

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 17, 2013  
PROJECT ANALYST: Gregory F. Yakaboski  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10066-12 / Bio-Medical Applications of North Carolina, Inc., d/b/a BMA Cary / Relocate four dialysis stations from BMA Raleigh to BMA Cary for a total of 24 dialysis stations upon completion of this project and Project ID #M-8596-10 (transfer of three stations to FMC Angier) / Wake 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 Cary (BMA Cary), whose parent company is Fresenius Medical Care Holdings, Inc., (FMC), proposes to relocate four dialysis stations from BMA Raleigh to BMA Cary for a total of 24 dialysis stations upon completion of this project and Project ID #M-8596-10 (transfer of three stations from BMA Cary, five stations from BMA Fuquay-Varina and two stations from BMA Dunn to develop FMC Angier). 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. In this application, the applicant proposes to relocate dialysis stations between facilities. Therefore, neither the county need nor facility need methodologies in the 2012 SMFP are applicable to this review. Additionally, Policy GEN-3 is not applicable because neither need methodology is applicable to the review. However, Policy ESRD-2 is applicable to this review. *Policy ESRD-2: Relocation of Dialysis Stations* states:

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

- 1. Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.*

The applicant proposes to relocate 4 existing certified dialysis stations from BMA Raleigh to BMA Cary. Both facilities are located within Wake County. Consequently, there is no change in inventory in Wake County and the application is consistent with Policy ESRD-2 and conforming to this criterion

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

## C

BMA proposes to relocate 4 existing certified stations from BMA Raleigh to BMA Cary for a total of 24 stations at BMA Cary upon completion of this project and CON Project ID # M-8596-10 (which includes, in part, transferring 3 stations from BMA Cary to develop a new facility- FMC Angier). This project is scheduled to be completed and certified June 30, 2013.

Population to be Served

In Section IV.1, page 39, the applicant identifies the population it serves, as illustrated in the table below.

<b>County of Residence</b>	<b># of In-Center Patients Dialyzing 09-30-12</b>	<b>Percent of Total</b>
Wake	78	100.0%
<b>Total</b>	<b>78</b>	<b>100.0%</b>

In Section III.7, page 35, 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 Cary- Projected Patient Origin**

<b>County</b>	<b>Operating Year 1</b>	<b>Operating Year 2</b>	<b>County Patients as a Percent of TOTAL</b>	
	<b>In Center Patients</b>	<b>In Center Patients</b>	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Wake	87.2	90.8	100%	100%
Total	87.2	90.8	100%	100%

On page 36, the applicant states Craig Smith, CON Section Chief, has previously indicated that patients are not partial patients, but rather are whole and that financial projections and utilization are rounded down to the whole number.

The applicant adequately identifies the population to be served.

### **Demonstration of Need**

In Section III.3(a), page 31, the applicant states that this application for the relocation of 4 existing certified dialysis stations from BMA Raleigh to BMA Cary is based upon:

1. Enhancing geographic accessibility for the patients residing in western Wake County.

In Section III.3, pages 31-33, the applicant states:

*“This application is based upon enhancing geographic accessibility for the patients residing in western Wake County... There are several patients currently dialyzing at BMA Raleigh who actually reside closer to BMA Cary.*

...

*There are at least 10 dialysis patients from BMA Raleigh who reside closer to the BMA Cary location.*

...

*Three of the patients reside closer to the FMS Apex facility and further from the BMA Cary facility.*

*Thus, BMA estimates that at least seven patients could be better served at BMA Cary. BMA has included letters of support from four patients who have indicated an interest in transferring to BMA Cary upon completion of this project.”*

In Section III.3, page 32, the applicant states that while BMA Cary is currently a 23 station facility, three stations are being transferred to FMC Angier (Project ID # M-8596-10) upon completion of that project. After completion of Project ID # M-8596-10 BMA Cary will have only 20 dialysis stations which will be insufficient to provide treatment for the projected number of patients at BMA Cary unless the facility adds a third shift. The applicant states on page 32 that “...no patients have requested a third shift. Nor have any patients agreed to dialyze on a third shift.”

