

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

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

DECISION DATE: January 9, 2012

PROJECT ANALYST: F. Gene DePorter  
CON CHIEF: Craig Smith

PROJECT I.D. #: J-8754-11/ Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Four Oaks. Add three dialysis stations to FMC Four Oaks for a total of twenty-two dialysis stations upon project completion/ Johnston Co.

### 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.

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Bio-medical applications of North Carolina, Inc., [BMA] d/b/a FMC Four Oaks [FMC-FO] currently operates 19 dialysis stations at 5815 Highway 301 South, Four Oaks, North Carolina, 27524. BMA proposes to add three dialysis stations to FMC-FO for a total of 22 dialysis stations upon completion of this project # J-8754-11.

The 2011 State Medical Facilities Plan (2011 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2011 Semiannual Dialysis Report (SDR), the county need methodology shows a deficit of 3 stations.

The applicant is eligible to apply for additional stations based upon the facility need methodology because the facility use rate in the July 2011 SDR is 3.32 patients per station with a utilization rate of 83%. The use rate is calculated based upon 63 in-center patients and 19 certified dialysis stations [63 patients/19 stations = 3.32 patients per station].

**Table 1**  
**BMA-FMC Four Oaks-Facility Need Methodology**

Required SDR Utilization		80%
Center [7/31/11] Utilization Rate		82.9%
Certified Stations		19
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>19</b>
In-Center Patients as of [6/30/09] (SDR1)		63
In-Center Patients as of [12/31/10] (SDR2)		59
Difference (SDR2 - SDR1)		4
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change.	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of SDR1.	0.1356
(ii)	Divide the result of Step 2 by 12	0.0113
(iii)	Multiply the result of Step 3 by the number of months for the most recent month reported in the July 2011 SDR [12/31/10] until the end of calendar year 2011 [12 months]	0.1356
(iv)	Multiply the result of Step 4 by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	71.5424
(v)	Divide the result of Step 5 by 3.2 patients per station	22.3570
	and subtract the number of certified [19] and pending [0]stations as recorded in SDR2 [19] to determine the number of stations needed.	<b>3</b>

[NOTE: "Rounding" to the nearest whole number is allowed only in Step 1(C) and Step 2(B)(v). In these instances, fractions of 0.5000 or greater shall be rounded to the next highest whole number.

"The facility may apply to expand to meet the need established in Subpart (b)(2)(B)(v) [Step 6b in the table above], up to a maximum of ten stations."

Based upon application of the facility need methodology, additional stations are needed for this facility, as illustrated in the above table

Additionally, Policy Gen-3 on page 41, of the 2011 SMFP, is applicable.  
 Policy Gen-3: Basic Principles states:

*"A CON 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 (SMFP) shall demonstrate how the project shall promote safety and quality in the delivery of*

*health care services while promoting access and maximizing healthcare value for resources expended. A CON 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 CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”*

#### Promote Safety and Quality

In application Section II.3, page 30 the applicant states:

*“FMC Four Oaks, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. BMA-Four Oaks Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. These efforts receive full support and guidance of the clinical executive leadership team of BMA. Combined, the group brings hundreds of years of ESRD experience to the program. The program exemplifies the BMA total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals. Our Quality Management Program includes the following quality programs:*

- *Quality Improvement Methodology- Utilizing out-come driven, patient-centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System-integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Staff and Patient Education Program-ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program-systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team-experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team-experienced specialists in all aspects of Biomedical requirements (i.e. water treatment, reuse, disinfection and machine maintenance).*

*BMA’s Quality Management team works closely with each facility’s Quality Improvement team to:*

- *Improve patient outcomes*
- *Provide patient and staff training*
- *Develop Quality Improvement Programs*
- *Facilitate the Quality Improvement Process*

- *Continuously improve the care delivered*
- *Assure facilities meet high quality standards*

*Our goal is to have each facility serve as a quality improvement laboratory where successful outcomes can be disseminated throughout BMA.”*

