ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DATE: November 29, 2012
PROJECT ANALYST: Celia C. Inman
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: G-10045-12/ Bio-Medical Applications of North Carolina, Inc d/b/a BMA Rockingham/ Add two dialysis stations for a total of 17 certified stations upon completion of this project/ Rockingham 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.

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Rockingham, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add two dialysis stations for a total of 17 certified dialysis stations upon completion of this project. The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of twelve dialysis stations in Rockingham County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for BMA Rockingham (Rockingham Kidney Center) in the July 2012 SDR is 3.27 patients per station. This utilization rate was calculated based on 49 in-center dialysis patients and 15 certified dialysis stations. (49 patients / 15 stations = 3.2667 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 12/31/11		81.67%
Certified Stations		15
Pending Stations		0
Total Existing and Pending Stations		**15**
In-Center Patients as of 12/31/11 (SDR2)		49
In-Center Patients as of 6/30/11 (SDR1)		47
Difference (SDR2 - SDR1)		2
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/11	0.0851
(ii)	Divide the result of Step (i) by 12	0.00709
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the June 2012 SDR (12/31/11) until the end of calendar year 2012 (12 months)	0.0850
(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	53.17
(v)	Divide the result of Step (iv) by 3.2 patients per station	16.61
	and subtract the number of certified and pending stations as recorded in SDR2 [15] to determine the number of stations needed	2

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

Policy GEN-3: Basic Principles, page 40, of the 2012 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 II.3, page 26, the applicant states:

"BMA Rockingham 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. CQI membership includes the Medical Director, Area Manager, Clinical Manager, Chief Technician, Social Worker and Dietitian. The committee will meet monthly. Individual teams may be assigned to individual projects to gather data as needed to conduct the "Check, Plan, Do, and Check, Act" process for addressing the improvement opportunities."

See Exhibit 13 for copies of the CQI process.

In Section II.1, page 18, the applicant states:

"BMA is a high quality health care provider. … In addition, 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."

In Section 1.13, page 4-7, the applicant discusses the quality of services provided at BMA Rockingham, attributing much of its success in providing quality services to its corporate structure, specifically its Clinical Services Department, Technical Services

Department, Regulatory Affairs and Law Departments, and other management resources as discussed below.

- Clinical Services Department
  - Serves as a clinical resource for the entire FMC network
  - Provides facilities with the best procedures and equipment available
  - Assist facility managers and medical personnel with questions and concerns on clinical operations
  - Provides ongoing Clinical Review Program, guidelines for comprehensive training, and Quality Assurance Program

- Technical Services Department
  - Oversees the technical and mechanical aspects of dialysis
  - 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 Departments
  - Deal with legal and regulatory issues
  - Provides interpretation of legislation and government policy to ensure compliance

- Other Management Resources, including but not limited to:
  - Revenue Operations – draws experience through interaction with numerous Medicare intermediaries and third-party carriers
  - Accounting and Budget – 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 – responsible for 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.
  - Regional Vice Presidents – provide operational direction and monitoring of daily operations.

The applicant also credits its quality services to quality staffing and staff training. On page 17, the applicant states each new employee is required to complete an eight-week training program. Staff is trained in clinical aspects of their job, facility and corporate policies and procedures, safety precautions, regulations, and CPR. The applicant further states training is continually updated by the In-Service Instructor and Director of Nursing.

In Section V, page 40, the applicant states BMA facilities have done an excellent job of containing costs while providing quality care. The applicant further states BMA has eliminated the re-use concept in its facilities and provides every patient a new dialyzer at each treatment.

The applicant adequately demonstrates that the proposal will promote quality and safety.

Promote Equitable Access

In Section II.3, page 20, 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 76.7% of the In-Center dialysis treatments will be covered by Medicare. An additional 5.4% are expected to be covered by VA. Thus, 82.1% of the In-Center revenue is derived from government payors."*

The applicant states on page 21 it 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. The applicant further states, *"A patient in need of dialysis is always welcomed at a BMA facility; the only requirement is proper referral from a physician."*

The applicant states BMA of North Carolina historically provides service to underserved populations. As an example, the applicant states Medicare represented 79.7% of North Carolina dialysis treatments in BMA facilities in FY 2011 with Medicaid representing an additional 4.8%.

