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	24
	Multiply the difference by 2 for the projected net in-center change	48
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12	0.4286
(ii)	Divide the result of step (i) by 12	0.0357
(iii)	Multiply the result of step (ii) by 6 (the number of months from 12/31/12 until 6/30/13)	0.4286
(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	194.2857
(v)	Divide the result of step (iv) by 3.2 patients per station	60.7143
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	22

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is twenty-two 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 three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, pages 42-43 of the 2013 SMFP 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

In Section I.13, pages 5-9, the applicant discusses the quality of services provided at the Fayetteville Kidney Center. The applicant states that its success in providing quality services stems from its corporate structure, specifically its Clinical Services, Technical Services, Regulatory Affairs and Law Departments, as well as other management resources as discussed briefly below.

Clinical Services

- Serves as a clinical resource for the entire FMC network;
- Provides facilities with the best procedures and equipment available;
- Assists facility managers and medical personnel with questions and concerns on clinical operations; and
- Provides ongoing Clinical Review Program, guidelines for comprehensive training, and Quality Assurance Program with a full range of services to support home care.

Technical Services

- Oversees the technical and mechanical aspects of dialysis; and
- Supported by a research and quality control team that leads the industry in dealing with technically complex issues facing dialysis providers.

Regulatory Affairs and Law

- Skilled to deal with legal and regulatory issues; and
- Provides interpretation of legislation and government policy to ensure compliance

Other Management Resources include, but are not limited to:

- Revenue Operations – draws experience through interaction with numerous Medicare intermediaries and third-party carriers;
- Accounting and Budgeting – tailored to ensure effective financial management of dialysis treatment centers;
- Facility Design and Maintenance – experienced architectural staff promotes development of efficiently designed facilities;
- Human Resources – develops productivity standards, job descriptions, staff performance review, personnel policies and procedures and employee relations;
- Information Systems – develops comprehensive facility automation including enhanced software for clinical management to support delivery of high quality care;
- Marketing and Managed Care – competitive analysis and continuous development of dialysis services;
- Health, Safety and Risk Management – provides regulatory information used to ensure compliance in the dialysis setting and provides risk management services; and
- Regional Vice Presidents – provide operational direction and monitoring of daily operations

The applicant also credits its quality services to quality staffing and staff training. In Section II.3, page 32, the applicant states that each new employee is required to complete a ten week training program. Staff are trained in the clinical aspects of their job, facility and corporate policies and procedures, safety precautions, regulations, and CPR. On page 33, the applicant describes a *Continuous Quality Improvement* process.

In Section II.1, page 23, the applicant states:

“BMA is a high quality health care provider. ... BMA’s parent company, Fresenius Medical Care, encourages all BMA facilities to attain the FMC ‘UltraCare’ certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for ‘UltraCare’ certification.”

See Exhibit 13 for a copy BMA’s Continuous Quality Improvement Plan. In Section II.3, page 32, the applicant states:

“BMA Fayetteville has a well-defined Quality Improvement program whose purpose is to establish an outcome focused review and evaluation of the quality, safety and effectiveness of patient care. The program’s work is conducted by the Continuous Quality Improvement Team and coordinated by the Clinical Manager and the Regional Quality Manager. The primary method of review is patient care audits and monitoring of critical patient indicators. Audits will be conducted monthly and results presented to the Quality Improvement Team for evaluation and recommendation. Other audits include Patient Satisfaction Surveys and chart audits. ...”

The applicant adequately demonstrates that the proposal will promote safety and quality care at Fayetteville Kidney Center.

Promote Equitable Access

In Section II.1, pages 25-26, the applicant states:

“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, BMA is projecting that 86.3% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 3.2% are expected to be covered by VA. Thus 89.5% of the In-Center revenue is derived from government payors.

...

BMA is also keenly sensitive to the second element of “equitable access” – time and distance barriers. BMA continually strives to develop facilities and site dialysis stations in close proximity to the patient residence. ... BMA assumes that the patient population of BMA Fayetteville will continue to increase at a rate equal to the Cumberland County Five

Year Average Annual Change Rate ... Consequently, additional stations are needed in BMA Fayetteville.”