In Section III.7, pages 34-36, the applicant describes the methodology and assumptions used to project utilization at BMA Cary.

The assumptions relied upon by the applicant are set forth on pages 34-36 are summarized as follows:

- BMA Cary does not project to operate a third dialysis shift due to lack of patient interest.
- Three stations and a single patient will transfer to FMC Angier, Project ID # M-8596-10.
- The patient population of BMA Cary will increase at an annual rate of 4.2% (commensurate with the Wake County Five Year Annual Average Change Rate as published in the July 2012 SDR).
- Four dialysis patients from other Wake County dialysis facilities will transfer to BMA Cary upon project completion based on signed letters of support which indicate that BMA Cary is a more convenient setting for their dialysis treatment and that they would consider transferring to BMA Cary.
- Patient origin for BMA Cary will be Wake County.
- Patients are not partial patients but rather are whole. In utilization and financial projections BMA has rounded down to the whole number.

The table below illustrates the applicant’s methodology and assumptions to project patient utilization.

Wake County	In-Center
BMA begins with Wake County patients utilizing the BMA Cary dialysis facility as of September 30, 2012	78 Wake County patients
BMA projects growth of this patient population using the Wake County Five Year Average Annual Change Rate for a period of three months to December 3, 2012	$[78 \times (.042/12 \times 3)] + 78 = 78.819$
BMA subtracts the one patient proposed to transfer to FMC Angier upon completion of Project ID # M-8596-10. This is December 31, 2012.	$78.819 - 1 = 77.819$
BMA projects the patient population forward for six months to June 30, 2013.	$[77.819 \times (.042/ 12 \times 6)] + 77.819 = 79.638$ (The project analyst notes that the correct mathematical formula and answer is as follows: 79.45 or 79.5 $[77.819 \times 1.021 = 79.45$ . However, the mathematical errors are de minimus in that it does not change the fact that at the end of Project Year One Wake County patients are projected to be 87 by either calculation.)
BMA adds the four patients proposed to transfer to BMA Cary upon completion of this project. This is the beginning census for [June 30, 2013].	$79.638 + 4 = 83.638$
BMA projects the patient population from Wake County forward for 12 months at 4.2%. This is the projected Wake County patient population for June 30, 2014. This is the end of Operating Year 1.	$(83.638 \times .042) + 83.638 = 87.15$
BMA projects the patient population for Wake County forward for 12 months at 4.2%. This is the projected Wake County patient population for June 30, 2015. This is the end of Operating Year 2.	$(87.15 \times .042) + 87.15 = 90.81$

As indicated in the table above, the applicant projects to serve 87 in-center patients in Operating Year One and 90 in-center patients in Operating Year Two. The applicant’s projected patient census for the first two operating years is reasonable given the historical average annual growth rate for Wake County, as well as patient convenience and preference.

The applicant projects to serve 87 in-center patients or 3.63 patients per station ( $87 / 24 = 3.63$ ) by the end of Year 1 or a 90.6% utilization rate  $[87/ (4 \times 24) = 0.906]$  and 90 in-center patients or 3.75 patients per station ( $90 / 24 = 3.75$ ) by the end of Year 2 or 97.8% utilization rate  $[90 / (4 \times 24) = 0.978]$  for the proposed 24 station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access to Services

In Section VI, page 47, the applicant states that BMA currently operates 93 facilities in 40 North Carolina Counties which include low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. In Section VI.1(a), page 47, the applicant provides a breakdown of the population of the BMA Cary facility, as illustrated in the table below

Facility	Medicaid/Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Cary	30.4%	51.9%	93.7%	46.8%	69.6%

In Section VI.1(c), page 48, the applicant projects that 80.9% of its patients will be covered by Medicare or Medicaid.