In Section II.3, page 20, the applicant states:

> *"BMA is also keenly sensitive to the second element of "equitable access" – time and distance barriers. BMA continually strives to develop facilities and dialysis stations in close proximity to the patient residence."*

The applicant states the July 2012 SDR illustrates Rockingham County ESRD patient population is growing at an average annual change rate of 3.6%. The applicant also states the additional two stations are being added *"so that an adequate supply of necessary health resources remains in closer proximity to the residence location of patients residing in this area of Rockingham County"*.

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

Maximize Healthcare Value

In Section II.3, pages 20-21, the applicant states it is projecting a capital expenditure of $5,250 for this project and is not seeking State or Federal monies or charitable contributions to develop the project. Rather, BMA through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to ensure an adequate number of stations are available for the patients choosing to dialyze at BMA Rockingham. The applicant goes on to state:

> *"As an additional consideration, 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."*

The applicant adequately demonstrates that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the July 2012 SDR and Policy GEN-3. 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.

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The applicant, BMA Rockingham, proposes to add two dialysis stations to its existing facility for a total of 17 certified stations upon completion of this project.

Population to be Served

In Section IV.1, page 34, the applicant identifies the population it serves, as illustrated in the table below.

Historical Patient Origin

County of Residence	# of Patients Dialyzing In-Center 6/30/2012	Percent of Total
Rockingham	45	86.5%
Guilford	4	7.7%
Caswell	2	3.8%
Pittsylvania, VA	1	1.9%
Total	**52**	**100.0%**

In Section III.7, page 33, 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.

Projected Patient Origin

	Year 1 July 2013-June 2014	Year 2 July 2014-June 2015	County Patients as a Percent of Total	
County	**In-center Patients**	**In-center Patients**	**Year 1**	**Year 2**
Rockingham	48.3	50	87.34%	87.73%
Guilford	4	4	7.23%	7.01%
Caswell	2	2	3.62%	3.51%
Pittsylvania, VA	1	1	1.81%	1.75%
Total	55.3	57	100.0%	100.0%

The applicant adequately identified the population to be served.

Need Analysis

In Section III.7, page 32, the applicant states the application is filed pursuant to Facility Need Methodology utilizing data from the July 2012 SDR and it proposes to add two dialysis stations to BMA Rockingham for a total of 17 stations at that facility. In the assumptions, the applicant provides the following information:

1. The project is scheduled for completion and certification of stations on June 30, 2013 projecting July 1, 2013 through June 30, 2014 as “Operating Year 1”.

2. On June 30, 2012 BMA Rockingham was providing dialysis treatment for 45 Rockingham county patients and seven patients from other counties.

3. BMA assumes the ESRD patient population of Rockingham County will continue to increase at 3.6%, the Rockingham County Five Year Average Annual Change Rate (ACR) published in the July 2012 SDR.

4. BMA will not project increases for the patient population dialyzing at BMA Rockingham but residing in another county.

The applicant's methodology is provided in the following table.

	In-Center
BMA begins with Rockingham County in-center patient population of BMA Rockingham as of June 30, 2012.	45
BMA projects this patient population forward for 12 months to June 30, 2013.	(45 X 0.036)+ 45 =46.6
BMA adds the number of patients from other counties dialyzing at BMA Rockingham who are projected to continue at BMA Rockingham.	46.6 + 7 = 53.6
BMA projects the Rockingham County patient population forward for 12 months to June 30, 2014	(46.6 X .036) + 46.6 = 48.3
BMA adds the number of patients from other counties. This is the projected census for the end of Operating Year 1.	48.3 +7 = 55.3
BMA projects the Rockingham County patient population forward for 12 months to June 30, 2015.	(48.3 X .036) + 48.3 = 50
BMA adds the number of patients from other counties. This is the projected census for the end of Operating Year 2.	50 + 7 = 57

The applicant projects to serve 55 in-center patients or 3.24 patients per station (55/17=3.24) by the end of Year 1 and 57 in-center patients or 3.35 patients per station (57/17=3.35) by the end of Year 2 for the proposed 17 station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as

required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access

In Section VI, page 41, the applicant states that each of BMA's 93 facilities in 40 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The applicant projects 82% of its patients will be covered by Medicare and VA. The applicant demonstrates adequate access for the underserved to its services.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for two additional stations at BMA Rockingham, and demonstrates all residents of the area, and, in particular, 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.

