ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: November 30, 2012
PROJECT ANALYST: Julie Halatek
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: E-10046-12 / Bio-Medical Applications of North Carolina, Inc., d/b/a BMA Hickory / Add two dialysis stations for a total of 35 dialysis stations upon completion of this project. Two of the 35 stations will be dedicated to home hemo-dialysis training and support / Catawba 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 Hickory, whose parent company is Fresenius Medical Care Holdings, Inc., (FMC), proposes to add two dialysis stations for a total of 35 certified dialysis stations upon completion of this project. Two of the 35 dialysis stations will be dedicated to home hemo-dialysis training and support. 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 no need for an additional facility in Catawba County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for BMA Hickory is 3.42 patients per station. This utilization rate was calculated based on 113 in-center dialysis patients and 33 certified dialysis stations. (113 patients / 33 stations = 3.4242 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		85.61%
Certified Stations		33
Pending Stations		0
Total Existing and Pending Stations		**33**
In-Center Patients as of 12/31/11 (SDR2)		113
In-Center Patients as of 6/30/11 (SDR1)		113
Step	Description	
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change.	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/11	0.0000
(ii)	Divide the result of Step (i) by 12	0.0000
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July 2012 SDR (12/31/11) until the end of calendar year 2012) (12 months).	0.0000
(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	113.0000
(v)	Divide the result of Step (iv) by 3.2 patients per station	35.3125
	and subtract the number of certified and pending stations as recorded in SDR2 [33] 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. Although the table above shows no growth, the current utilization at the facility documents the need for 2 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 30, the applicant states:

"BMA Hickory will have 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 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 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."

In Section 1.13, page 4-7, the applicant discusses the quality of services provided at BMA Hickory, 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
  - Assists 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 21, 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 46, 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.

<u>Promote Equitable Access</u>

In Section II.1, page 24, the applicant quotes the State Facilities Medical Plan (SMFP) in regards to the amelioration of economic barriers and time and distance barriers, and 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 82.1% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 2.8% are expected to be covered by VA. Thus, 84.9% of the In-Center revenue is derived from government payors."*

Additionally, the applicant provides documentation in Section VI and Exhibit 8 regarding admission policies and payment. While the facility requires some form of insurance coverage to be admitted to the facility, it also documents that the Regional Vice President has the ability to override that requirement.

On page 47, the applicant also documents its commitment to provide service to all patients regardless of income, racial/ethnic origin, disabilities, or any other factor that would classify a patient as underserved. As an example, the applicant states Medicare represented 79.7% of North Carolina dialysis treatments at BMA facilities in FY 2011, with Medicaid representing an additional 4.8%.

In Section II.1, page 24, 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 Catawba County ESRD patient population is growing at an average annual change rate of 4.8%. 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 Catawba County."*

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

Maximize Healthcare Value

In Section II.1, page 24, the applicant notes that it is able to complete this project with no capital expenditure because of the utilization of vacant space that will occur when the peritoneal dialysis stations are transferred to FMC Hickory Home Program (see CON Project I.D. E-8760-11). The applicant also notes that it does not seek out government or charitable contributions to expand; rather, it assumes the entire financial burden.

The applicant goes on to state:

Census 6/30/2012			
County of Residence	**Home patients**	**In-Center patients**	**% of total**
Catawba	18	96	74.5%
Caldwell	6	7	8.5%
Burke	5	4	5.9%
Iredell	0	1	0.6%
Cleveland	0	2	1.3%
Alexander	4	1	3.3%
Lincoln	4	5	5.9%
Total	**37**	**116**	**100.0%**

"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."

Additionally, the applicant takes on "bad debt" and provided almost $400,000 in uncompensated care in 2011.

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.

C

The applicant, BMA Hickory, proposes to add two dialysis stations to its existing facility for a total of 35 certified stations upon completion of the project. Two of the 35 stations will be dedicated to home hemo-dialysis training and support.