In Section II.1, page 26, the applicant states:

“BMA has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, Medicaid and Medicare recipients, gender, or other considerations. A patient in need of dialysis is always welcomed at a BMA facility; the only requirement is proper referral from a physician.”

On page 26, the applicant has projected that the facility will be comprised of the following demographics.

<i>Facility</i>	<i>Medicaid/Lo w Income</i>	<i>Elderly (65+)</i>	<i>Medicar e</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>BMA Fayetteville Kidney Center</i>	<i>37.8%</i>	<i>33.0%</i>	<i>86.2%</i>	<i>51.6%</i>	<i>75.5%</i>

The applicant adequately demonstrates that the proposal will promote equitable access.

Maximize Healthcare Value

In Section II.1, page 25, the applicant states:

“BMA is not projecting a capital expenditure associated with this project. BMA is not seeking State or Federal monies to accomplish this transfer of stations [sic]; BMA is not seeking charitable contribution to accomplish this addition of stations. Rather, BMA, through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment close to the patient homes. ... BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. ... The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence, BMA must work diligently to control costs of delivery for dialysis. BMA does.”

However, the applicant does not adequately demonstrate that the proposed project is the least costly or most effective alternative and that the project will not result in unnecessary duplication of existing health service capabilities or facilities. See discussion in Criterion (4) and (6), which is incorporated hereby as if fully set forth herein. Based on those facts the applicant does not adequately demonstrate that the proposal will maximize healthcare value.

The applicant does not adequately demonstrate the proposal will incorporate the basic principles of Policy GEN 3. Therefore the application is nonconforming 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

Bio-Medical Applications of Fayetteville, Inc, d/b/a Fayetteville Kidney Center whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add three dialysis stations to its existing facility for a total of 42 certified dialysis stations upon completion of the proposed project

Population to be Served

In Section IV.1, page 42, the applicant identifies the population it served in-center, as of June 30, 2013, as illustrated in the table below.

Fayetteville Kidney Center Current Patient Origin		
COUNTY	In-center Patients	Percent of Total
Cumberland	138	98.6%
Hoke	2	1.4%
Total	100	100.0%

In Section III.7, page 39, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

County	Operating Year 1			Operating Year 2			County Patients as Percent of Total	
	In-Center	PD	HH	In-Center	PD	HH	Year 1	Year 2
Cumberland	145	46	9	149	47	9	96.2%	96.3%
Hoke	2	2	0	2	2	0	1.9%	1.9%
Sampson	0	3	0	0	3	0	1.4%	1.4%
Harnett	0	1	0	0	1	0	0.5%	0.5%
TOTAL	147	52	9	151	53	9	100.0 %	100.0%

*On page 39, the applicant states that it recognizes that the CON Section Chief, Craig Smith, has previously indicated that patients are not partial patients, but rather whole. In financial projections and utilization projections BMA has rounded down to the whole number.

The applicant adequately identifies the population to be served.

Need Analysis

In Section III, page 35, the applicant states the application is filed pursuant to the Facility Need Methodology. The applicant utilizes data from the July 2013 SDR and proposes to add

three dialysis stations to the Fayetteville Kidney Center for a total of 42 stations upon project completion.

In Section III.7, page 37, the applicant provides the following assumptions for the proposed project:

- As of December 31, 2012 the utilization at BMA Fayetteville was 87.18% or 3.48 patients, the facility had 39 dialysis stations and was serving 136 patients.
- The applicant projected population growth at BMA Fayetteville for the patients residing in Cumberland County at 2.8%, the Cumberland County Five Year Average Annual Change Rate as published in the July 2013 SDR.
- Operating Year 1 is July 1, 2014 to June 30, 2015 and Operating Year 2 is July 1, 2015 to June 30, 2016. The project is scheduled to be completed in June, 2014.
- That there are currently two patients dialyzing in-center at BMA Fayetteville from Hoke County, that these patients are utilizing the BMA Fayetteville facility as a matter of patient choice, these two patients will be kept in the in-center patient census but BMA Fayetteville will not project any patient growth utilizing these two patients.