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.

CA

In Section III.9, page 33, the applicant discusses the alternatives considered prior to the submission of this application, which include:

1) Maintain the Status Quo – Do Nothing. This alternative is not consistent with BMA's stated effort to provide equitable access by removing time and distance barriers. BMA states on page 20, *"Over the years, BMA has sought to develop new facilities and new dialysis stations in an effort to make dialysis convenient to the patient."*

2) Add two dialysis stations for a total of 17 stations at BMA Rockingham. The applicant proposes to add two additional stations to the existing treatment space

at BMA Rockingham to provide adequate access to dialysis services to the growing Rockingham County ESRD patient population.

On page 33, the applicant states:

> *"There are not suitable alternatives to this project. The decision was either a Do, or Do Not. BMA has demonstrated that the additional dialysis stations will be utilized at a rate greater than 80%. As the ESRD patient population of Rockingham County continues to increase, BMA must also provide access for the patients. BMA believes that this is the most suitable alternative: apply to develop this facility to serve a growing patient population."*

The applicant adequately demonstrates the need for two additional stations based on the continued growth of the ESRD patient population of Rockingham County and the facility's projected utilization. See Criterion (3) for further discussion on need which is incorporated hereby as if fully set forth herein. Maintaining the status quo will do nothing toward meeting the need for additional dialysis service at BMA Rockingham.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rockingham shall materially comply with all representations made in the certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rockingham shall develop no more than two additional stations for a total of no more than 17 stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rockingham shall install plumbing and electrical wiring through the walls for no more than two additional dialysis stations for a total of 17 stations which shall include any isolation stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rockingham shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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

In Section VIII.1, pages 49-50, the applicant projects a capital cost of $5,250 for the proposed project, funded through accumulated reserves. In Section IX, page 54, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 24 includes a letter dated September 17, 2012 from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

> *"This is to inform you that Fresenius Medical Holdings, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*
>
> *BMA proposes to add two dialysis stations to the BMA Rockingham dialysis facility.*
>
> …
>
> *As Vice President, I am authorized and do hereby authorize the addition of two new dialysis stations for a total capital cost of $5,250. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of $5,250."*

In Exhibit 10, the applicant provides the audited financial statements for FMC and Subsidiaries for the years ended December 31, 2010 and 2011. As of December 31, 2011, FMC and Subsidiaries had cash and cash equivalents totaling $204,142,000 with $13,864,539,000 in total assets and $8,388,027,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the proposed project.

In Section X.1, page 55, the applicant projects the following charge per treatment for each payment source:

Payor	In-Center Charge
Commercial	$1,375.00
Medicare	$234.00
Medicaid	$137.29
VA	$146.79
Private Pay	$1,375.00

The applicant states the commercial charge listed does not reflect actual reimbursement. In addition, the applicant states BMA has "opted in" completely to Medicare's "Bundling" reimbursement program, which provides one basic fee for the dialysis treatment, $234; this fee includes all ancillary services which were previously billed separately.

The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application. The applicant projected revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below and supported by the accompanying assumptions.

	Project Year 1	Project Year 2
Net Revenue	$2,804,951	$2,914,085
Operating Expenses	$2,401,138	$2,529,207
Profit	$403,813	$384,878

Source: Application pages 56 and 59

Assumptions:

1. Average number of patients for the current year as increased by the county growth rate for the first two operating years.
2. Average of 3 treatments per patient per week reduced by 6.5% allowance for missed treatments.
3. Ancillary revenues: treatment numbers = In-center treatments less Medicare treatments; Average reimbursement per treatment is based upon applicant's historical experience and expected future reimbursement.

In Section VIII, page 52, the applicant states, "*Machine leases are executed as the machines are needed. FMC works with a capital leasing firm to ensure the best possible rates, which are competitive with regard to financial terms, at the time the lease is executed.*" Exhibit 26 contains an example lease. The applicant further states all FMC leases are "arm's length" negotiations.