Population to be Served

In Section IV.1, page 40, the applicant identifies the population it serves, as illustrated in the table below.

In Section III.7, page 38, 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.

BMA Hickory	Operating Year 1		Operating Year 2		County patients as a % of TOTAL	
	Home	In-Center	Home	In-Center	Year 1	Year 2
Catawba	5.5	105.4	5.8	110.5	84.7%	85.4%
Caldwell	0.0	7.0	0.0	7.0	5.4%	5.1%
Burke	0.0	4.0	0.0	4.0	3.0%	2.9%
Iredell	0.0	1.0	0.0	1.0	0.8%	0.7%
Cleveland	0.0	2.0	0.0	2.0	1.5%	1.5%
Alexander	0.0	1.0	0.0	1.0	0.8%	0.7%
Lincoln	0.0	5.0	0.0	5.0	3.8%	3.7%
Total	5.5	125.4	5.8	130.5	100.0%	100.0%

The applicant adequately identified the population to be served.

Need Analysis

In Section III.7, page 34, 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 Hickory for a total of 35 stations serving the 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. BMA Hickory will not project to serve any home peritoneal dialysis patients at the facility in the future, as home peritoneal dialysis support and training will be moved to FMC Hickory Home Program facility.
3. As of June 30, 2012, BMA Hickory was providing dialysis treatment for 5 home hemo-dialysis patients from Catawba County, 96 in-center patients from Catawba County, and 20 in-center patients from other counties.

4. BMA Hickory assumed the ESRD patient population of Catawba County will continue to increase at a rate of 4.8%, the Catawba County Five Year Average Annual Change Rate (ACR) published in the July 2012 SDR.
5. BMA Hickory will not project increases for the patient population dialyzing at BMA Hickory but residing in a county other than Catawba.

The applicant's methodology for in-center patients is provided in the following table:

	In-center
BMA begins with the Catawba County in-center population of BMA Hickory as of June 30, 2012.	96
BMA projects this patient population forward for 12 months to June 30, 2013.	(96 X .048) + 96 = 100.6
BMA adds the 20 patients dialyzing at BMA hickory but residing in other counties. This is the beginning census for this project.	100.6 + 20 = 120.6
BMA projects the Catawba County patient population forward for 12 months to June 30, 2014.	(120.6 X .048) + 120.6 = 126.4* [(100.6 X .048) + 100.6 = 105.4]
BMA adds the 20 patients dialyzing at BMA Hickory but residing in other counties. This is the Operating Year 1 census.	105.4 + 20 = 125.4
BMA projects the Catawba County patient population forward for 12 months to June 30, 2015.	(105.4 X .048) + 105.4 = 110.5
BMA adds the 20 patients dialyzing at BMA Hickory but residing in other counties. This is the Operating Year 2 ending census.	110.5 + 20 = 130.5

*There is a typo in the table. 120.6 is listed as the Catawba County ESRD population when it should be 100.6. The calculations, however, are done correctly through the table.

The applicant projects to serve 125 in-center patients or 3.57 patients per station (125 / 35 = 3.57) by the end of Year 1 and 130 in-center patients or 3.71 patients per station (130 / 35 = 3.71) by the end of Year 2 for the proposed 35 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.

For home hemo-dialysis patients, the applicant's methodology is provided in the following table:

	Home Hemo-dialysis
BMA begins with the Catawba County home hemo-dialysis population of BMA Hickory as of June 30, 2012.	5
BMA projects this patient population forward for 12 months to June 30, 2013.	(5 X .048) + 5 = 5.2
BMA projects the Catawba County patient population forward for 12 months to June 30, 2014. This is the Operating Year 1 census.	(5.2 X .048) + 5.2 = 5.5
BMA projects the Catawba County patient population forward for 12 months to June 30, 2015. This is the Operating Year 2 ending census.	(5.5 X .048) + 5.5 = 5.8

