

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: November 29, 2012  
PROJECT ANALYST: Fatimah Wilson  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: F-10047-12 / Bio-Medical Applications of North Carolina, Inc.  
d/b/a BMA West Charlotte / Add two dialysis stations for a  
total of 29 stations / Mecklenburg 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 West Charlotte, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add two dialysis stations to its existing facility for a total of 29 certified dialysis stations upon completion of this project. The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of 15 dialysis stations in Mecklenburg County. The applicant is also eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported for BMA West Charlotte in the July 2012 SDR is 3.56 patients per station. This utilization rate was calculated based on 96 in-center dialysis patients and 27 certified dialysis stations. (96 patients / 27 stations = 3.5555 patients per station).

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

<b>OCTOBER 1 REVIEW—BMA West Charlotte—F-10047-12</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/11		88.89%
Certified Stations		27
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>27</b>
In-Center Patients as of 12/31/11 (SDR2)		96
In-Center Patients as of 6/3/11 (SDR1)		80
Difference (SDR2 - SDR1)		16
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	32
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/11	0.4000
(ii)	Divide the result of step (i) by 12	0.0333
(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)	0.4000
(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	134.4000
(v)	Divide the result of step (iv) by 3.2 patients per station	42.0000
	and subtract the number of certified and pending stations as recorded in SDR2 [27 ] to determine the number of stations needed	<b>15</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 15 stations. Step (C) of the facility need methodology states “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, page 40, of the 2012 SMFP is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial*

*resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### Promote Safety and Quality

In Section I.13, pages 4-7, the applicant discusses the quality of services provided at BMA West Charlotte, 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 Budgeting – tailored to ensure effective financial management of dialysis treatment centers
  - Facility Design and Maintenance – experienced architectural staff promotes development of efficiently designed facilities
  - Human Resources – develops productivity standards, job descriptions, staff performance review, personnel policies and procedures and employee relations
  - Information Systems – develops comprehensive facility automation including enhanced software for clinical management to support delivery of high quality care
  - Marketing and Managed Care – 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 16, the applicant states that 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 II.1, page 17, 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 II.3, page 25, the applicant states:

*“BMA West Charlotte 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 to individual projects to gather data as needed to conduct the “Check, Plan, Do, and Check, Act” process for addressing improvement opportunities.”*

See Exhibit 13 for copies of the CQI process.

In Section V, page 38, the applicant states that BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. The applicant goes on to state that the proposed project will not adversely affect quality, but rather, will enhance the quality of life for ESRD patients.

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

### Promote Equitable Access

In Section II.1, pages 18-19, the applicant states:

*“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, BMA is projecting that 84.8% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 5.4% are expected to be covered by VA. Thus, 90.2% [90.3%] of the In-Center revenue is derived from government payors. ...*

*BMA is also keenly sensitive to the second element of “equitable access” – time and distance barriers. BMA continually strives to develop facilities and dialysis stations in close proximity to the patient residence. At this time, Mecklenburg County has two [14] operational dialysis facilities. The July 2012 SDR reports that Mecklenburg County ESRD patient population is growing at an Average Annual Change Rate of 5.6%. As the dialysis patient population of Mecklenburg County continues to increase, the need for dialysis stations will continue to increase. ... BMA is planning to add two stations so that an adequate supply of necessary health resources remains in closer proximity to the residence location of patients residing in this area of Mecklenburg County.”*

The applicant states on page 20 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. The applicant further states, “A patient in need of dialysis is always welcomed at a BMA facility; the only requirement is proper referral from a physician.”

In Section VI.1, page 39, the applicant states that BMA has a long history of providing dialysis services to the underserved populations of North Carolina. On page 40, the applicant states that Medicare represents 81.5% of the payment source for treatments at BMA West Charlotte and Medicaid represents an additional 3.4%. Thus 84.9% of the in-center revenue is derived from government payors.