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

Promote Equitable Access

In application Section VI.1 (a), page 45, the applicant states:

*“FMC Four Oaks Dialysis Center, projects to provide service to historically underserved populations. It is a 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*

*....For example, Medicare represented 80.3% of North Carolina Dialysis treatments in North Carolina dialysis treatments in BMA facilities in FY 2010. Medicaid represents an additional 4.3% in BMA facilities in FY 2010. Low income and medically underserved underinsured persons will continue to have access to all services provided by BMA.”*

The facility will conform to the North Carolina State Building Code, The National Fire Protection Association, 101 Life Safety Code, The Americans with Disabilities Act, ANSI Standards for Handicapped Access, and any other applicable requirements of federal, state and local bodies

The applicant adequately demonstrated that its projected volumes for the additional ESRD stations incorporate the basic principles in meeting the needs of patients to be served. Therefore, the application is consistent with Policy GEN-3 in the 2011 SMFP and the application is conforming to this criterion.

The medical reimbursement of the FMC Four Oaks facility is reflected in the patient categories that follow:

Facility	Medicaid Low Income	Elderly (65+)	Medicare	Women	Minorities
FMC Four Oaks	49.1%	47.3%	83.6%	50.1%	60.0%

The applicant indicates that it is clear FMC Four Oaks provides service to historically underserved populations.

Maximize Healthcare Value

In Section VI.1, pages 45-46, the applicant describes how the proposal will maximize healthcare value approaches. The applicant offers the following reasons for the BMA success in its 86 facilities in 40 North Carolina Counties:

*“The application calls for the purchase of dialysis machines, chairs and TVs [see Section VIII, (b), Table VIII.1, page 54 of the application]. The parent corporation, BMA, utilizes the most current information available in preparing estimates for the development of its dialysis service centers. BMA relies upon its national contracts for securing the best pricing possible for equipment and facility leasing among other costs associated with operations.*

*The BMA/FMC-Four Oaks purchases all the products utilized in the facility, from office supplies to dialysis stations, TVs and drugs to clinical supplies, under national contracts to secure the best products at the best prices.”*

The applicant adequately demonstrates the proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion. Consequently, the application is consistent with Policy GEN-3 and is conforming to this criterion.

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

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The June 30, 2010 SDR indicates a total of 19 certified dialysis stations at FMC-Four Oaks including an isolation station. By December 31, 2010 the facility continued to provide in-center dialysis service with 19 existing certified stations [inclusive of one isolation station] and no pending stations. With the filing of this application [J-8754-11] the applicant proposes to add three additional stations.

The Population to be Served

In application Section IV.7, page 19, the applicant indicates that as of December 31, 2010, 100% of its patients come from Johnston County. The applicant indicates that FMC Four Oaks had an in-center patient census of 63 as of 12/31/2010. At the close of Operating Year 2 (FY 2013/2014) the census is projected to be 74 with 100% of the patients continuing to come from Johnston County.

**Table 2**  
**DVA North Charlotte Dialysis Center**  
**In-Center and Home Patient Projections**  
**Operating Years 1 and 2**

COUNTY	Operating Year 1 FY 2012/2013		Operating Year 2 FY 2013/2014		County Patients as a Percent of TOTAL	
	In- Center Patients	Home Dialysis Patients	In- Center Patients	Home Dialysis Patients	Year 1	Year 2
Johnston	71.3	00.0	74.3	00.0	100%	100%
TOTAL	71.3	00.0	74.3	00.0	100%	100%

Source: Application J-8754, Section II, 4, page 13.

The applicant projected in-center patient origin for Operating Years 1 and 2 to be 100% Johnston County residents. In Exhibit 27 the applicant provides a service area map of patient origin for the current FMC Four Oaks facility. In Section II, 8, page 14, the applicant states the following;

*“At this time BMA is not projecting to serve patients from other counties at FMC Four Oaks. BMA will not restrict admissions based upon county of residence; there simply are not patients from other counties currently dialyzing in FMC Four Oaks and thus no basis to provide such projection.”*

In Operating Year 1, the applicant projects the patients per station ratio will be 3.75 [71.3 in-center patients/19 stations = 3.75]. In Operating Year 2 the ratio will be 3.91 [74.3 in-center patients/19 stations = 3.91] patients per station.