The applicant projects to serve 5 home hemo-dialysis patients by the end of Year 1 and 5 hemo-dialysis patients by the end of Year 2. Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access

In Section VI, page 47, 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 notes that 2% of its population is Medicaid/low income; 37.3% is elderly (defined as 65+ years old), 75.2% is Medicare; 34.6% are women; and 32.7% are racial minorities. 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 the two additional stations at BMA Hickory, and demonstrates all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

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 39, the applicant discusses the alternatives considered prior to the submission of this application, which include:

1. Maintain the Status Quo—Do Nothing. The applicant states that this alternative is not consistent with BMA's stated effort to provide equitable access by removing time and distance barriers. BMA states on page 28, *"A dedicated home training program will offer many cost containment advantages. A larger home training unit, a well-trained and well-qualified staff can more efficiently specialize in home training as an education program for patients and families."*

2. Add two dialysis stations for a total of 35 stations at BMA Hickory. The applicant proposes to add two additional stations to the existing BMA Hickory facility to provide adequate access to dialysis services to the growing Catawba County ESRD patient population.

On page 39, the applicant states:

> *"There are not suitable alternatives to this project. This 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 Catawba 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 Catawba 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 Hickory.

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 Hickory 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 Hickory shall develop no more than two additional stations for a total of no more than 35 stations. Two of the 35 stations will be dedicated to home hemo-dialysis training and support.**

3. **Bio-Medical Applications of North Carolina, Inc., d/b/a BMA Hickory 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, page 55, the applicant projects no capital cost for the two station addition. In Section IX, page 58, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

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 $13,864,359,000 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 59, the applicant projects the following charge per treatment for each payment source:

Payor	In-center	Home Hemo
Commercial	$1375.00	$1375.00
Medicare	$234.00	$234.00
Medicaid	$137.29	$137.29
VA	$146.79	$147.85
Private Pay	$1375.00	$1375.00

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 feel 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 is as illustrated in the table below and supported by the accompanying assumptions.

	Project Year 1	Project Year 2
Net revenue	$6,146,153,000	$6,341,059,000
Operating expenses	$5,385,173,000	$5,575,275,000
Profit	$760,980,000	$765,784,000

Source: Application pages 60 and 64

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 + home treatments less Medicare treatments.
4. Average reimbursement per treatment is based upon applicant's historical experience and expected future reimbursement.

In Section VII, page 52, the applicant provides projected staffing and salaries. On page 53, the applicant states BMA Hickory will comply with all staffing requirements as stated in 42 C.F.R. Section 494. Staffing by shift is provided on page 54. 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 on 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.

C

The applicant proposes to add two dialysis stations to the existing facility for a total of 35 stations upon completion of the proposed project. The applicant adequately demonstrates the need for two additional stations based on the number of patients it proposes to serve. Per the July 2012 SDR, as of December 31, 2011, the 33 station BMA Hickory facility was operating at 85.61% capacity (113/33 = 3.4242; 3.42/4 = 85.61%). The target utilization rate is 80%. The applicant therefore is eligible to expand its facility and may apply for additional stations under the facility need methodology. Upon completion of the project, the facility will have 35 stations serving 125 patients (end of year 1) which is a utilization rate of 89.25% (125/35 = 3.57; 3.57/4 = 89.25%). The applicant is therefore conforming with the requirement in 10A NCAC 14C .2203.

Catawba County has one other dialysis center which is operated by the same dialysis provider. FMC Catawba Valley, with a utilization rate of 61.96%, is located in Conover, approximately 7.5 miles away. On page 363, the 2012 SMFP states, "*As a means of making*

ES RD ser vic es mo re acc essible 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."