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

### Maximize Healthcare Value

In Section II.1, page 19, the applicant states:

*“BMA is not projecting a capital expenditure for this project. In projects which do involve capital expenditure BMA does not seek State or Federal monies to accomplish routine expansions or relocations; BMA does not seek charitable contributions to accomplish expansions. Rather, BMA through its parent company, FMC assumes the financial burden to complete addition of stations in an effort to ensure and adequate number of stations are available for the patients choosing to*

*dialyze at BMA West Charlotte. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. For example, within this application, BMA projects that 84.8% [84.9%] of the treatments are covered by Medicare and Medicaid, and an additional 5.4% are covered by VA. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence, BMA must work diligently to control costs of delivery for dialysis. BMA does.”*

The applicant adequately demonstrates that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed services 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 2012 SMFP 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, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA West Charlotte, proposes to add two dialysis stations to its existing facility for a total of 29 certified stations upon completion of this project.

Population to be Served

In Section IV.1, page 32, the applicant identifies the population it serves, as illustrated in the table below.

<b>County of Residence</b>	<b># of In-Center Patients Dialyzing 06-30-12</b>	<b>Percent of Total</b>
Mecklenburg	90	100.0%
<b>Total</b>	<b>90</b>	<b>100.0%</b>

In Section III.7, page 30, 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.

<i>County</i>	<i>Operating Year 1</i>	<i>Operating Year 2</i>	<i>County Patients as a Percent of TOTAL</i>	
	<i>In-center Patients</i>	<i>In-center Patients</i>	<i>Year 1</i>	<i>Year 2</i>
<i>Mecklenburg</i>	<i>100.4</i>	<i>106.0</i>	<i>100.0%</i>	<i>100.0%</i>
<b><i>Total</i></b>	<i>100.4</i>	<i>106.0</i>	<i>100.0%</i>	<i>100.0%</i>

On page 31, 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.7, page 30, the applicant states the application is filed pursuant to the Facility Need Methodology utilizing data from the July 2012 SDR and it proposes to add two dialysis stations to BMA West Charlotte for a total of 29 stations at the facility upon project completion.

In Section III.7, page 30, the applicant provides the following assumptions for the proposed project:

“Assumptions:

1. *This project is scheduled for completion and certification of stations at June 30, 2013. Thus, Operating Year 1 is the period from July 1, 2013 through June 30, 2014. Operating Year 2 is the period from July 1, 2014 through June 30, 2015.*
2. *On June 30, 2012 BMA Mecklenburg [West Charlotte] was providing dialysis treatment for 90 Mecklenburg County patients.*
3. *BMA assumes that the ESRD patient population of Mecklenburg County will continue to increase at a rate equal to the Mecklenburg County Five Year Average Annual Change Rate as published in the July 2012 SDR. That rate is 5.6%*

Methodology:

<i>BMA begins with the Mecklenburg County in-center patient population of BMA Mecklenburg [West Charlotte] as of June 30, 2012.</i>	90
<i>BMA projects this patient population forward for 12 months to June 30, 2013.</i>	$(90 \times .056) + 90 = 95.0$
<i>BMA projects the Mecklenburg County patient population forward for 12 months to June 30, 2014. This is the Operating Year 1 ending census.</i>	$(95.0 \times .045 [.056]) + 95.0 = 100.4$
<i>BMA projects the Mecklenburg County patient population forward for 12 months to June 30, 2015. This is the Operating Year 2 ending census.</i>	$(100.4 \times .056) + 100.4 = 106$

The applicant projects to serve 100 in-center patients or 3.45 patients per station ( $100 / 29 = 3.4482$ ) by the end of Year 1 and 106 in-center patients or 3.66 patients per station ( $106 / 29 = 3.6551$ ) by the end of Year 2 for the proposed 29 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 39, 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. The applicant projects that 90.3% of its patients will be covered by Medicare, Medicaid or VA. 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 two 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.

- (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, page 31, the applicant states the alternatives considered by BMA West Charlotte prior to the submission of this application, which include:

- 1) Maintain the Status Quo – Do Nothing. This alternative is not consistent with the facility need methodology for determining need for new dialysis stations. The applicant adequately identifies the population to be served, demonstrates the need the population has for two additional stations and the extent to which all residents of the area are likely to have access to the services proposed. Therefore, this alternative was not a viable option.
- 2) Add two dialysis stations for a total of 29 stations at BMA West Charlotte. The applicant states that the additional dialysis stations will be utilized at a rate greater than 80%, therefore, as the ESRD patient population of Mecklenburg County continues to increase, BMA must also provide access for the patients. BMA believes that this is the most suitable alternative.