In Section III.7, pages 37-38, the applicant provides the following methodology for the proposed project:

	<i>In-Center</i>
<i>BMA begins with facility census of Cumberland County patients as of June 30, 2013.</i>	138
<i>This patient population is projected forward for 12 months using the Cumberland County Five Year Average Annual Change Rate to produce a calculated census of Cumberland County patients for June 30, 2014.</i>	$(138 \times .028) + 138 = 141.9$
<i>BMA projects the calculated census of Cumberland County patients forward for one year to June 30, 2015.</i>	$(141.9 \times 0.28) + 141.9 = 145.8$
<i>BMA adds the patients from other counties to determine the calculated ending census for Operating Year 1. This is June 30, 2015.</i>	$145.8 + 2 = 147.8$
<i>BMA again projects the calculated census of Cumberland County patients forward for one year to June 30, 2016.</i>	$(145.8 \times .028) + 145.8 = 149.9$
<i>BMA adds the patients from other counties to determine the calculated ending census for Operating Year 2. This is June 30, 2016.</i>	$149.9 + 2 = 151.9$

The applicant projects to serve 47 in-center patients or 3.5 patients per station ($147 / 42 = 3.5$) by the end of Year 1 (June 30, 2015) and 151 in-center patients or 3.6 patients per station ($151 / 42 = 3.595$) by the end of Year 2 (June 30, 2016) for the proposed 42 stations

facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Furthermore, as of June 30, 2013 the BMA Fayetteville facility was serving 138 in-center patients. The project analyst notes that if no growth was projected and the patient census held constant at 138 as of the end of project Year 1 (June 30, 2015), and the proposed three dialysis stations were added, utilization of the BMA Fayetteville facility would have been 3.28 patients per station ($138 / 42 = 3.285$) which would have exceeded the minimum of 3.2 patients per station required by the performance standard.

Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access to Services

In Section VI, page 50, the applicant states that BMA currently operates 100 facilities in 42 North Carolina Counties which include low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The applicant projects that 89.6% of its in-center patients and 84.8% of its HH patients will be covered by either Medicare, Medicaid or the VA. (See application p. 51) The applicant adequately demonstrates 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.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for three additional stations and the extent to which all residents of the area 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.

NA

- (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.

NC

In Section III.9, pages 40-41, the applicant describes the alternatives considered prior to the submission of its application, which were to either maintain the status quo or increase the number of dialysis stations at the facility. The applicant failed to consider transferring three

existing dialysis stations from FMC Dialysis Services of South Ramsey to BMA Fayetteville. As discussed in Criterion (6), which is incorporated hereby as if fully set forth herein, the applicant did not adequately demonstrate that the alternatives it considered were less costly or more effective than the option of transferring three existing dialysis stations from FMC Dialysis Services of South Ramsey to BMA Fayetteville.

The application is not conforming or conditionally conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (6) and (18a). An application that cannot be approved is not an effective alternative. Therefore, applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative.

Consequently, the application is nonconforming to this criterion

- (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

In Section VIII, page 59 the applicant projects that there will be no capital costs associated with the proposed project.

In Section IX, page 64, the applicant projects no initial start-up costs or initial operating expenses.

In Section X.1, page 64, the applicant provides the allowable charges per treatment for each payment source for the Fayetteville Kidney Center, as illustrated in the table below:

Payor	Allowable Charge Per In-center Treatment	Home PD	Home Hemo
Commercial Insurance	\$1,375.00	\$1,375.00	\$1,375.00
Medicare	\$234.00	\$234.00	\$234.00
Medicaid	\$137.29	\$137.29	\$137.29
VA	\$146.79	\$147.85	\$147.85
Private Pay	\$1,375.00	\$550.20	\$1,375.00

The applicant states that the commercial charge listed does not reflect actual reimbursement. In addition, the applicant states that BMA has “*opted in*” completely to Medicare’s “*bundling*” reimbursement program, which provides one basic fee per dialysis treatment (\$234). This fee includes all ancillary services which were previously billed separately.