	Times	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
Morning	6:00AM—11:30AM	0	10	10	10	10	10	10
Afternoon	11:30AM—4:30PM	0	10	10	10	10	10	10
Evening								

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

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1, page 52, the applicant provides the following current and projected number of full-time equivalent (FTE) positions. The applicant does not project adding any FTEs to BMA Hickory following completion of the project, as illustrated below:

Position	**Current # of FTEs**	**Projected # of FTEs**	**Total # of FTEs**
RN	5.00	0.00	5.00
Tech.	12.00	0.00	12.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Not an FTE of the facility; contract position		
Admin. (FMC Dir. Ops)	0.15	0.00	0.15
Dietician	0.88	0.00	0.88
Social Worker	1.15	0.00	1.15
Home Training Nurse	4.00	0.00	4.00
Chief Tech	0.40	0.00	0.40
Equipment Tech	0.75	0.00	0.75
In-Service	0.20	0.00	0.20
Clerical	1.50	0.00	1.50
Total	**27.03**	**0.00**	**27.03**

In Section VII.10, page 54, the applicant provides the following information on the number of direct care staff for each shift offered at BMA Hickory.

In Section V.4(c), page 45, the applicant states that Dr. David Harvey is the medical director at BMA Hickory. Exhibit 21 contains a letter from Dr. Harvey agreeing to continue in that position.

The information regarding staffing provided in Section VII and the pro forma, and statements regarding projected staffing, are 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.

C

In Section V.1, page 42 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 20 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 Catawba Valley Medical Center or Frye Regional Medical Center. Dialysis maintenance, isolation, vocational counseling and social services will be provided by BMA on site. The other services will be provided at the specified facility. Exhibits 16-20 contain documentation on service agreements.

The information regarding coordination of services in Section V.2, pages 42-43, acute hospital agreement, transplant agreement, and follow-up care; Section V.4, pages 44-45, physician referral relationships and physician support; Section V.5, page 45, relationships with physicians, hospitals and other health professionals; and Section VII, pages 52-54, healthcare staffing; and the documentation referenced in Exhibits 16-20 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 (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(a), page 47, 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. The patient population of the BMA Hickory facility comprised [sic] *of the following:*

Facility	*Medicaid/ Low Income*	*Elderly (65+)*	*Medicare*	*Women*	*Racial Minorities*
BMA Hickory	*2.0%*	*37.3%*	*75.2%*	*34.6%*	*32.7%*

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 75.2% of the facility treatment reimbursement is from Medicare.

It is clear that MBA 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 48, the applicant indicates that historically, 79.1% of patients at BMA Hickory have some or all of their services paid for by Medicare. An additional 3.0% are covered by Medicaid. Thus 82.1% of the center revenue is derived from Medicare/Medicaid. The table below illustrates the historical payor mix for the facility.

Historical Payor Source	**In-center**	**Home**
Private Pay	0.0%	0.0%
Commercial Insurance	15.1%	26.6%
Medicare	79.1%	73.4%
Medicaid	3.0%	0.0%
Medicare/Medicaid	0.0%	0.0%
Medicare/Commercial	0.0%	0.0%
State Kidney Program	0.0%	0.0%
VA	2.8%	0.0%
Other: Self/Indigent	0.0%	0.0%
Total	**100.0%**	**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 Catawba County and statewide. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of	**Total # of Medicaid**	**% Uninsured CY**

	Medicaid Eligibles as % of Total Population	Eligibles Age 21 and older as % of Total Population	2009 (Estimate by Cecil B. Sheps Center)
Catawba	17%	6.2%	19.1%
Statewide	17%	6.7%	19.7%

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 Hickory. In fact, only 5.8% of all 2011 Incident ESRD patients in North Carolina's Network 6 were under the age of 35.