The applicant adequately demonstrated the need for two additional stations based on the continued growth of the ESRD patient population in Mecklenburg County and the facility's projected utilization. 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 West Charlotte shall materially comply with all representations made in the certificate of need application and in the supplemental information requested by the Certificate of Need Section. In those instances where representations conflict, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA West Charlotte shall materially comply with the last-made representation.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA West Charlotte shall develop no more than two additional stations for a total of no more than 29 stations, which shall include any isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA West Charlotte 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 47, the applicant projects no capital cost for the proposed project. In Section IX, page 50, 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 September 17, 2012 from the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

*“BMA proposes to add two dialysis stations to the BMA West Charlotte dialysis facility. The project does not call for any capital expense on behalf of BMA.”*

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, if required, for the proposed project.

In Section X.1, page 51, 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 51 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 of the application and operating expenses in Section X.4 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	\$4,243,655	\$4,514,410
Operating Expenses	\$4,029,281	\$4,279,905
Profit	\$214,374	\$234,505

Source: Application pages 52 and 55.

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

In Section VIII.9, page 49, 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 44 and Section X pages 55 and 56, the applicant provides projected staffing and salaries. On page 45, the applicant states that BMA West Charlotte 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 46. 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

The applicant proposes to add two dialysis stations to its existing facility for a total of 29 certified dialysis stations upon completion of the proposed project. The July 2012 SDR shows there is a deficit of 15 dialysis stations in Mecklenburg County; however, in this application, the applicant is applying for additional stations based on the facility need

methodology. According to the July 2012 SDR, BMA West Charlotte is one of 14 dialysis facilities in Mecklenburg County with utilization rates ranging from 38.89% to 121.43%. The applicant adequately demonstrates the need for two additional stations based on the number of in-center patients it proposes to serve. Per the July 2012 SDR, as of June 25, 2012, the 27 station BMA West Charlotte facility was operating at 88.9% capacity ( $96 / 27 = 3.55$ ;  $3.55 / 4 = .8888$  or 88.9%). 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. Based on the calculations above, the applicant is eligible to expand its facility and may apply for additional stations. Upon completion of the proposed project, the facility will have 29 stations serving 100 patients (end of year 1) which is a utilization rate of 86.21% ( $100 / 29 = 3.45$ ;  $3.45 / 4 = .8621$  or 86.21%). 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 health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

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In Section VII.1, page 44, 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>3.00</i>	<i>0.00</i>	<i>3.00</i>
<i>Tech</i>	<i>10.00</i>	<i>0.00</i>	<i>10.00</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>0.20</i>	<i>0.00</i>	<i>0.20</i>
<i>Dietitian</i>	<i>0.50</i>	<i>0.00</i>	<i>0.50</i>
<i>Social Worker</i>	<i>0.70</i>	<i>0.00</i>	<i>0.70</i>
<i>Chief Tech</i>	<i>0.25</i>	<i>0.00</i>	<i>0.25</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>27.00</i>	<i>0.33</i>
<i>Clerical</i>	<i>1.00</i>	<i>12.00</i>	<i>1.00</i>

The table above, from page 44 of the application shows a total of 27.00 positions are to be filled for in-service and 12.00 positions are to be filled for clerical, however, the applicant clarified in supplemental information that the numbers 27 and 12 noted here are actually typographical errors and should not have been included on these lines within the table. Analysis of the salary budgeted on pages 55-56 confirms the use of 17.78 FTE in the calculations.

In Section VII.10, page 46, 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	6am to 11:30am	8	8	8	8	8	8
Afternoon	11:30am to 4:30pm	8	8	8	8	8	8

The applicant states in Section V.4 (c) that Dr. George Hart is the Medical Director for the facility. In Exhibit 21, the applicant provides a letter from Dr. Hart 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.