The applicant adequately demonstrates the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

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

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

C

BMA proposes to relocate 4 existing certified dialysis stations from BMA Raleigh to BMA Cary. On page 31 the applicant states that BMA has letters from four existing BMA Raleigh patients who have indicated an interest in transferring to BMA Cary upon completion of this proposed project. The methodology described on page 36 to project utilization at BMA Cary includes the transfer of 4 patients from BMA Raleigh to BMA Cary.

On page 33 the applicant states that each of the patients who signed letters of support actually live closer to the BMA Cary facility than to the BMA Raleigh facility.

In Section III.1(c), pages 32-33, the applicant demonstrates that the needs of the dialysis patients continuing to use the BMA Raleigh facility will be adequately addressed with by the remaining number of dialysis stations at BMA Raleigh after completion of this project and Project ID # J-8777-12 (transfer 2 dialysis stations and 13 patients from BMA Raleigh to

FMC Central Raleigh). BMA Raleigh currently has 49 certified stations. However, pursuant to Project ID # J-8777-12 two dialysis stations and 13 patients are scheduled to transfer to FMC Central Raleigh. Upon completion of the proposed project and Project ID # J-8777-12 BMA Raleigh will have 43 certified dialysis stations ( $49 - 4 - 2 = 43$ ).

The applicant projects a utilization rate for BMA Raleigh of 3.33 patients per stations upon completion of Project ID # J-8777-12 and this proposed project. The methodology and assumptions utilized to project the utilization rate for BMA Raleigh are illustrated in the table below

BMA begins with the In-center patient population as published in the July 2012 SDR. This was for December 31, 2011.	151
BMA projects this patient population forward for 12 months to December 31, 2012, using the Wake County Five Year Average Annual Change Rate of 4.2%	$(151 \times .042) + 151 = 157.3$
BMA subtracts the 13 patients from BMA Raleigh proposed to transfer to FMC Central Raleigh.	$157.3 - 13 = 144.3$
BMA projects this population forward for six months to June 30, 2012. This is the projected certification date for this project.	$(144.3 \times .042) + [144.3] = 147.4$ [The project analyst notes that the correct mathematical formula and answer is $144.3 \times 1.021 = 147.33$ ]
BMA subtracts 4 patients projected to transfer to BMA Cary with this project. This is the patient population to be served at BMA Raleigh upon completion of this project.	$147.33 - 4 = 143.3$

Project ID #J-8777-12 is scheduled to be complete by December 31, 2012 and the proposed project is scheduled to be complete on June 30, 2013. In the table above, the applicant projects to serve 143 in-center patients as of June 30, 2013. This equates to 3.33 patients per station ( $143 / 43 = 3.325$  or 3.33) by the end of Year 1 for a 83.1% utilization rate [ $143 / (4 \times 43) = 0.8313$ ]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

The applicant's analysis of the effect the relocation of a total of 6 certified dialysis stations and 17 patients (the combination of this project and Project ID #J-8777-12) from BMA Raleigh will have on the remaining and projected dialysis patients of BMA Raleigh is reasonable and shows that the needs of the population presently served will continue to be met following the relocation of the 4 existing dialysis stations from BMA Raleigh to BMA Cary. In terms of access, the proposed relocation of 4 existing dialysis stations will improve access to dialysis services for patients who live closer to BMA Cary than to BMA Raleigh while still providing sufficient dialysis stations at BMA Raleigh to serve projected patients. There is no indication that the reduction of dialysis stations at BMA Raleigh will have a detrimental effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly currently receiving dialysis at BMA Raleigh to obtain needed dialysis services.



- (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.

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In Section III.9, pages 37-38 , the applicant states the alternatives considered by BMA prior to the submission of this application, which include:

- 1) Maintain the Status Quo – Do Nothing. This alternative is not consistent with the with the projected high utilization rate at BMA Cary. The applicant adequately identifies the population to be served, demonstrates the need the population has for four additional stations at BMA Cary and the ability of BMA Raleigh to continue to effectively serve its projected population after relocation of 4 dialysis stations from BMA Raleigh to BMA Cary. Therefore, this alternative was not a viable option.
- 2) Apply for fewer stations- The applicant has demonstrated that the BMA Cary facility is projected to exceed a utilization rate greater than 80% by the end of the first operating year. Therefore, this alternative was not a viable option.
- 3) Move stations to another Wake County facility- This was not a viable alternative as the additional stations are needed at BMA Cary.