In Sections X.2-X.4, pages 65-71, the applicant projects revenues and operating expenses for the Fayetteville Kidney Center, as illustrated in the table below:

	Operating Year 1	Operating Year 2
Total Net Revenue	\$8,395,693	\$8,614,522

Total Operating Costs	\$7,397,186	\$7,583,865
Net Profit	\$998,507	1,030,657

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X, pages 65-73, for the applicant's assumptions.

The applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable and supported projections regarding revenues and operating expenses. 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.

NC

Bio-Medical Applications of Fayetteville, Inc, d/b/a Fayetteville Kidney Center whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add three dialysis stations to its existing facility for a total of 42 certified dialysis stations upon completion of the proposed project.

According to the July 2013 North Carolina Semiannual Dialysis Report, including BMA Fayetteville, there are four ESRD facilities in Cumberland County. All of the facilities are operational and operating a total of 170 available stations. All four of the facilities have a Fayetteville address, including BMA Fayetteville. All four of the facilities are ultimately operated and controlled by Fresenius Medical Care Holdings, Inc. (FMC). The four facilities are briefly discussed below:

Name of facility	# of Certified dialysis stations as of 12/31/12	# of Stations approved per CON conditional approval*	# of In-center Patients	Utilization by % as of 12/31/12
Fayetteville Kidney Center (BMA)	39	0	136	87.18%

Fayetteville)				
FMC Dialysis Services North Ramsey	40	0	125	78.13%
FMC Dialysis Services South Ramsey	51	0	117	57.35%
FMC Services of West Fayetteville	40	0	127	79.38%
Total	170	0	505	74.26%

As shown in the table above, the other three FMC facilities are operating below the target with a collective utilization of 2.8 patients per station ($369 / 131 = 2.816$). However, the applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported for BMA Fayetteville in the July 2013 SDR is 87.18% or 3.49 patients per station. This utilization rate was calculated based on 136 in-center dialysis patients and 39 certified dialysis stations ($136 \text{ patients} / 39 \text{ stations} = 3.487 \text{ patients per station}$) or ($136 / 39 = 3.487$; $3.487 / 4 = 0.87175$ or 87.18%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. The applicant is eligible to expand its facility and may apply for additional stations based on the calculations above. Upon completion of the proposed project, the facility will have 42 stations serving 147 patients at the end of Year 1 (July 1, 2014 – June 30, 2015) which is a utilization rate of 87.5% or 3.5 patients per station ($147 / 42 = 3.5$; $3.5 / 4 = 0.875$ or 87.5 %), exceeding 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

The table below shows the number of in-center patients as of 6/30/12 and 12/31/12 for the four FMC facilities in Cumberland County. The project analyst notes that in the referenced six month period there was a total increase of 47 in-center patients in Cumberland County with over half (24) going to the BMA Fayetteville facility. The project analyst also notes that the facilities are comparable in size and are located within a relatively short distance of each other in Fayetteville.

Name of facility	# of Certified dialysis stations as of 12/31/12	# of In-center Patients as of 12/31/12	# of In-center Patients as of 6/30/12	Difference
Fayetteville Kidney Center (BMA Fayetteville)	39	136	112	24

FMC Dialysis Services North Ramsey	40	125	123	2
FMC Dialysis Services South Ramsey	51	117	107	10
FMC Services of West Fayetteville	40	127	116	11
Total	170	505	458	47

FMC Dialysis Services of South Ramsey (“FMC South Ramsey”) in particular has a very low utilization rate of only 57.35%. Per the July 2013 SDR FMC South Ramsey was serving 117 in-center patients as of December 31, 2012 and had 51 certified stations with a utilization rate of 57.35% or 2.2941 patients per station. This utilization rate was calculated based on 117 in-center dialysis patients and 51 certified dialysis stations (117 patients / 51 stations = 2.2941 patients per station) or $(117 / 42 = 2.2941; 2.2941 / 4 = 0.5735$ or 57.35%).