In Exhibit 27. the applicant provides a map with a 30 mile radius red circle and a green boundary inside the red circle that delineates the FMC-Four Oaks patient origin boundary.

Therefore, the applicant has adequately identified the population it will serve.

#### Need Analysis

In application Section III.7, pages 34-36, the applicant states the following:

*“The BMA-FMC-Four Oaks Dialysis Center had 63 in-center patients as of December 31, 2010 based on information included in Table A of the July 2011 Semiannual Dialysis Report (SDR). This is a station utilization rate of 88% based on the 19 certified stations in the facility. Of the 63 in-center patients cited in the SDR, 100% live in Johnston County The July 2011 SDR indicates in Table B that Johnston County has experienced an average annual change rate of 4.2% for the past five years.”*

The in-center patient population of FMC-FO as of December 31, 2010 was 63 patients. The calculations below continue from 2010 and go through June 30, 2014:

July 1, 2011- June 30, 2012- 63 patients X 1.042 = 66.6,  
 Utilization Rate-86.5% or 3.46 patients per station  
 July 1, 2012- June 30, 2013- 66 patients X 1.042 = 69.0,  
 Utilization Rate- 82% and 3.3 patients per station  
 July1, 2013-June 30, 2014-68.403 patients X 1.042 = 71.3  
 Utilization Rate- 81% and 3.2 patients per station  
 Operating Year 1 - July 1, 2012-June 30, 2013-68.4 X 1.042 = 71.3  
 Utilization Rate 81% and 3.3 patients per station  
 Operating Year 2-July 1, 2013-June 30, 2014- 74.3 X -042 = 74.3  
 Utilization Rate 85% and 3.4 patients per station.

The following table illustrates the applicant's assumptions and method used to project utilization.

**Table 3**  
**BMA-FMC-Four Oaks**  
**In-Center Patient Volume**

	<b>In-Center</b>
BMA beginning facility census as of 12/31/10	63 Johnston County Patients
BMA-FMC-Four Oaks projects growth for the FMC-FO patient population for one year using the Johnston County Five Year Average Annual Change Rate for one year to December 31, 2011.	$[63 \times 0.042] + 63 = 66$
BMA-FMC-Four Oaks projects growth of this population for one year closing 12/31/12. This is the expected completion date for the three station expansion project.	$[66 \times 1.042] = 68.4$
BMA-FMC-Four Oaks projects Johnston County dialysis patient population growth at 4.2%. This is the projected average annual population growth per year. This is the ending census for Operating Yr 2 [12/31/13].	$[68.4 \times 1.042] = 71.3$
BMA-FMC-FO projects the patient population forward for 12 months at 4.2%. This is the projected Johnston County Patient population for December 31, 2014. This is the end of operating year 2.	$[71.3 \times .042] + 71.3 = 74.3$

Based upon the above information and the growth from 63 to 74 in-center patients by 6/31/2014, FMC Four Oaks will have the following projected utilization rates for FMC-Four Oaks:

Operating Year 1:  
December 31, 2013

Station utilization: 71 Patients dialyzing on 22 stations = 3.23 patients per station  
 Facility utilization:  $71/(4 \times 22) = 0.8068$  or 81% utilization

Operating Year 2:  
December 31, 2014

Station utilization: 74 Patients dialyzing on 22 stations = 3.36 patients per station  
Facility utilization:  $74/(4 \times 22) = 0.8409$  or 84% utilization

Based upon the rounding adjustment, the applicant will have an in-center utilization of 3.23 patients per station by the end of Year 1 [December 31, 2013 or 71 patients / 22 stations = 3.23 patients per station] and a utilization of 3.36 patients per station by the end of Year 2 [74 patients / 22 stations = 3.36 patients per station]. The applicant's projections exceed the performance criteria for the proposed three additional stations in Operating Year 1. The average number of patients per station per week will exceed 3.2 patients per station per week as required by the performance standard 10A NCAC 14C .2203 (b). The application is conforming with 10A NCAC 14C. 2203 (b)-Required Performance Standards. Therefore, the applicant is approved for three additional stations.