In Section III.9, page 38, the applicant states “*Considering the alternatives, BMA has chosen the most effective and least costly alternative for meeting the needs of the patients choosing to receive treatment at the BMA Care facility.*”

The applicant adequately demonstrated the need to relocate 4 existing certified dialysis stations from BMA Raleigh to BMA Cary. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, 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 Cary shall materially comply with all representations made in the certificate of need application and additional information.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Cary shall relocate no more than four dialysis stations from the BMA Raleigh facility to the BMA Cary facility for a total of no more than 24 certified dialysis stations at BMA Cary following the completion of the project and Project ID #M-8596-10, which shall include any home hemodialysis training or isolation stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Cary shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations, for a total of no more than 24 certified dialysis stations, which shall include any isolation stations.**
  4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Cary shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
  5. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Cary shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to insurance 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 56, the applicant projects a total capital cost of \$2,550 which includes \$1,200 for water treatment equipment and \$1,350 in equipment/furniture costs. In Section IX, page 61, the applicant further states that there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 24 includes a letter dated November 15, 2012 from the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

*“BMA proposes to transfer four dialysis stations from BMA Raleigh to the BMA Cary dialysis facility in Wake County. The project calls [for] the following capital expenditures on behalf of BMA.*

*Capital Expenditure:       \$2,550.”*

*As Vice President, I am authorized and do hereby authorize the transfer of four dialysis stations to BMA Cary, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$2,550 as may be needed for this project.”*

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2011 and 2010. As of December 31, 2011, Fresenius Medical Care Holdings, Inc. 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 62, the applicant projects the following charge per treatment for each payment source:

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

The applicant states on page 62 that the commercial charges above do not reflect actual reimbursement rates, and should not be taken as absolute. In addition, the applicant states that 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, page 63, of the application and operating expenses in Section X.4, page 66, of the application. The applicant projects revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	Project Year 1	Project Year 2
Net Revenue	\$4,614,749	\$4,844,760
Operating Expenses	\$3,788,308	\$3,968,731
Profit	\$826,441	\$876,029

Assumptions:

1. Average number of patients for the current year is increased by the county growth rate for the first two operating years;
2. Average of 3 treatments per week per patient for 52 weeks reduced by a 6.5% allowance for missed treatment; and
3. Ancillary revenues: treatment numbers = In-center revenue table treatments less Medicare treatments; Average reimbursement per treatment is based upon applicant’s historical experience and expected future reimbursement.

In Section VIII.9, page 59, 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 a sample dialysis machine lease. The applicant further states that all FMC leases are “arms length” negotiations.

In Section VII.1, page 52 and Section X, pages 66-67, the applicant provides projected staffing and salaries. On page 53, the applicant states that BMA Cary will comply with all staffing requirements as stated in 42 C.F. R. Section 494 (formerly 405.2100). Staffing by

shift is provided on page 55. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

The applicant adequately demonstrates that 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.

C

BMA proposes to relocate four dialysis stations from BMA Raleigh to BMA Cary for a total of 24 stations at the BMA Cary dialysis facility upon completion of the proposed project and Project ID #M-8596-10. The applicant demonstrated the need to relocate 4 stations within the same county from BMA Raleigh to BMA Cary based enhanced geographic accessibility, patient letters of support, utilization of the Five Year Average Annual Growth Rate for Wake County and the number of in-center patients it proposes to serve at both facilities. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. Upon completion of the proposed project, at the end of the first operating year the facility will have 24 stations serving 87 patients which is a utilization rate of 90.6% ( $87 / 24 = 3.63$ ;  $3.63 / 4 = .906$  or 90.6%). Therefore, the applicant is conforming with the requirement in 10A NCAC 14C .2203.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved dialysis stations. 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.

