

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 1, 2012
FINDINGS DATE: June 1, 2012
PROJECT ANALYST: Fatimah Wilson
SECTION CHIEF: Craig Smith

PROJECT I.D. NUMBER: F-8792-12 / Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Nations Ford / Add two dialysis stations to the existing facility for a total of 24 stations upon project completion / 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.

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Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Nations Ford currently operates a 22-station dialysis facility located at 7901 England Street in Charlotte, NC. The applicant proposes to add two dialysis stations to the existing facility for a total of 24 stations upon completion of this project and Project I.D. #F-8699-11. The January 2012 SDR indicates a total of 26 certified dialysis stations at BMA Nations Ford as of June 30, 2011. On April 13, 2012, the Licensure and Certification Section of the Division of Health Service Regulation (DHSR) decreased the certified number of dialysis stations at BMA Nations Ford from 24 to 22 stations (transferred to FMC Matthews) and increased the certified dialysis stations at FMC Matthews from 19 to 21 (transferred from BMA Nations Ford) pursuant to CON Project I.D. #F-8699-11. The effective date for the certification of 22 stations at BMA Nations Ford is April 16, 2012. Therefore, the facility is currently certified for 22 stations.

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 January 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility. However, the applicant is eligible

to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for the BMA Nations Ford in the January 2012 SDR is 3.346 patients per station. This utilization rate was calculated based on 87 in-center dialysis patients and 26 certified dialysis stations as of June 30,2011 (87 patients / 22 stations = 3.35 patients per station). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

**ESRD Facility Need Methodology
 April Review—January SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/11		84%
Certified Stations		26
Pending Stations		0
Total Existing and Pending Stations		26
In-Center Patients as of 6/30/11 (SDR2)		87
In-Center Patients as of 12/31/10 (SDR1)		84
Difference (SDR2 - SDR1)		3
Step	Description	Result
(i)	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/ __	0.0714
(ii)	Divide the result of step (i) by 12	0.0060
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January [2012] SDR (6/30/11) until the end of calendar year 2011 (6 months)	0.0357
(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	90.1071
(v)	Divide the result of step (iv) by 3.2 patients per station	28.1585
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	2

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

Step C of the facility need methodology states *“The facility may apply to expand to meet the need established in (2)(B)(v) [Step (v) in the table above], up to a maximum of ten stations.”* Based on the facility need methodology for dialysis stations, the number of stations needed is two and the applicant proposes to add no more than two new stations. Therefore, the application is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2012 SMFP is also applicable to this review. Policy GEN-3 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 will promote safety and quality in the delivery of health care services while promoting equitable 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 Section II.1, pages 18-22, the applicant states:

“BMA is a high quality health care provider. The Table at II.3 D provides a comparison of quality indicators for the BMA Nations Ford dialysis facility. In addition, BMA 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 application Section II.3, pages 25-28, the applicant describes the methods it uses to ensure and maintain quality of care which include the following:

Facility programs

- 1) Quality Improvement Program;*
- 2) Staff Orientation and Training; and*
- 3) In-service Education*

Corporate programs

- 1) Technical Audits;*
- 2) Continuous Quality Improvement*
- 3) External Surveys - DFS Certification Surveys*
- 4) Core Indicators of Quality; and*
- 5) Single Use Dialyzers”*

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

Promote Equitable Access

In Section II.1, page 20, the applicant states,

“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare/Medicaid; in fact, within this application, BMA is projecting that 82.3% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 3.4% are expected to be covered by VA. Thus, 85.7% of the In-Center revenue is derived from government payors.

10A NCAC 2202 (b)(8) requires a commitment by BMA ‘to admit and provide 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.’ BMA provides such assurances within Section VI of this application.

...

BMA is also keenly sensitive to the second element of ‘equitable access’ - time and distance barriers. At this time, Mecklenburg County has eleven operational dialysis facilities. The January 2012 SDR reports that Mecklenburg County ESRD patient population is growing at an Average Annual Rate of 5.1%. As the dialysis patient population of Mecklenburg County continues to increase, the need for dialysis stations will continue to increase. Over the years, BMA has sought to develop new facilities and new dialysis stations in an effort to make dialysis more convenient to the patient. This application to add two dialysis stations to BMA Nations Ford is another example of BMA efforts to meet the needs of the ESRD patient population of Mecklenburg County. 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.”

In application Section VI.1 (a), page 41, the applicant states,

“...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.