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In Section V.1, page 34, 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 15 of the application. Diagnostic and evaluation services, x-ray services, blood bank services, acute dialysis in an acute care services and transplantation services will be provided by Carolinas Medical Center. The applicant provided a copy of an existing transfer agreement between BMA West Charlotte and Carolinas Medical Center. The other services will be provided at the individually stated facility. Exhibits 16-20 and supplemental information contain documentation on service agreements to include: hospital affiliation agreements, transplant agreement, SPECTRA Lab agreement, Health Professional Education Facility agreements and Home Training agreements.

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;

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In Section VI.1(a), page 39, 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 West Charlotte facility [is] comprised of the following:*

Facility	Medicaid/Low	Elderly (65+)	Medicare	Women	Racial Minorities
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	<i>Income</i>				
<i>BMA West Charlotte</i>	2.2%	33.3%	73.3%	41.1%	83.3%

*Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 73.3% of the facility treatment reimbursement is from Medicare.*

*It is clear that BMA West Charlotte 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 40, the applicant states that historically, 81.5 % of patients at BMA West Charlotte have some or all of their services paid for by Medicare, 3.4% have some or all of their services paid for by Medicaid and an additional 5.4 % are covered by VA. Thus, 90.3% of the center revenue is derived from government payors. The table below illustrates the current historical payor mix for the facility.

<b>Payor Source</b>	<b>In-Center</b>
Commercial Insurance	9.7%
Medicare	81.5%
Medicaid	3.4%
VA	5.4%
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 Mecklenburg 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>2008-2009 % Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)</b>
Mecklenburg	15.0%	5.1%	20.1%
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 West Charlotte. 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 applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

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

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

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:

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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)

*“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:

<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 41, 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 43, 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 40, the applicant states it does not anticipate any change to the future payor mix as indicated in this table.

<b>Payor Source</b>	<b>In-Center</b>
Commercial Insurance	9.7%
Medicare	81.5%
Medicaid	3.4%
VA	5.4%
Other: Self/Indigent	0.1%
<b>Total</b>	100.0%

As shown in the table above, the applicant projects that 84.9% of all in-center patients will have some or all of their services paid for by Medicare or Medicaid with VA covering another 5.4%.

In Section VI.1(d), page 41, 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 42, the applicant states the facility design provides easy access for handicapped persons and complies with the Americans with Disabilities Act (ADA) requirements. On page 43, 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 42, 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 West Charlotte 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 36, 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 Gaston College. See Exhibit 19 for a copy of a letter from the Operations Manager for FMC West Charlotte to the Dean of Nursing for Gaston College offering BMA West Charlotte as a clinical training site. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add two dialysis stations to its existing facility for a total of 29 certified dialysis stations upon completion of the proposed project. The July 2012 SDR shows there is a deficit of 15 dialysis stations in Mecklenburg County; however, in this application, the applicant is applying for additional stations based on the facility need methodology. According to the July 2012 SDR, BMA West Charlotte is one of 14 dialysis facilities in Mecklenburg County with utilization rates ranging from 38.89% to 121.43%.

In Section V.7, page 38, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states its proposal to add two dialysis stations will not adversely affect quality, but rather, enhance the quality of the 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 West Charlotte 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 Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding two dialysis stations to the existing BMA West Charlotte will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- ◆ The applicant adequately demonstrates the need, based on "Facility Need", to add two dialysis stations for a total of 29 certified dialysis stations upon completion of the proposed project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to BMA West Charlotte patients;
- ◆ The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 and VII, pages 34-38 and 44-46, respectively, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.