C

In Section VII.1, page 52, the applicant provides the current and projected number of full-time equivalent (FTE) positions following completion of the proposed project, as illustrated in the table below:

<i>Position</i>	<i>Current # of FTEs</i>	<i>Total Positions to be Filled</i>	<i>Total FTE Positions Upon Completion</i>
<i>RN</i>	<i>2.50</i>	<i>0.50</i>	<i>3.00</i>
<i>Tech</i>	<i>7.00</i>	<i>1.00</i>	<i>8.00</i>
<i>Medical Director</i>	<i>Contract position; not an FTE of the facility</i>		

<i>Clinical Manager</i>	<i>1.00</i>	<i>0.00</i>	<i>1.00</i>
<i>Administrator</i>	<i>0.15</i>	<i>0.00</i>	<i>0.15</i>
<i>Dietitian</i>	<i>0.60</i>	<i>0.15</i>	<i>0.75</i>
<i>Social Worker</i>	<i>0.60</i>	<i>0.15</i>	<i>0.75</i>
<i>Medical Records</i>	<i>0.50</i>	<i>0.00</i>	<i>0.50</i>
<i>Chief Tech</i>	<i>0.33</i>	<i>0.00</i>	<i>0.33</i>
<i>Equipment Tech</i>	<i>0.80</i>	<i>0.00</i>	<i>0.80</i>
<i>In-Service</i>	<i>0.33</i>	<i>0.00</i>	<i>0.33</i>
<i>Clerical</i>	<i>0.50</i>	<i>0.00</i>	<i>0.50</i>

Analysis of the salary budgeted on pages 66-67 confirms the use of 16.11 FTE in the calculations.

In Section VII.10, page 55, the applicant provides the direct care staff for each shift offered in the facility as shown in the table below:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7:00am to 12:00pm	8	8	8	8	8	8
Afternoon	12:00pm to 5:00pm	8	8	8	8	8	8

The applicant states in Section V.4 (c), page 44, that Dr. Eckel will be the Medical Director for the facility. In Exhibit 21, the applicant provides a letter from Dr. Eckel in support of the proposed project and states his willingness to continue to serve as the Medical Director for the facility. The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity 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 41, the applicant lists the providers of the necessary ancillary and support services. The applicant states the method for providing these services in response to 10A NCAC 14C .2204, beginning on page 17 of the application. Western Wake Med, Cary and Wake Med Raleigh will provide BMA Cary patients the following services - acute dialysis in acute care setting, diagnostic evaluation services and x-ray services; Cary Radiology will also provide diagnostic and evaluation services; x-ray services will also be provided by Rex Hospital. UNC Medical Center and Duke UMC will provide transplantation services; laboratory work will be provided by SPECTRA. The other services will be provided at the individually stated facility. Copies of the agreements with Wake Medical Center, UNC Healthcare, Spectra Laboratories and the Raleigh Home Training Center are found in Exhibits 16-18 and 20 respectively.

The information regarding coordination of services in Section V of the application and referenced in exhibits 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 Cary facility comprised of the following:*

<i>Facility</i>	<i>Medicaid/Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>BMA Cary</i>	<i>30.4%</i>	<i>51.9%</i>	<i>93.7%</i>	<i>46.8%</i>	<i>69.6%</i>

*Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 93.7% of the facility treatment reimbursement is from Medicare.*

*It is clear that BMA Cary 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(b), page 48, the applicant states that historically, 73.4 % of patients at BMA Cary have some or all of their services paid for by Medicare and 7.5% have some or all of their services paid for by Medicaid. Thus, 80.9% of the center revenue is derived from government payors. The table below illustrates the current historical payor mix for the facility.