FMC-FO has 19 certified operational stations and 4 proposed stations requested in this application [Project #- J-8754-11] for a total of 22 stations by June 30, 2014 project. The total of 22 stations also includes a one isolation station [see application Exhibit 28]. Home Dialysis training for FMC-FO is provided at Raleigh Clinic Dialysis Facility, Smithfield [reference the "Letter of Agreement" between FMC Four Oaks and Raleigh Clinic Dialysis Center. Exhibit 20].

In summary, the applicant adequately identified the population to be served and demonstrated the need the population has for the three additional dialysis stations inclusive of one isolation station. Therefore, the application is conforming to this criterion for a total of 22 ESRD stations inclusive of one isolation station.

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

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In application Section III.9, page 36, the applicant indicates that they considered; a) applying for less stations. However, the applicant realized they would be over 80% occupancy by the end of the first operating year and b) BMA could have elected not applying. However, considering the utilization rate of FMC-FO and the Four Oaks and BMA historical commitment to providing dialysis treatment in a setting as convenient for the patient, not applying would not be appropriate.



The application is conforming or conditionally conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20) and the Criteria and Standards for End Stage Renal Disease Services. Therefore, the application is conforming to this criterion subject to the following conditions.

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care-Four Oaks shall materially comply with all representations made in its certificate of need application.**
  2. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care-Four Oaks shall develop no more than three additional stations for a total of 22 stations including an isolation room.**
  3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care-Four Oaks shall install plumbing and electrical wire through the walls for no more than a total of 22 dialysis stations including any isolation stations.**
  4. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care-Four Oaks shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.1(b), page 54, the applicant projects that the total capital cost of this project will be \$16,375 including the lease for the dialysis machines which will be leased, \$6,375 will be for other equipment and furniture not included elsewhere in the budget, \$5,000 for other contractor fees, \$4,000 for water treatment equipment and \$5,000 for total construction contract. The applicant projects no initial start-up costs or initial operating expenses. BMA will be using accumulated reserves to finance this project. Please reference a letter of commitment from Mark Fawcett, Vice President and Assistant Treasurer, Fresenius Medical Care Holdings, Inc. [Exhibit 24]. This letter will verify the availability of FMC funds for this project.

In Section VIII.7. (a) Exhibit 10. contains copies of the most recent audited FMC Holdings. The 2010 Consolidated Balance sheet reflects more than \$153 million in cash and current assets exceeding \$2.6 billion. FMC has the resources necessary for all its projects. The amount shown on page 2 of the consolidated balance sheet in the financial statements is more than adequate to finance all CON projects proposed by BMA.

Exhibit 24 contains a letter from Mark Fawcett, Vice President Fresenius Medical Care Holdings and the parent company of National Medical Care and Bio-Medical Applications of North Carolina. Mr. Fawcett indicates that the capital expenditure for this project is \$16,375. Further, Mr. Fawcett states that as Vice President he is authorized and does hereby authorize the addition of the proposed stations and states further that he is authorized to commit the cash reserves for the capital cost of \$16,375 as may be needed for this project.