BMA of North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. For example, Medicare represented 79.7% of North Carolina dialysis treatments in BMA facilities in FY 2011. Medicaid treatments represented an additional 4.8% of treatments in BMA facilities for FY 2011. Low income and medically underserved 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 requirement of federal, state, and local bodies.”

In Section VI.2, page 43, the applicant states,

“The design of the facility is such that handicapped persons will have easy access to the facility; the facility will comply with ADA requirements. It was constructed in compliance with applicable sections of North Carolina State Building Code, Vol. #1-General Construction, which lists minimum requirements for the handicapped applicable to institutional and residential structures. In addition, wheelchairs are always available for transporting patients who are unable to stand or walk.”

In Section VI.7, page 45, the applicant states,

“BMA’s admission policy states that ‘patients shall be accepted for treatment at BMA when such treatment is deemed indicated and appropriate according to the clinical judgment of the patients’ attending physician. No arbitrary criteria with respect to the patient’s age or magnitude of complicating medical problems are established.’

BMA also has an AIDS policy that states ‘a diagnosis of AIDS or HIV-positive status (absent other contraindications) is not acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.’

Please see Exhibit 9 for a copy of policy/procedure.”

The applicant adequately demonstrates that medically underserved groups will have equitable access to the proposed services.

Maximize Healthcare Value

In Section II.1, page 20, the applicant states:

“BMA is not projecting a capital expenditure for this project. BMA is not seeking State or Federal monies to develop the CON application or the additional dialysis stations at the facility; BMA is not seeking charitable contributions. ”

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.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities of the 2012 SMFP states, “Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.” There is no capital cost of the proposed project. Therefore, Policy GEN-4 is not applicable.

The application is consistent with the facility need methodology and 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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BMA Nations Ford proposes to add two dialysis stations to the existing facility for a total of 24 stations upon completion of this project and Project I.D. #F-8699-11. The January 2012 SDR indicates a total of 26 certified stations at BMA Nations Ford, as of June 30, 2011. Based on patient origin information provided in the table in Section III.7, page 31 of the application, the applicant does not propose any home training.

Population to be Served

The following table illustrates the current patient origin at BMA Nations Ford, as reported by the applicant in Section IV.1, page 33.

**BMA Nations Ford
 Patient Origin as of 12/30/11**

County of Residence	# of Patients Dialyzing In-Center
Mecklenburg	99
Total	99

In Section III.7, page 31, the applicant provides the projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

BMA Nations Ford -Projected Patient Origin

COUNTY	YEAR ONE: 2012/2013	YEAR TWO: 2013/2014	COUNTY PATIENTS AS A PERCENT OF TOTAL
	In-center patients	In-center patients	Operating Year 1
Mecklenburg	108.0	113.5	100%
TOTAL	108.0	113.5	100%

The applicant adequately identified the population proposed to be served.

Demonstration of Need

The January 2012 SDR indicates a total of 26 certified dialysis stations at BMA Nations Ford as of June 30, 2011. On April 13, 2012, the Licensure and Certification Section of the Division of Health Service Regulation (DHSR) decreased the certified number of dialysis stations at BMA Nations Ford from 24 to 22 stations (transferred to FMC Matthews) and increased the certified dialysis stations at FMC Matthews from 19 to 21 (transferred from BMA Nations Ford) pursuant to CON Project I.D. #F-8699-11. The effective date for the certification of 22 stations at BMA Nations Ford is April 16, 2012. Therefore, the facility is currently certified for 22 stations. In this application, the applicant will add two dialysis stations for a total of 24 stations upon completion of this project.

In Section III.7, pages 31-32, the applicant states,

“Table IV.1 demonstrates that BMA Nations Ford is serving 99 Mecklenburg County patients as of December 31, 2011. In CON Project I.D. #F-8699-11, BMA proposed that four patients from BMA Nations Ford would transfer to FMC Matthews. At the time this application is prepared, two of the four stations have been relocated from Nations Ford to FMC Matthews. BMA also notes that the FMC Matthews census has significantly increased and assumes that all patients desiring to transfer from BMA Nations Ford have completed their transfer.”

The January 2012 SDR states that the Average Annual Change Rate for the last 5 years for Mecklenburg County is 5.1%. The applicant utilized the growth rate of 5.1% for in-center patients to project utilization through Year 2.