According to Table B of the July 2013 SDR there is currently a surplus of four dialysis stations in Cumberland County. Following, is an alternative scenario to the proposed project developed by the project analyst, that would transfer 3 stations from FMC South Ramsey to the BMA Fayetteville facility reducing the number of stations at FMC South Ramsey to 48 while still increasing the number of stations at BMA Fayetteville to 42 (this would not include the number of surplus dialysis stations in Cumberland County). The project analyst projects utilization and patients per station for FMC South Ramsey as of the beginning (July 1, 2014) of the proposed project at BMA Fayetteville, as assuming its approval.

FMC South Ramsey – As of July 1, 2014

Step 1: December 31, 2012: 117 patients

Step 2: Growth the patients at the Cumberland County Five Year Average Annual Change Rate for the period January 1, 2013 to December 31, 2013: $117 \times 1.028 = 120.276$ patients.

Step 3: January 1, 2014 to June 30, 2014 (the beginning of proposed Project Year 1)- $120.276 \times 1.014 = 121.959$ or 121 patients.

Step 4: $121 / 51 = 2.3725$ patients per station) or $(121/51 = 2.3725; 2.3725 / 4 = 0.5931$ or 59.3%

At the start of the proposed project Year 1, the FMC South Ramsey facility would have a utilization rate of 59.31% or 2.3725 patients per station. Next, the project analyst calculated the utilization rate and patients per station at FMC South Ramsey facility as if that FMC facility had transferred three existing dialysis stations to the BMA Fayetteville facility rather than proposed developing three new dialysis stations at BMA Fayetteville. Thus, as of July 1, 2014 FMC South Ramsey facility would only have 48 dialysis stations (51 minus 3 dialysis stations transferred to BMA Fayetteville).

As of July 1, 2014 (the proposed start of Project Year 1 for the BMA Fayetteville project):

FMC South Ramsey: $121 / 48 = 2.52$ patients per station or $121 / 48 = 2.52$; $2.52 / 4 = 0.63$ or 63% utilization.

BMA Fayetteville and the FMC South Ramsey facilities are approximately 6 miles and 9 minutes driving time from each other. Cumberland County, in the July 2013 SDR, is showing a surplus of four dialysis stations. If BMA Fayetteville developed three new dialysis stations, as proposed, FMC would be adding to the Cumberland County surplus. In contrast, as shown above, if FMC transferred 3 dialysis stations from FMC South Ramsey to BMA Fayetteville: 1) the demonstrated need at BMA Fayetteville would be met; and 2) FMC would not be adding three dialysis stations to the existing Cumberland County surplus of dialysis stations.

The applicant adequately does not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is nonconforming 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 VII.1, page 55, the applicant states that the Fayetteville Kidney Center currently employs 35.25 full time equivalent staff (FTEs). The applicant further states on page 55, that the Fayetteville Kidney Center proposes to hire 3.5 additional FTEs upon project completion. Those FTE positions for which the applicant will hire are illustrated in the table below.

Fayetteville Kidney Center Proposed New(FTE) Positions	
RN	1.50
Tech.	2.00
Total Proposed FTEs	3.50

The applicant projects a total of 38.75 FTE positions upon project completion and states on page 56 that there is no difficulty expected in recruiting staff. In Section VII.10, page 58, the applicant states provides a chart showing a third shift being offered Monday, Wednesday and Friday. In Section V.4(c), page 47, and Exhibit 21 the applicant identifies the Medical Director for Fayetteville Kidney Center as Dr. Maureen Achuko. In Exhibit 21 the applicant provides a letter from Dr. Achuko indicating her willingness to continue to serve as Medical Director of the facility. The applicant adequately documents the availability of resources, including health manpower and management personnel, for provision of the proposed dialysis 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 V.1, page 43, the applicant lists the providers of the necessary ancillary and support services. See Exhibits 16-18 for service agreements documentation. Also see the applicant's response to 10A NCAC 14C .2204, Section II, pages 21-22. The applicant adequately demonstrates the necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare 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 VI.1, page 50 the applicant states:

“BMA of Fayetteville has a long history of providing dialysis services to the underserved populations of Fayetteville, Cumberland County and surrounding areas. ... The patient population of the BMA Fayetteville facility is comprised of the following:”

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
<i>BMA Fayetteville</i>	<i>37.8%</i>	<i>33.0%</i>	<i>86.2%</i>	<i>51.6%</i>	<i>75.5%</i>

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 86.2% of the facility treatment reimbursement is from Medicare.