In Section X, page 60, the applicant provides projected staffing and salaries. On page 47 the applicant states BMA Rockingham does and will comply with all staffing

requirements as stated in 42 C.F.R. Section 494. Staffing by shift is provided on page 48. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. 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.

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The applicant proposes to add two dialysis stations to the existing facility for a total of 17 stations upon completion of the proposed project. The applicant adequately demonstrates the need for two additional stations based on the number of in-center patients it proposes to serve. Per the July 2012 SDR, as of June 25, 2012, the 15 station BMA Rockingham facility was operating at 81.67% capacity (49/15 = 3.2667; 3.27/4 = 81.67%). The target utilization rate is 80%. The applicant therefore is eligible to expand its facility and may apply for additional stations. Upon completion of this project, the facility will have 17 stations serving 55 patients (end of year 1) which is a utilization rate of 80.8% (55/17 = 3.235; 3.235/4 = 80.8%). Therefore the application is conforming with the requirement in 10A NCAC 14C .2203.

Rockingham County has one other dialysis provider operating three dialysis centers dispersed across the county. DaVita Reidsville, with a utilization rate of 72.37% is located in southeastern Rockingham County along with BMA Rockingham. Dialysis Care of Rockingham in western Rockingham and Madison Dialysis Center in northern Rockingham County have utilization rates of 68.48% and 72.37%, respectively. On page 363, The 2012 SMFP states, "*As a means of making ESRD services more accessible to patients, one of the goals of the N.C. Department of Health and Human Services is to minimize patient travel time to and from the center.*"

The applicant adequately demonstrates the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, 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.

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In Section X.5, page 60, the applicant provides the following current and projected number of full-time equivalent (FTE) positions and projects an additional 2.0 FTEs will be added to BMA Rockingham following completion of the proposed project, as illustrated in the table below.

Position	Current # of FTEs	Projected # of New FTEs	Total # of FTEs
Salary RN	2.00	1.00	3.00
Salary – Patient Care Tech	6.00	1.00	7.00
Dietitary Consultant	0.33	0.00	0.33
Social Services	0.33	0.00	0.33
Salary - Admin	Contract position - Not an FTE		
Clinical Manager	1.00	0.00	1.00
Area Manager	0.15	0.00	0.15
In-Service	1.00	0.00	1.00
Chief Tech	0.10	0.00	0.10
Equipment Tech	0.50	0.00	0.50
Nurse Assistant	0.50	0.00	0.50
Clerical	2.00	0.00	2.00
Total	**13.91**	**2.00**	**15.91**

In Section VII, page 46, the applicant provides the current and projected FTEs as illustrated in the following table.

Position	Current # of FTEs	Projected # of New FTEs	Total # of FTEs
RN	2.00	1.00	3.00
Tech	6.00	1.00	7.00
Nurse Assistant	0.50		0.50
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract Position – Not an FTE		
Admin. (FMC Area Manager)	0.15	0.00	0.15
Dietitian	0.33	0.00	0.33
Social Worker	0.33	0.00	0.33
Chief Tech	0.10	0.00	0.10
Equipment Tech	0.50	0.00	0.50
In-Service	0.50	0.00	0.50
Clerical	2.00	0.00	2.00
Total	**13.41**	**2.00**	**15.41**

The table on page 46 shows 0.50 current and projected FTEs for In-Service. The table on page 60 shows 1.0 current and projected FTEs for In-Service. Analysis of the salary budgeted on page 60 as compared to the Estimated Annual Operating Costs presented on

page 59 confirms the use of 1.0 FTE In-Service in the calculations. Therefore, the operating cost estimates are based on the higher FTE. The Medical Director is a contract position, not an FTE.

In Section VII.10, page 48, the applicant provides the following information on the number of direct care staff for each shift offered at BMA Rockingham.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7am to 12 pm	6	6	6	6	6	6
Afternoon	12 pm to 5 pm	6	6	6	6	6	6
Evening	NA						

The information regarding staffing provided in Section VII is reasonable and credible. Therefore, the application is conforming with 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.