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 standings.*
> *…*
> *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*

[1] www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/Downloads/ESRDNetworkProgramBackgroundpublic.pdf; accessed on 11/20/2012

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%

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

Number and Percent of NC 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	4237	45.4%
Male	5105	54.6%
Race		
African American	5096	54.5%
White	4027	43.1%
Other	219	2.3%
Total	9342	100.0%

Source: 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 49, 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 51, 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 48, 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**	**Home**
Private Pay	0.0%	0.0%
Commercial Insurance	15.1%	26.6%
Medicare	79.1%	73.4%
Medicaid	3.0%	0.0%
Medicare/Medicaid	0.0%	0.0%
Medicare/Commercial	0.0%	0.0%
State Kidney Program	0.0%	0.0%
VA	2.8%	0.0%
Other: Self/Indigent	0.0%	0.0%
Total	**100.0%**	**100.0%**

As shown in the table, the applicant projects 79.1% of all in-center patients and 73.4% of all home patients will have some or all of their services paid for by Medicare. The applicant also projects that the VA will cover 2.8% of in-center patients and Medicaid will cover 3.0% of in-center patients.

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 47, the applicant states that the facility will conform to the Americans with Disabilities Act and any other applicable requirements of federal state, and local bodies.

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 50, 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 Hickory 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 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 44, 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 that like the other BMA facilities, it expects BMA Hickory to also provide ESRD and dialysis information to students and program directors, and thereafter have the students observe, tour the facility, and talk with patients. The facility has formalized a relationship with Catawba Valley Community College, an agreement with which is displayed in Exhibit 19. 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 facility, for a total of 35 certified stations upon completion of the project. The July 2012 SDR shows there is no need for stations in Catawba County; however, the applicant qualifies for additional dialysis stations based on the facility need methodology.

In Section V.7, page 46, 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 notes that BMA is the only provider of dialysis services within Catawba County. The applicant states that the proposal will enhance the quality, rather than adversely affect the quality, of ESRD patients' lives.

The applicant further states:

"This facility has added value stemming from the strength of our relationship with the nephrology physicians already referring to BMA at the BMA Hickory dialysis facility.

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 Hickory facility will have a positive impact on cost-effectiveness, quality, and access to the proposed services because:

- The applicant adequately demonstrates the need, based on Facility Need, to add two dialysis stations for a total of 35 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 Hickory patients.

- The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII and discussed in Criterion 7 is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R. Section 494. The information regarding ancillary and support services and coordination of services with the existing health care system in Section V, pages 42-46, and staffing, in Section VII, pages 52-54, and referenced in exhibits is reasonable and credible and demonstrates the provision of quality care services.

  On page 23, 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 47, 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 Hickory	*2.0%*	*37.3%*	*75.2%*	*34.6%*	*32.7%*

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 75.2% of the facility treatment reimbursement is from Medicare."

The applicant states that 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 Hickory has operated in compliance with all Medicare Conditions of Participation within the 18 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 85.61% with 3.42 (113/33 = 3.42) patients per station.

(2) Mortality rates;

-C- In Section II.1, page 10, the applicant provides the mortality rates as 15.3%, 16.0%, and 13.8% for 2009, 2010, and 2011, respectively.

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

-C- In Section II.1, page 10, the applicant states that BMA Hickory trained 24 home patients in 2011. They are currently following 37 home dialysis patients (35 peritoneal dialysis and 2 home hemo-dialysis).

(4) The number of transplants performed or referred;

-C- In Section II.1, page 10, the applicant states BMA Hickory referred 20 transplants in 2010 and 42 in 2011. Eight transplants were performed in 2010 and nine in 2011.

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

-C- In Section II.1, page 10, the applicant states that they have 24 patients on the transplant waiting list.

(6) Hospital admission rates, by admission diagnosis, i.e., dialysis versus non-dialysis related;

-C- In Section II.1, page 10, the applicant documents that there were 205 admissions in 2011. Thirty-one were dialysis related and 174 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, pages 10-11, the applicant states in 2010 and 2011 there were no patients at the facility with an infections disease. There is currently one patient at the facility with Hepatitis B.

(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 Hickory 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 Hickory is an existing facility.