In Section, VI.1, page 51, the applicant provides the current and projected in-center payor mix for the Fayetteville Kidney Center. The current payor mix is illustrated in the table below.

Historical Payor Source

Payor Source	Percentage
Commercial Insurance	9.6%
Medicare	83.3%
Medicaid	3.1%
VA	3.2%
Other:: Self/Indigent	0.9%

Total	100.0%
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The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Cumberland County and statewide.

	CY 2009 Total # of Medicaid Eligibles as % of Total Population *	CY 2009 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	CY 2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Cumberland County	18%	7.4%	20.3%
Statewide	17%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by the Fayetteville Kidney Center. In fact, only 5.8% of all newly diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

“Although the ESRD population in less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010: *“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”* Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”

The report provides 2010 ESRD spending, by payor as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender as shown below:

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%

55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6. Includes North Carolina, South Carolina and Georgia

The applicant demonstrates the medically underserved populations have adequate access to the services provided at the Fayetteville Kidney Center. 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 VI.6(a), page 54, the applicant states there have been no civil rights access complaints filed against BMA in the past 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 VI.1(c), pages 51-52, the applicant provides the projected payor mix for the proposed services at the Fayetteville Kidney Center as shown in the table below.

Projected Payor Mix

Payor Source	Percentage	
	In-Center Patients	HH Patients
Commercial Insurance	9.6%	14.7%
Medicare	83.3%	80.0%
Medicaid	3.1%	0.0%
VA	3.2%	4.8%
Other: Self/Indigent	0.9%	0.4%

Total	100.0%	100.0%
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The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. 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 VI.5, page 53, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA Fayetteville will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

The applicant adequately demonstrates that the Fayetteville Kidney Center will provide a range of means by which a person can access its 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 V.3, page 46, the applicant states that Exhibit 19 includes a letter from the applicant requesting to establish a Health Occupations Agreement with Fayetteville Community College such that *“students are provided tours through the facilities and discussions regarding different aspects of dialysis and facility operations”* and for the facility to be added as part of the clinical rotation of the school’s nursing students.

- (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.

NC

Bio-Medical Applications of Fayetteville, Inc, d/b/a Fayetteville Kidney Center proposes to add three dialysis stations to its existing facility for a total of 42 certified dialysis stations upon completion of the proposed project.

The July 2013 SDR shows there is a surplus of four dialysis stations in Cumberland County, however, in this proposal the applicant is applying for additional stations based on the facility need methodology. According to the July 2013 SDR there are 4 ESRD facilities (including Fayetteville Kidney Center) which are currently operational in Cumberland County. The July 2013 SDR reports that as of December 31, 2012, the 39 stations at the Fayetteville Kidney Center were operating at 87% capacity ($136 / 39 = 3.49$; $3.44 / 4 = 0.87$ or 87 %[^]). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility.

In Section V.7, page 49, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states:

“This proposal will not have any effect on competition within Cumberland County; this is a proposal to expand the existing facility by adding three needed dialysis stations for BMA Fayetteville. The patients to be served by this facility are existing dialysis patients, and future patients residing in Cumberland County. At this time, there are no providers of dialysis services other than BMA/FMC operating within Cumberland County. Consequently, this project will not change the competitive environment within Cumberland County.

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ... In this application, BMA projects that 86.3% of the In-center patients will be relying upon either Medicare or Medicaid. The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ...

This proposal will ... enhance the quality of the ESRD patients' lives.”