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In Section V.1, page 36 of the application, the applicant lists the providers of the necessary ancillary and support services. The applicant states the method for providing the services in response to 10A NCAC 14C .2204, beginning on page 16 of the application. Acute hospital care, diagnostic evaluation services, X-ray services, blood bank services and emergency care beyond facility capability will be provided by Moses Cone Health System and Annie Penn Hospital. Dialysis maintenance, isolation, vocational counseling and social services will be provided by BMA on site. The other services will be provided at the individually stated facility. Exhibits 17-21 contain documentation on service agreements.

The information regarding coordination of services in Section V.2, pages 36-37, acute hospital agreement, transplant agreement, and follow-up care; Section V.4, page 38, physician referral relationships and physician support; Section V.5, page 39, relationships with physicians, hospitals and other health professionals; and Section VII, pages 46-48, healthcare staffing; and the documentation referenced in Exhibits 17-21 is reasonable and credible and supports a finding of conformity with 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

NA

(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;

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In Section VI.1(a), page 41, the applicant discusses BMA's history of providing dialysis services to the underserved populations of North Carolina. The applicant states:

"Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. [sic] *patient population of the BMA Rockingham facility is comprised of the following:*

Facility	*Medicaid/ Low Income*	*Elderly (65+)*	*Medicare*	*Women*	*Racial Minorities*
BMA Rockingham	*0.0%*	*44.9%*	*73.5%*	*51.0%*	*61.2%*

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 73.5% of the facility treatment reimbursement is from Medicare.

It is clear that BMA projects to provide 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."

In Section VI.1, page 42, the applicant indicates that historically, 76.7 percent of patients at BMA Rockingham have some or all of their services paid for by Medicare. An additional 5.4% are covered by VA. Thus 82.1% of the center revenue is derived from government payors. The table below illustrates the current historical payor mix for the facility.

Historical Payor Source

Payor Source	In-Center
Commercial Insurance	17.8%
Medicare	76.7%
Medicaid	0.0%
VA	5.4%
Other: Self/Indigent	0.0%
Total	100.0%

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 & county and statewide.

	Total # of Medicaid Eligibles as % of Total Population	**Total # of Medicaid Eligibles Age 21 and older as % of Total Population**	**% Uninsured CY 2008 (Estimate by Cecil G. Sheps Center)**
Rockingham	20%	9.3%	19.0%
Statewide	17%	6.71%	19.7%

Data for BMA Rockingham is not available on the DMA web site.

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 BMA Rockingham. In fact, only 5.8% of all 2011 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.

The Centers for Medicare & Medicaid Services (CMS) website states:

> *"Although the ESRD population is 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 standing.*
> …
> *Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 70. 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."*[1]

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010:

> *"On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy … ."*

The report validates the statistical constancy reported by the CMS above. 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%

[1]www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender demonstrating the following:

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	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
Total	9,342	100.0%

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.

The applicant demonstrates it 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 VI.1(f), page 43, the applicant states:

"BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act."

In Section VI.6(a), page 45, the applicant states, "*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years."* 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), page 42, the applicant states it does not anticipate any significant changes in the payor mix resulting from this proposal, as illustrated in the table below.

Projected Payor Source

Payor Source	In-Center
Commercial Insurance	17.8%
Medicare	76.7%
Medicaid	0.0%
VA	5.4%
Other: Self/Indigent	0.0%
Total	100.0%

As shown in the table, the applicant projects 76.7% of all in-center patients will have some or all of their services paid for by Medicare with VA covering another 5.4%. In Section II, page 20 the applicant states that absent some reason to include Medicaid patients in its projections, BMA cannot suggest an artifical payor source. It will accept Medicaid patients referred for care.

In Section VI.1(d), page 49, 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." [emphasis in original]

In Section VI, page 44, the applicant states the facility design provides easy access for handicapped persons and complies with the Americans with Disabilities Act (ADA) requirements. On page 45, the applicant states patients will be accepted for treatment based on medical criteria not age or other factors.