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

-NA- BMA Hickory 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 Hickory'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 Hickory 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 regulations.

-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 Hickory."*

(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 34-38, for the methodology and assumptions the applicant uses to project patient origin as presented in the following table.

BMA Hickory	Operating Year 1		Operating Year 2		County patients as a % of TOTAL	
	Home	In-Center	Home	In-Center	Year 1	Year 2
Catawba	5.5	105.4	5.8	110.5	84.7%	85.3%
Caldwell	0.0	7.0	0.0	7.0	5.4%	5.1%
Burke	0.0	4.0	0.0	4.0	3.1%	2.9%
Iredell	0.0	1.0	0.0	1.0	0.8%	0.7%
Cleveland	0.0	2.0	0.0	2.0	1.5%	1.5%
Alexander	0.0	1.0	0.0	1.0	0.8%	0.7%
Lincoln	0.0	5.0	0.0	5.0	3.8%	3.7%
Total	5.5	125.4	5.8	130.5	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 Hickory 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 16, 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 stations 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 Hickory 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 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 Hickory projects utilization of 3.57 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 16-17, and Section III.7, pages 34-35. See discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

(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 13-18, and Section III.7, pages 34-38. Additionally, see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein. The applicant projects an annual increase in its current Catawba County patient utilization using the county 5-year AACR. 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 20, the applicant states, *"Patients will be referred to Catawba Valley Medical Center or Frye Regional Medical Center."* See Exhibit 16 for a copy of the hospital agreement with Frye Regional Medical Center.

(2) maintenance dialysis;

-C- The applicant states in Section II.1, page 20, *"The facility will provide in-center dialysis."*

(3) accessible self-care training;

-C- In Section II.1, page 20, the applicant states, *"Patients desiring self care training will be referred to the facility home training department for on site training and follow-up care."*

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

-C- In Section II.1, page 20, the applicant states, *"The facility will provide training for home hemo-dialysis. PD patients will be referred to the new FMC Hickory Home Program."*

(5) x-ray services;

-C- In Section II.1, page 20, the applicant states, *"Patients in need of X-ray services will be referred to Catawba Valley Medical Center or Frye Regional Medical Center."* See Exhibit 16 for a copy of the hospital agreement with Frye Regional Medical Center.

(6) laboratory services;

-C- In Section II.1, page 20, 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, pages 20-21, the applicant states, *"Patients in need of blood transfusion will be referred to Catawba Valley Medical Center or Frye Regional Medical Center."* See Exhibit 16 for a copy of the hospital agreement with Frye Regional Medical Center.

(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 in need of hospital admission will be referred to Catawba Valley Medical Center or Frye Regional Medical Center.

(10) vascular surgery for dialysis treatment patients;

-C- In Section II.1, page 21, the applicant states, *"Patients will be referred to Dr. Randal Bast at Horizon Surgical Specialists, or Dr. Charles Kiell at Hickory Surgical Clinic."*

(11) transplantation services;

-C- In Section II.1, page 21, the applicant states, "*BMA Hickory has a transplant agreement with NC Baptist Hospital."* Exhibit 17 contains an executed transplant agreement between the applicant and NC Baptist Hospital.

(12) vocational rehabilitation counseling and services; and

-C- In Section II.1, page 21, the applicant states, "*Patients in need of vocational rehabilitation services will be referred to the Catawba County Vocational Rehabilitation."*

(13) transportation.

-C- In Section II.1, page 21, the applicant states, "*Transportation services will be provided by Department of Social Services, Greenway Transportation and Specialty Transportation."*

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 53, the applicant states that BMA Hickory 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, pages 21-22, the applicant states BMA Hickory 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 in-service training on changes/developments in procedures, product line, equipment, Center for Disease Control and Prevention guidelines and OSHA compliance. See Section VII.5, page 53, for information concerning the training and continuing education programs currently in place at BMA Hickory. 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.