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding three dialysis stations to the existing Fayetteville Kidney Center facility will have a positive impact on quality and access to the proposed service based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to add three additional stations to the existing facility based on facility need methodology. However, the applicant does not

adequately demonstrate that the proposed project is a cost-effective alternative to meet the need to provide additional access to Fayetteville Kidney Center patients. See discussion in Criterion (6), which is incorporated hereby as if fully set forth herein;

- The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 (pages 44-48), and VII. (pages 55-58), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.
- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 50, the applicant states:

“It is clear that BMA Fayetteville provides service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

The applicant provides the following table in Section VI.1(a), page 50, to demonstrate that medically underserved populations will continue to have adequate access to BMA services, as illustrated below.

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Fayetteville	37.8%	33.0%	86.2%	51.6%	75.5%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 86.2% of facility treatment reimbursement is from Medicare.

The applicant further states on page 50, *“FMC and BMA of North Carolina have a lengthy history of providing dialysis services to the underserved populations of North Carolina. ... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly or other traditionally underserved persons.”*

However, the applicants did not adequately demonstrate that the proposed project will have a positive impact on cost-effectiveness. Thus the application is nonconforming 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.

The applicant currently provides dialysis services at the Fayetteville Kidney Center. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, Fayetteville Kidney Center has operated in compliance with all Medicare Conditions of

Participation within the eighteen months immediately preceding the date of this decision. 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 proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:

(1) *Utilization rates;*

-C- In Section II.1, page 11, the applicant provides the utilization rate of 87.18% with 3.5 patients per station ($136 / 39 = 3.487$) as reported in the July 2013 SDR.

(2) *Mortality rates;*

-C- In Section II.1, page 11, the applicant provides the mortality rates as 7.1%, 8.6% and 9.9% for 2010, 2011 and 2012, respectively.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section II.1, page 11, the applicant states, in 2012 55 patients were home trained and as of June 30, 2013 there were 65 patients on home dialysis.

(4) *The number of transplants performed or referred;*

- C- In Section II.1, page 11, the applicant states the Fayetteville Kidney Center referred 46 transplants in 2011 and 55 in 2012. Two transplants were performed in 2011 and none in 2012.
- (5) The number of patients currently on the transplant waiting list;
- C- In Section II.1, page 11, the applicant states, “*BMA Fayetteville has 17 patients on the transplant waiting list.*”
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section II.1, page 12, the applicant states that there were 261 hospital admissions in 2012, of which 30 were dialysis related and 231 that were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section II.1, page 12, the applicant states that there were no patients at the facility in 2011 or 2012 with an infectious disease.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-NA- Fayetteville Kidney Center is an existing facility.

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) composition of the assessment/evaluation team at the transplant center,*
- (C) method for periodic re-evaluation,*

- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- Fayetteville Kidney Center is an existing facility.

(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

-NA- Fayetteville Kidney Center is an existing facility.

(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.

-C- See Exhibit 12 for a copy of the Emergency/Disaster Manual (which has policies and procedures for back-up electrical service in the event of a power outage) for the Fayetteville Kidney Center.

(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.

-NA- Fayetteville Kidney Center is an existing facility.

(6) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.

-C- In Section II.1, page 13, the applicant states, “BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at BMA Fayetteville.”

(7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.

-C- In Section II.1, pages 13-16, and Section III.7, pages 36-39, the applicant provides the methodology and assumptions used to project patient origin, as illustrated in table below:

County	Operating Year 1			Operating Year 2			County Patients as Percent of Total	
	In-Center	PD	HH	In-Center	PD	HH	Year 1	Year 2
Cumberland	145	46	9	149	47	9	96.2%	96.3%
Hoke	2	2	0	2	2	0	1.9%	1.9%
Sampson	0	3	0	0	3	0	1.4%	1.4%
Harnett	0	1	0	0	1	0	0.5%	0.5%
TOTAL	147	52	9	151	53	9	100.0 %	100.0%

*On page 16, the applicant states that it recognizes that the CON Section Chief, Craig Smith, has previously indicated that patients are not partial patients, but rather whole. In financial projections and utilization projections BMA has rounded down to the whole number.