**Historical Payor Source**

<b>Payor Source</b>	<b>In-Center</b>
Commercial Insurance	18.9%
Medicare	73.4%
Medicaid	7.5%
Self/Indigent	0.1%
<b>Total</b>	<b>100.0%</b>

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 Wake County and Statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population</b>	<b>CY2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)</b>

Wake	10.0%	3.3%	18.4%
Statewide	17.0%	6.7%	19.7%

Source: <http://www.ncdhhs.gov/dma/countyreports/index.htm>

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by BMA Cary. In fact, only 5.8% of all 2011 Incident ESRD patients in North Carolina's Network 6 were under the age of 35.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

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 applicant's 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 standings. ...*

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”<sup>1</sup>*

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<sup>1</sup> [www.cms.gov/medicare/end-stage-renal\\_disease/esrdnetworkorgainziations/downloads/esrdnetworkprogrambackgroundpublic.pdf](http://www.cms.gov/medicare/end-stage-renal_disease/esrdnetworkorgainziations/downloads/esrdnetworkprogrambackgroundpublic.pdf)



Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010:

*“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy...”*

The report validates the statistical constancy reported by 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:

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

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

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

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<b>Number and Percent of Dialysis Patients by Age, Race and Gender</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

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

The applicant demonstrates that 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 change to the future payor mix as indicated in this table.

Payor Source	In-Center
Commercial Insurance	18.9%
Medicare	73.4%
Medicaid	7.5%
Other: Self/Indigent	0.1%
<b>Total</b>	100.0%

As shown in the table above, the applicant projects that 80.9% of all in-center patients will have some or all of their services paid for by Medicare or Medicaid.

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 50, the applicant states the facility design provides easy access for handicapped persons and complies with the Americans with Disabilities Act (ADA) requirements. On page 51, 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 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 Cary 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.3, page 43, the applicant states that all health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. The facility has requested to establish a formal relationship with Wake Technical Community College. See Exhibit 19 for a copy of a letter from the Director of Operations, Raleigh Area, Fresenius Medical Care Cary Dialysis to the Department Head of the Nursing Program for Wake Technical Community College offering Cary 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

BMA proposes to relocate four dialysis stations to enhance geographic accessibility within Wake County from BMA Raleigh to BMA Cary for a total of 24 certified dialysis stations at BMA Cary upon completion of the proposed project and Project ID #M-8596-10.

In Section V.7, pages 45-46, 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 states its proposal will not have any effect on competition within Wake County. *“The patients to be served by this facility are existing dialysis patients, and future patients residing in western Wake County.”*

The applicant further states:

*“The DaVita Wake Forest facility is approximately 25 road miles from the BMA Cary facility. In addition, there are at least three other BMA facilities closer to the DaVita proposed facility. Consequently, this facility is not likely to be serving patients who might otherwise choose to receive dialysis treatment at the DaVita location.*

*...This facility has added value stemming from the strength of our relationship with Capital Nephrology.*

...

*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.*

...

*This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives.”*

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that relocating four dialysis stations from BMA Raleigh to BMA Cary will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- ◆ BMA adequately demonstrates the need, based on policy ESRD-2: Relocation of Dialysis Stations and enhancing geographic accessibility for patients within Wake County, to relocate four dialysis stations from BMA Raleigh to BMA Cary for a total of 24 certified dialysis stations at BMA Cary upon completion of the proposed project and Project ID # M-8596-10. The applicant also demonstrates

that the proposed project is a cost-effective alternative to meet the need to provide additional access to BMA Cary patients;

- ◆ BMA 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, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.

On page 21, 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 Cary 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.

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>BMA Cary</i>	<i>30.4%</i>	<i>51.9%</i>	<i>93.7%</i>	<i>46.8%</i>	<i>69.6%</i>

*Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 93.7% of facility treatment reimbursement is from Medicare.*

The applicant states on page 23 that BMA has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, Medicaid and Medicare recipients, gender, or other considerations. 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

The applicant currently provides dialysis services at BMA Cary. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Cary 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 78.26% with 3.13 patients per station.
- (2) Mortality rates;
- C- In Section II.1, page 10, the applicant provides the mortality rates as 20.4%, 10.7% and 20.3% 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.3, page 10, the applicant states, “*BMA Cary does not have a home training program.*” On page 17, the applicant states, “*Patients desiring to dialyze at home will be referred to the BMA Raleigh home training department.*”
- (4) The number of transplants performed or referred;