**Table 4**  
**BMA-FMC-Four Oaks Dialysis Center**  
**Four Oaks, North Carolina**  
**Capital Cost Components (All Equipment is Leased)**

Dialysis Machines	Leased
Equipment & Furniture	\$ 6,375
Water Treatment Equipment	\$ 4,000
Architect Fee	\$ 500
<b>TOTAL</b>	<b>\$16,375</b>

In Section IX.2, page 58, the applicant states that once these [three] stations are certified they will have no effect on the operating budget of the facility. In Section VIII.3(a), page 55, the applicant states that the capital cost for this project will be funded with accumulated reserves of Bio-Medical Applications the ultimate parent of the applicant. Exhibit 24 contains a letter from Mr. Mark Fawcett; Vice President of Fresenius Medical Care Holdings, dated September 15, 2011, in which he states the following:

*“As Vice President, I am authorized and do hereby authorize the addition of [three] dialysis stations, for the capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$16,375 as may be needed for this project.”*

The Medicare/Medicaid rates in Section X.1 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare/Medicaid Services. The applicant projects net revenue in Section X.2, pg. 60 of the application and operating expenses in Section X 4, pg. 63 of the application. The applicant projected revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the following table.

	Project Year 1	Project Year 2
Net Revenue	\$3,030,374	\$3,167,306
Operating Expenses	\$2,866,946	\$2,988,644
Net Earnings	\$163,428	\$178,662

Therefore, the applicant has adequately demonstrated that the financial feasibility of the proposal is based on reasonable and supported projections regarding revenues and operating expenses. Therefore, the application is conforming to this criterion.

In application Section X.1, page 59, the applicant provides the following table showing BMA/FMC-Four Oaks the allowable charge per treatment and payment source.

**Table 5**  
**BMA-FMC-Four Oaks Dialysis Center**  
**Allowable Charges per Treatment**

Source of Payment	Allowable Charge per Treatment
Medicare	\$136.00
Medicaid	\$136.00
Medicare/Medicaid	\$136.00
Commercial Insurance	\$520.00
Medicare/Commercial	\$136.00
VA	\$136.00

The rates in the above table are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services. In the revenue and expense statements in Sections X.2, X.3, and X.4, pages 59-63, the applicant projects that revenues will exceed operating costs in each of the first two years of operation. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including the number of treatments to be provided. See application Section X.1 through 5, pages 59-65, for the applicant's assumptions.

In summary, the applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project. Further, the applicant adequately demonstrated that the financial feasibility of the project is based on reasonable projections of procedures, revenues and operating costs. Therefore, the application is conforming with this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

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The applicant is proposing to add three additional dialysis stations to the existing BMA-FMC-Four Oaks for a total 22 dialysis stations upon completion of this project. The methodology used by the applicant to determine the number of new stations that are needed to serve the facility's projected number of patients is consistent with the facility need methodology in the 2011 State Medical Facilities Plan and the July 2011 SDR. Therefore, the applicant adequately demonstrated that the proposal will not result in unnecessary duplication of existing or approved health service capabilities or facilities and 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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The following table illustrates current staffing and projected staffing during the first two operating years following completion of the project, as reported by the applicant in application Section VII.1, page 50-51.

**Table 6**  
**Bio-Medical Applications of North Carolina, Inc.**  
**D/b/a FMC-Four Oaks, North Carolina.**  
**Current and Proposed Staffing**

<b>Position</b>	<b>Current # of Full Time Equivalent Positions (FTEs)</b>	<b>Proposed # of Full Time Equivalent Positions (FTEs)</b>	<b>Difference</b>
Registered Nurses	1.75	0.25	0.25
Tech.	6.00	1.00	1.00
HT RN	0.00		
PCT	0.00		
LPN/Nurse Asst.	0.00		
Techs	6.00		
Clinical Nurse Manager	1.00		
Medical Director		Contract Employee	
Administrator	0.15	0.00	0.0
Dietician	0.36	0.00	0.0
Social Worker	0.42	0.00	0.0
Chief Technician	0.20		
Equipment Techs	0.60		
Biomed Tech.	0.00	0.00	0.0
Unit Secretary	0.00	0.00	0.0
Clerical/Purchasing	0.80		
In-Service	0.20		
Medical Records	0.00		
Other -Reuse	0.00	0.00	0.0
<b>TOTAL</b>	<b>18.48</b>	<b>1.25</b>	<b>1.25</b>

As shown in the above table, the applicant proposes to employ a total of 19.73 FTEs.