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- Fayetteville Kidney Center is an existing facility.

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II.1, page 17, the applicant states, *“BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Fayetteville Kidney Center does not propose to establish a new End Stage Renal Disease facility.

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

-C- Fayetteville Kidney Center projects utilization of 3.5 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 13-15, and Section III.7, pages 36-39.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 13-15, and Section III.7, pages 36-39. The applicant projects a 2.8% increase in its current Cumberland County patient utilization using the county five year average annual change rate.

10A NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

(1) diagnostic and evaluation services;

-C- In Section II.1, page 21, the applicant states, *“Patients will be referred to Cape Fear Valley Hospital.”*

(2) maintenance dialysis;

-C- In Section II.1, page 21, the applicant states, *“The facility will provide in-center dialysis.”*

(3) accessible self-care training;

C- In Section II.1, page 21, the applicant states, *“The facility will provide self-care training.”*

(4) accessible follow-up program for support of patients dialyzing at home;

C- In Section II.1, page 21, the applicant states, *“Patients desiring to dialyze at home will be referred to the BMA Fayetteville home training program.”*

(5) x-ray services;

- C- In Section II.1, page 21, the applicant states, “*Patients in need of X-ray services will be referred to Cape Fear Valley Hospital or one of the local out patient imaging centers.*”
- (6) laboratory services;
- C- In Section II.1, page 21, the applicant states, “*BMA provides on site laboratory services through contract with Spectra Labs.*” See Exhibit 18 for the laboratory services agreement with Spectra Laboratories.
- (7) blood bank services;
- C- In Section II.1, page 21, the applicant states, “*Patients in need of blood transfusion will be referred to Cape Fear Valley Hospital.*”
- (8) emergency care;
- C- In Section II.1, page 21, the applicant states, “*Emergency care for patients is provided on site by BMA staff until emergency responders arrive. In the event of an adverse event while in the facility, BMA staff are appropriately trained; in addition a fully stocked ‘crash cart’ is maintained at the facility. If the patient event requires transportation to a hospital, emergency services are summoned via phone call to 911.*”
- (9) acute dialysis in an acute care setting;
- C- In Section II.1, page 21, the applicant states, “*Patients admitted to hospital will be referred to Cape Fear Valley Hospital. BMA provides acute dialysis at these hospitals [sic] via contract with the hospital.*”
- (10) vascular surgery for dialysis treatment patients;
- C- In Section II.1, pages 21-22, the applicant states, “*Patients will be referred, at patient choice, to Carolina Kidney Vascular Access Center; Village Surgical; Dr. Hussain, Dr. Morfesis, Dr. Lake, Dr. Chang, or Dr. Ross.*”
- 11) transplantation services;
- C- In Section II.1, page 22, the applicant states, “*BMA Fayetteville has a transplant agreement with Pitt County Memorial Hospital.*” See Exhibit 17 for a copy of the transplant agreement.
- (12) vocational rehabilitation counseling and services; and

-C- In Section II.1, page 22, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the Division of Vocational Rehabilitation of Cumberland County.*”

(13) transportation.

-C- In Section II.1, page 22, the applicant states, “*Transportation services are provided by Fayetteville Area System Transit, Cumberland County Department of Social Services and local taxi services.*”

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.

-C- In Section II., page 22, the applicant states that sufficient staffing for each shift is provided. In Section VII.10, page 58, the applicant states BMA offers a third shift on Mondays, Wednesdays and Fridays. In Section VII.2, page 56, BMA states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.

(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

-C- In Section II.1, page 22 and Section VII.5, pages 56-57, the applicant describes the training and continuing education required for all BMA clinical employees. The applicant states that new employees are required to successfully complete a ten week training program, staff training is continually updated and documented in employee records. The applicant further states that training includes dialysis techniques, safety precautions, CPR, corporate policies and procedures. Exhibit 14 contains an outline of the training program and Exhibit 15 contains the outline of continuing education information.