On page 18, 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 39, the applicant states:

*“It is clear that BMA West Charlotte 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 West Charlotte</i>	<i>2.2%</i>	<i>33.3%</i>	<i>73.3%</i>	<i>41.1%</i>	<i>83.3%</i>

*Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 73.3% of facility treatment reimbursement is from Medicare.*

The applicant states on page 20 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 West Charlotte. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA West Charlotte 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 88.89% with 3.56 ( $96 / 27 = 3.5555$ ) patients per station.
- (2) Mortality rates;
  - C- In Section II.1, page 10, the applicant provides the mortality rates as 8.9%, 17.5% and 10.5% 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 West Charlotte is not certified for home dialysis.*" On page 15, the applicant states, "*Patients desiring home dialysis training will be referred to the BMA Charlotte home training department for training and follow-up care.*"
- (4) The number of transplants performed or referred;
  - C- In Section II.1, page 10, the applicant states BMA West Charlotte referred 18 transplants in 2010 and 22 in 2011. Two transplants were performed in 2010 and one in 2011.
- (5) The number of patients currently on the transplant waiting list;
  - C- In Section II.1, page 10, the applicant states "*BMA West Charlotte has three 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 10, the applicant states that there were 76 total hospital admissions in 2011, 23 of which were dialysis related and 53 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 West Charlotte 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 West Charlotte is an existing facility.

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

-NA- BMA West Charlotte 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 West Charlotte’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 West Charlotte 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 West Charlotte.”

(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 29-31 for the methodology and assumptions the applicant uses to project patient origin as presented in the following table:

County	Operating Year 1 2014	Operating Year 2 2015	County Patients as a Percent of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
Mecklenburg	100.4	106.0	100.0%	100.0%
<b>Total</b>	100.4	106.0	100.0%	100.0%

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

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

-NA- BMA West Charlotte 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 13, 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 West Charlotte 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 West Charlotte projects utilization of 3.45 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 13-15 and Section III.7, pages 29-31.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 13-15 and Section III.7, pages 29 -31. The applicant projects an increase in its current Mecklenburg 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 15, the applicant states, "*Patients will be referred to Mecklenburg Carolinas Medical Center.*" See supplemental information provided by the applicant dated November 7, 2012 for a copy of the hospital agreement with Carolinas Medical Center.
- (2) maintenance dialysis;
  - C- In Section II.1, page 15, the applicant states, "*The facility will provide in-center dialysis.*"
- (3) accessible self-care training;
  - C- In Section II.1, page 15, the applicant states, "*Patients desiring self care training will be referred to the BMA Charlotte 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 15, the applicant states, "*Patients desiring home dialysis training will be referred to the BMA Charlotte home training department for training and follow-up care.*" Exhibit 20 contains a copy of the home training center program agreement.
- (5) x-ray services;
  - C- In Section II.1, page 15, the applicant states, "*Patients in need of x-ray services will be referred to Carolinas Medical Center.*" See supplemental information provided by the applicant dated November 7, 2012 for a copy of the hospital agreement with Carolinas Medical Center.
- (6) laboratory services;
  - C- In Section II.1, page 15, 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 15, the applicant states, “*Patients in need of blood transfusion will be referred to Carolinas Medical Center.*” See supplemental information provided by the applicant dated November 7, 2012 for a copy of the hospital agreement with Carolinas Medical Center.
- (8) emergency care;
- C- In Section II.1, page 15, 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 15, the applicant states, “*Patients in need of hospital admission will be referred to Carolinas Medical Center.*” See supplemental information provided by the applicant dated November 7, 2012 for a copy of the hospital agreement with Carolinas Medical Center.
- (10) vascular surgery for dialysis treatment patients;
- C- In Section II.1, page 15, the applicant states, “*Patients will be referred to Metrolina Nephrology Access Center.*”
- (11) transplantation services;
- C- In Section II.1, page 15, the applicant states, “*BMA West Charlotte has a transplant agreement with Carolinas Medical Center.*” See supplemental information provided by the applicant dated November 7, 2012 for a copy of the hospital agreement with Carolinas Medical Center.
- (12) vocational rehabilitation counseling and services; and
- C- In Section II.1, page 16, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the Charlotte Mecklenburg Vocational Rehabilitation.*”
- (13) transportation.
- C- In Section II.1, page 16, the applicant states, “*Transportation services will be provided by Charlotte Area Transit System, CATS.*”

*(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 45, the applicant states that BMA West Charlotte 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 16, the applicant states that BMA West Charlotte 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 45, of the application, for information concerning the training and continuing education programs currently in place at BMA West Charlotte. 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.