Staffing of the proposed dialysis stations during the first two full operating years following completion of the project will result in the addition of 1.25 FTE positions; [1.0 PCT/FTE and 0.25 R.N/FTE]. In application Section V.4(c), page 43, the applicant states that Dr. Kevin Lee, M.D [Certified Nephrologist] will serve as medical director of the facility. Application Exhibit 21. contains a letter signed by Dr. Bruce a practicing Nephrologists' and medical director of BMA-FMC-Four Oaks Dialysis Center.

The applicant adequately demonstrated the availability of resources, including health manpower and administrative personnel, including the medical director, for the proposed service. Therefore, the information provided in application Sections V. and VII and application Exhibit 14. are reasonable and credible. The applicant demonstrates the availability of adequate health man power and management personnel, including a medical director, for the provision of the proposed services. Therefore, the applicant is conforming to this application..

- (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 application Section V.1, page 40, the applicant lists the providers of the necessary ancillary and support services that are currently provided at BMA/FMC-Four Oaks. The applicant states that the existing ancillary or support services have sufficient capacity to support the 3 new dialysis stations. The applicant adequately demonstrated the availability of the necessary ancillary and support services and coordination with the existing health care system and therefore is conforming to this criterion. [See also 10A NCAC 14C .2204 in these findings.]

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

- (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;  
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;  
(iii) would cost no more than if the services were provided by the HMO; and  
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.

- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

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In application Section VI.1 (a), page 45, the applicant states:

*“BMA has a long history of providing dialysis services to underserved populations in North Carolina. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly or other traditionally underserved persons.*

*BMA-FMC-Four Oaks makes every reasonable effort to accommodate all of its patients; especially those with needs such as the handicapped, patients attending school or patients who work. BMA-FMC-Four Oaks provides dialysis six days per week with two patient shifts per day to accommodate patient need.*

*BMA-FMC-Four Oaks does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.*

*BMA/FMC-Four Oaks maintains an open door policy of accepting all patients, regardless of ability to pay, who develop end stage renal disease while residing in the service area of BMA/FMC-Four Oaks.”*

The applicant indicates that approximately 84.6% of BMA/FMC Four Oaks current patients have some or all of their services paid for by Medicare or Medicaid [80.3% Medicare + 4.3% Medicaid = 84.6%].

**Table 7.**  
**BMA/FMC-Four Oaks Dialysis**  
**Current and Projected Reimbursement**  
**Percentage by Payor**

June 30, 2011 Payor	IC Payor Source
Private Pay	0.0%
Commercial Insurance	8.5%
Medicare	78.8%
Medicaid	7.3%
Medicare/Medicaid	0.0%
State Kidney Program	0.0%
VA	3.7%
Medicare/Commercial	0.0%
Total	100.0%

The applicant projects that the reimbursement percentage based on historic experience will continue to be the same as shown in the above table. The applicant makes note that payer mix should be considered dynamic and not fixed.

“In Section VI, 46 (c) the applicant states; “*Projections of future reimbursement are a function of historical performance. As the above table demonstrates, BMA does not expect any significant changes in the payer mix for this facility. BMA has projected the same payer mix as noted above; however, the payer mix is dynamic and not fixed.*”

The North Carolina Division of Medical Assistance (NCDMA) 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 as of June, 2010. The data in the table was obtained on November 28, 2011. More current data, particularly with regard to the estimated uninsured percentages, was not available.

**Table 8.**  
**Medicaid Eligible's**  
**Johnston County**

COUNTY	TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION ①	TOTAL # MEDICAID ELIGIBLE'S AGE 21 AND OLDER AS % OF TOTAL POPULATION ②	% UNINSURED CY 2005 (ESTIMATE BY CECIL G. SHEPS CENTER) ③
Johnston	17%	43%	20%
Statewide	17%	44%	20%

Source: [www.ncdhhs.gov/dma](http://www.ncdhhs.gov/dma) -Medicaid Eligible's. Johnston County June 2010.