- C- In Section II.1, page 10, the applicant states BMA Cary referred 15 transplants in 2010 and 13 in 2011. Three transplants were performed in 2010 and two in 2011.
- (5) The number of patients currently on the transplant waiting list;
- C- In Section II.1, page 10, the applicant states “*BMA Cary has ten patients on the transplant waiting list.*”
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- C- In Section II.1, page 11, the applicant states that there were 149 total hospital admissions in 2011, 28 of which were dialysis related and 121 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, the applicant states that there were no patients at the facility in 2010 and 2011 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 Cary 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 Cary is an existing facility.

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

-NA- BMA Cary 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 Cary'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 Cary 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 Cary.*"

(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 34-36 for the methodology and assumptions the applicant uses to project patient origin as presented in the following table:

**BMA Cary- Projected Patient Origin**

County	Operating Year 1	Operating Year 2	County Patients as a Percent of TOTAL	
	In Center Patients	In Center Patients	Operating Year 1	Operating Year 2
Wake	87.2	90.8	100%	100%
Total	87.2	90.8	100%	100%

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 Cary 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, pages 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 Cary 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 Cary projects utilization of 3.63 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 15-17 and Section III.7, pages 34-36.

(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 15-17 and Section III.7, pages 34-36. The applicant projects an increase in its current Wake County patient utilization using the county 5-year AACR.

#### **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 17, the applicant states, "*Patients will be referred to Wake Med Cary or Wake Med Raleigh for diagnostic and evaluation services.*"

(2) maintenance dialysis;

-C- In Section II.1, page 17, the applicant states, "*The facility will provide in-center dialysis.*"

(3) accessible self-care training;

C- In Section II.1, page 17, the applicant states, "*Patients desiring self care training for in-center hemo-dialysis will be trained at BMA Cary; patients desiring self care training for home dialysis will be referred to the BMA Raleigh 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 17, the applicant states, "*Patients desiring to dialyze at home will be referred to the BMA Raleigh home training department.*" Exhibit 20 contains a copy of the home training center program agreement.

(5) x-ray services;

C- In Section II.1, page 18, the applicant states, "*Patients in need of x-ray services will be referred to Wake Med Cary, or Wake Med Raleigh.*"

(6) laboratory services;

- C- In Section II.1, page 18, the applicant states, “*BMA provides on site laboratory services through contract with Spectra Labs.*” See Exhibit 18 for the laboratory services agreement with Spectra Laboratories.
- (7) blood bank services;
- C- In Section II.1, page 18, the applicant states, “*Patients in need of blood transfusion will be referred to Rex Hospital in Raleigh.*”
- (8) emergency care;
- C- In Section II.1, page 18, 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 18, the applicant states, “*Patients in need of hospital admission will be referred to Wake Med Cary, or Wake Med Raleigh.*”
- (10) vascular surgery for dialysis treatment patients;
- C- In Section II.1, page 18, the applicant states, “*Patients will be referred to Capital Vascular Access Center or to Triangle Interventions; patients may also be referred to Wake Med.*”
- (11) transplantation services;
- C- In Section II.1, page 18, the applicant states, “*BMA Cary has a transplant agreement with University of North Carolina Medical Center.*” Exhibit 17 contains a copy of the executed transplant agreement.
- (12) vocational rehabilitation counseling and services; and
- C- In Section II.1, page 18, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the Wake Vocational Rehabilitation.*”
- (13) transportation.
- C- In Section II.1, page 18, the applicant states, “*Transportation services will be provided by C-Tran and Wake County Social Services.*”

*(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.2, page 53, the applicant states that BMA Cary 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 19, the applicant states that BMA Cary 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, pages 53-54, of the application, for information concerning the training and continuing education programs currently in place at BMA Cary. 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.