The applicant demonstrates it will provide adequate access to elderly and medically underserved populations. 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(a), page 44, 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 Rockingham 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 physician or, Nephrologists or hospital emergency rooms."*

The applicant adequately demonstrates that it will provide a range of means by which a person can access 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, page 38, the applicant states health related education and training programs can visit the facility, receive instruction and observe the operation of the unit while patients are treated. The applicant further states BMA Rockingham provides ESRD and dialysis information to students and program directors, and thereafter the students observe, tour the facility and talk with patients. The facility has requested to establish a formal relationship with Rockingham Community College (RCC). See

Exhibit 19 for a copy of a letter to the Dean of Division of Health Sciences at RCC from the Director of Operations for Fresenius Medical Care offering BMA Rockingham as a clinical training site. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add two dialysis stations to its existing center for a total of 17 certified stations upon completion of the proposed project The July 2012 SDR shows there is a surplus of twelve dialysis stations in Rockingham County; however, the applicant qualifies for additional dialysis stations based on the facility need methodology. In Section V, page 40, the applicant states DaVita is the only other dialysis provider within the county. DaVita Reidsville, with a utilization rate of 72.37% is located in southeastern Rockingham County along with BMA Rockingham. DaVita also operates Dialysis Care of Rockingham in the western Rockingham and Madison Dialysis Center in northern Rockingham County, with utilization rates of 68.48% and 72.37%, respectively.

In Section V.7, page 40, 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 its proposal to add two stations will not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives. The applicant further states:

> *"There are two dialysis providers within the county: BMA Rockingham and DaVita Reidsville. Both providers are working to meet the needs of patients choosing to dialyze at their respective facilities. Given the facts as they exist, BMA does not anticipate any impact to the competitive climate of Rockingham County.*

…

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

…

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

See also Sections II, III, V, VI and VII. The information the applicant provides in those sections is reasonable and credible and adequately demonstrates that adding two dialysis stations to the existing BMA Rockingham facility will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- The applicant adequately demonstrates the need, based on "Facility Need", to add two dialysis stations for a total of 17 certified dialysis stations following completion of this project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to BMA Rockingham patients.

- 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, and VII, pages 36, 36-37, 38, 39, and 46-48, respectively, and referenced in exhibits is reasonable and credible and demonstrates the provision of quality care services.

  On page 19, the applicant states, *"Let there be no doubt: BMA is committed to providing quality care for all patients."*

- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 41, the applicant states:

  > *"It is clear that BMA projects to provide 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 to demonstrate that the medically underserved population will have access to its services, as illustrated below.

Facility	*Medicaid/ Low Income*	*Elderly (65+)*	*Medicare*	*Women*	*Racial Minorities*
BMA Rockingham	*0.0%*	*44.9%*	*73.5%*	*51.0%*	*61.2%*

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 73.5% of the facility treatment reimbursement is from Medicare.

The applicant states on page 21 it 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.

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

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Rockingham 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 10, the applicant provides the utilization rate as reported in the July 2012 SDR of 81.67% with 3.27 (49/15=3.2667) patients per station.

(2) Mortality rates;

-C- In Section II.1, page 10, the applicant provides the mortality rates as 9.8%, 9.4% and 10.4% for 2009, 2010 and 2011, respectively.

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

-NA- In Section II.1, page 10, the applicant states, *"BMA Rockingham is not certified to provide home dialysis. Patients who are candidates for home training are referred to the home training program at either BMA Greensboro or BMA Burlington facilities.*

(4) The number of transplants performed or referred;

-C- In Section II.1, page 10, the applicant states BMA Rockingham referred 2 transplants in 2010 and 3 in 2011. Three transplants were performed in 2010 and 1 in 2011.

(5) The number of patients currently on the transplant waiting list;

-C- In Section II.1, page 10 and Section IV.5, page 34, the applicant states, *"BMA Rockingham has one patient 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 10 and Section IV.6, page 35, the applicant states there were 87 hospital admissions, all of which 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 11 and Section IV.7, page 35, the applicant states in 2010 and 2011 there were no patients at the facility 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- BMA Rockingham is an existing facility.

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a 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- BMA Rockingham is an existing facility.

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

-NA- BMA Rockingham 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 BMA Rockingham's Emergency/Disaster Manual which has policies and procedures for back-up electrical service in the event of a power outage.

(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- BMA Rockingham 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 12, 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 Rockingham."*

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

-C- See Section III.7, pages 31-33 for the methodology and assumptions the applicant uses to project patient origin as presented in the following table.