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 the older segment of the population, particularly for services offered by BMA/FMC-Four Oaks.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligible's who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA compares the number of persons eligible for dental services to the number actually receiving services. The statewide percentage was 45.9% for those age 20 and younger and 30.6% 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 applicant adequately demonstrated that it provides 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 application Section VI.1 (f), page 47 he applicant states:

*"BMA of North Carolina facilities do not have an 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 application Section VI.6 (a), page 48, the applicant states that there have been no civil rights equal access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services;

C

In application Section VI.1(c), page 45 the applicant states:



*“The following table represents the most recent historical experience for FMC Four Oaks.”*

**Table 9.**  
**Biomedical Applications of North Carolina**  
**d/b/a-FMC-Four Oaks**  
**Historic Payor Source for FMC Four Oaks**

IC Payor Source	Percentage
Private Pay	0.0%
Commercial Insurance	8.5%
Medicare	78.8%
Medicaid	7.3%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
VA	3.7%
Self Pay/Indigent	1.8%
Total	100.00%

**Table 10.**  
**Biomedical Applications of North Carolina**  
**d/b/a-FMC-Four Oaks**  
**Projected Payor Source for FMC Four Oaks**

IC Payor Source	Percentage
Private Pay	0.0%
Commercial Insurance	8.5%
Medicare	78.8%
Medicaid	7.3%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
VA	3.7%
Self Pay/Indigent	1.8%
Total	100.00%

As shown in the above table, 86% [78.8%-Medicare + 7.3% Medicaid = 86%] of the projected payer mix will continue to represent the 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 application Section VI.5 (a), page 48 the applicant states:

*“Those Nephrologists who apply for and receive medical staff privileges will admit patients with end stage renal disease to*

*the facility. FMC Four Oaks will have an open policy, which means that any Nephrologist may apply to admit patients to the facility. The attending physicians receive referrals from other Nephrologists or hospital emergency rooms."*

The applicant demonstrated that it will provide a range of means by which a person can access services. Therefore, the information provided is reasonable and creditable with 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

See Exhibits 14 and 15 for training materials and Exhibits 19 and 20 for training agreements with Johnston Community College and the Raleigh Clinic Dialysis Facility. The applicant demonstrated that the proposed project will accommodate the clinical needs of health professional training programs at Johnston Community College [reference Exhibit 19]. The information provided in Section V.3 and related exhibits is reasonable and credible and supports the finding of conformity with 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

See Sections II.6, II.7, III.1, III.2, III.3, III.6, III.7, V.7, VI, VII, and XI.7. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the FMC Four Oaks addition of three dialysis stations for a total of 22 stations upon project completion would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The addition of three dialysis stations to FMC Four Oaks is needed to meet the needs of the increasing dialysis population in the area. The proposal is a cost-effective alternative to meet the need and to improve access to the proposed services. [see Criteria (1), (3), (4) (5) and (12) for additional discussion];
- The applicant has and will continue to provide quality services [see Criteria (7), (8) and (20) for additional discussion];

- The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

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 as Bio-medical Applications of North Carolina, Inc. d/b/a -Fresenius Medical Care-Four Oaks. According to the files in the Certification Section of DHSR, the facility operated in compliance with Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore the applicant 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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200, with the exception of .2202(b) (3). The specific findings are discussed below.

**.2202 INFORMATION REQUIRED OF APPLICANTS**

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

.2202(a)(1) *Utilization rates;*

-C- See application Section III.2 and 7, pages 33 and 34-35.

.2202(a)(2) *Mortality rates;*

-C- See application Section IV.2, page 38 FY 2010 Mortality Rate-2008-11.3%; 2009-12.7% and 2010-6.6%.

- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*  
-NA- Applicant does not provide home dialysis training.
- .2202(a)(4) *The number of transplants performed or referred;*  
-C- See application Section IV.4, page 38, in FY 2010, 34 patients were referred and 1 received a transplant.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*  
-C- See application Section IV.5, page 38, 2 patients are on the waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*  
-C- See application Section IV.6, page 38, There were 11 dialysis related hospital admissions and 35 non-dialysis related hospital admissions.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*  
-C- See application Section IV.7, page 38-39, there are 0 infectious disease patients.

*(b) An applicant that proposed development a new facility, to 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:*

- .2202(b)(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- Bio-Medical Applications of North Carolina-FMC-Four Oaks Dialysis Center is an existing facility.
- .2202(b)(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- FMC-Four Oaks is an existing facility  
[Reference Exhibit 17].

.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- FMC-Four Oaks is an existing facility.

.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Section XI.6(f), FMC-Four Oaks is an existing facility. See page 68 and Exhibit 11.

.2202(b)(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- FMC Four Oaks Dialysis is an existing facility.

.2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements*

-C- See application Section XI.6(g), page 68., the applicant states;

*“BMA of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations for staffing, fire safety and equipment, physical environment and other relevant safety and health requirements.”*

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected must be stated.*

-C- See application Section III.7, pages 334-35.

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- FMC-Four Oaks is an existing facility with all patients residing in Johnston County.

.2202(b)(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- See application Section VI.1 (d), pages 46-47 and Exhibit 8.

### **.2203 PERFORMANCE STANDARDS**

.2203(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 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/FMC-Four Oaks is an existing facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility 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- In Section III.7, page 35 the applicant projects to serve 71 in-center patients by the end of Year 1, which equates to 3.23 patients per station [ $71 / 25 = 3.23$ ].

.2203(c) *An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected*

-C- In application Section III.7, pages 34-36, the applicant provided the assumptions and methodology used to project utilization of the additional stations. See Criteria 3 for discussion.

### **.2204 SCOPE OF SERVICES**

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

.2204(1) *Diagnostic and evaluation services;*

-C- See application Section V.1 (e), page 40 [Johnston Memorial Hospital] Exhibit 16- Hospital Affiliation Agreement.

.2204(2) *Maintenance dialysis;*

-C- See application Section V.1(c) [provided by applicant], page 40.

.2204(3) *Accessible self-care training- Home training is provided at BMA Raleigh.*

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- See application Section V.2 (d), page 41—Home dialysis support provided by BMA Raleigh Home Training Clinic.

.2204(5) *X-ray services;*

-C- See application Section V.1 (g), page 40 [Johnston Medical Center].

.2204(6) *Laboratory services; Section V.1.(h), page 40*

-C- See Exhibit 18- Service provided by SPECTRA Laboratory Services.

.2204(7) *Blood bank services;*

-C- See application Section V.1 (i), page 40 [Johnston Medical Center] and application Exhibit 18.

.2204(8) *Emergency care;*

-C- See application Section V.1 (b), page 40 and application Exhibit 16.

.2204(9) *Acute dialysis in an acute care setting;*

-C- See application Section V.1 (a), page 40 and application Exhibit 16.

- .2204(10) *Vascular surgery for dialysis treatment patients;*
  - C- See application Section V.1 (p), page 40 [Capital Access Center; Johnston Medical Center] and application Exhibit 16.
- .2204(11) *Transplantation services;*
  - C- See application Section V.1(f), page 40 [Duke UMC, UNC Medical Center and CMC]
- .2204(12) *Vocational rehabilitation counseling and services;*
  - C- See application Section V.1 (o), page 40. [Johnston Count Voc. Rehab.
- .2204(13) *Transportation*
  - C- See application Section V.1(q), page 40 [JCATS Services and various other providers].

**.2205 STAFFING AND STAFF TRAINING**

- .2205(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- See application Sections VII.1 and 2. ; pages 50-51.
- .2205(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- See application Section VII.5, page 51 and application Exhibits 14 and 15.