	Year 1 July 2013-June 2014	**Year 2 July 2014-June 2015**	**County Patients as a Percent of Total**	
County	**In-center Patients**	**In-center Patients**	**Year 1**	**Year 2**
Rockingham	48.3	50.0	87.34%	87.73%
Guilford	4.0	4.0	7.23%	7.01%
Caswell	2.0	2.0	3.62%	3.51%
Pittsylvania, VA	1.0	1.0	1.81%	1.75%
Total	55.3	57.0	100.0%	100.0%

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- BMA Rockingham 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 14, 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- BMA Rockingham 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- BMA Rockingham projects utilization of 3.24 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 14-15 and Section III.7 pages 31-33.

(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 14-15, and Section III.7, pages 31-33. The applicant projects an annual increase in its current Rockingham County patient utilization using the county 5-year ACR. The utilization of non-resident patients is held constant through the projected years.

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 16, the applicant states, *"Patients will be referred to Annie Penn Hospital or Moses Cone Hospital."* See Exhibit 16 for a copy of the hospital agreement with Moses Cone.

(2) maintenance dialysis;

-C- The applicant states in Section II.1, page 16, *"The facility will provide in-center dialysis."*

(3) accessible self-care training;

-C- In Section II.1, page 16 the applicant states, *"Patients desiring self care training will be referred to the BMA Greensboro or BMA Burlington home training department for on site training and follow-up care."* Exhibit 20 contains a copy of the home training center program agreement.

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

-C- In Section II.1, page 16, the applicant states, *"Patients desiring to dialyze at home will be referred to the BMA Greensboro or BMA Burlington home training department for on site training and follow-up care."* See Exhibit 20 for a copy of the home training center program agreement.

(5) x-ray services;

-C- In Section II.1, page 16, the applicant states patients will be referred to Annie Penn Hospital or Moses Cone Hospital for x-ray services. See Exhibit 16 for a copy of the hospital agreement with Moses Cone.

(6) laboratory services;

-C- In Section II.1, page 16, the applicant states, *"BMA provides on site laboratory services through contract with Spectra Labs."* See Exhibit 18 for the laboratory services agreement.

(7) blood bank services;

-C In Section II.1, page 16, the applicant states patients in need of blood bank services will be referred to Annie Penn Hospital or Moses Cone Hospital.

(8) emergency care;

-C- In Section II.1, page 16, 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. Patients requiring emergent care are transferred to Annie Penn Hospital or Moses Cone Hospital."*

(9) acute dialysis in an acute care setting;

-C- In Section II.1, page 16, the applicant states patients in need of hospital admission will be referred to Annie Penn Hospital or Moses Cone Hospital.

(10) vascular surgery for dialysis treatment patients;

-C- In Section II.1, page 16, the applicant reports that patients in need of vascular surgery will be referred to the Vein and Vascular Surgeons, Greensboro.

(11) transplantation services;

-C- In Section II.1, page 17, the applicant states, *"BMA Rockingham has a transplant agreement with UNC Hospital."* Exhibit 17 contains executed transplant agreements between the applicant and UNC Hospitals, Wake Forest University Medical Center, and Duke University Medical Center.

(12) vocational rehabilitation counseling and services; and

-C- In Section II.1, page 17, the applicant states, *"Patients in need of vocational rehabilitation and counseling services will be referred to the Division of Vocational Rehabilitation of Rockingham County."*

(13) transportation.

-C- In Section II.1, page17, the applicant states, *"Transportation services will be provided by Rockingham County Council on Aging."*

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 VII, page 47, the applicant states BMA Rockingham does and will comply with all staffing requirements 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 17, the applicant states BMA Rockingham will provide ongoing program training for nurses and technicians in dialysis techniques, including training in facility and corporate policies and procedures; safety precautions; regulations; CPR; and inservice training on changes/developments in procedures, product line, equipment, Center for Disease Control and Prevention guidelines and OSHA compliance. See Section VII.5, page 47, of the application, for information concerning the training and continuing education programs currently in place at BMA Rockingham. Exhibit 14 contains copies of FMC's Dialysis Services Training Manual which outlines its training program and Exhibit 15 contains examples of information presented as part of staff's mandatory in-service and continuing education training.