<i>BMA Nations Ford</i>	<i>In-Center</i>
<i>BMA begins with facility census as of December 31, 2011</i>	99
<i>The census is increased by the Mecklenburg County Five Year Average Annual Change Rate for nine months to December 31, 2012</i>	$[99 \times (.051 / 12 \times 9)] + 99 = 102.8$ $[(99 \times .051) / 12 \times 9 + 99] = 102.8$
<i>BMA projects the patient population forward for 12 months to December 31, 2013</i>	$(102.8 \times .051) + 102.8 = 108.0$
<i>BMA projects patient population forward for 12 months to December 31, 2014</i>	$(108.09 \times .051) + 108.0 = 113.5$

“BMA also recognizes that Craig Smith, CON Section Chief, has previously indicated that patients are not partial patients, but rather are whole. In financial projections and utilization projections for this application, BMA has rounded down to the whole number.

BMA projected utilization calculation are a function of the projected year end census rounded down to the whole number. Utilization at BMA Nations Ford is expected to be

Operating Year 1

*113 patients dialyzing on 24 stations = 4.71 patients per station
 $113 / (4 \times 24) = 1.177$, or 117.7%*

Operating Year 2

*120 patients dialyzing on 24 stations = 5.0 patients per station
 $120 / (4 \times 24) = 1.25$, or 125.0%*

It is noted by the project analyst that the projected utilization stated above is inconsistent with projected utilization previously stated by the applicant. The applicant stated above that the facility would have 113 in-center patients in operating year one and 120 in-center patients in operating year two. In the projected utilization and assumptions tables illustrated previously, the applicant stated that the facility would have 108 in-center patients dialyzing in operating year one and 113.5 in-center patients dialyzing in operating year two. The applicant clarified in a response letter for request for additional information dated May 16, 2012 that the projected utilization is 108 in-center patients for operating year one and 113.5 in-center patients for operating year two. Thus, the corrected projected utilization should be:

Operating Year 1

*108 patients dialyzing on 24 stations = 4.5 patients per station
 $108 / (4 \times 24) = 1.125$, or 112.5%*

Operating Year 2

*113 patients dialyzing on 24 stations = 4.7 patients per station
 $113 / (4 \times 24) = 1.177$, or 117.7%*

Projected utilization at the end of Year 1 is equal to or greater than 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b) and the number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future

growth. It is also noted that with no growth in utilization, the current population of 99 in-center patients utilizing 24 stations would exceed four patients per station.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for two additional dialysis stations. Therefore, the application is conforming to this criterion.

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

NA

The January 2012 SDR indicates a total of 26 certified dialysis stations at BMA Nations Ford as of June 30, 2011. On April 13, 2012, the Licensure and Certification Section of the Division of Health Service Regulation (DHSR) decreased the certified number of dialysis stations at BMA Nations Ford to 22 stations pursuant to CON Project I.D. #F-8699-11.

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

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In Section III.9, pages 32, the applicant discusses the alternatives it considered to meet the need for the proposed services prior to the submission of its application. As shown in Criteria (1), the application is conforming to the facility need methodology for additional stations. Furthermore in Criteria (3), the applicant adequately demonstrates the need for two additional stations based on the number of in-center patients it proposes to serve. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (5), (6), (7), (8), (13), (14), (18a), (20), and the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The applicant adequately demonstrates that the proposal to add two dialysis stations 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, d/b/a, BMA Nations Ford shall materially comply with all representations made in its certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, d/b/a, BMA Nations Ford shall develop and operate no more than two (2) additional dialysis stations for a total of 24 certified stations following completion of this project and Project I.D. #F-8699-11 (FMC Matthews shall relocate four dialysis stations from**

BMA Nations Ford), which shall include any home hemodialysis training or isolation stations.

- 3. Bio-Medical Applications of North Carolina, d/b/a, BMA Nations Ford shall install plumbing and electrical wiring through the walls for two additional dialysis stations for a total of 24 certified stations which shall include any isolation stations.**
 - 4. Bio-Medical Applications of North Carolina, d/b/a, BMA Nations Ford shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
 - 5. Bio-Medical Applications of North Carolina, d/b/a, BMA Nations Ford 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, page 50, the applicant states that there will be no capital costs associated with the proposed project. In Section IX.3, page 53, the applicant states that there will be no start-up costs or initial operating expenses.

In Exhibit 10, the applicant provides an audited balance sheet for Fresenius Medical Care Holdings, Inc. and Subsidiaries, parent company of Bio-Medical Applications of North Carolina, which shows that as of December 31, 2010, FMC had \$12,017,618,000 in total assets, including \$163,292,000 in cash and cash equivalents. The balance sheet also shows that FMC had \$6,561,629,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the financial solvency of the company.

In Sections X, page 55-59, the applicant projects operating costs and net revenue for each of the first two operating years of the proposed project, shown in the following table:

Projected Operating Costs and Net Revenue	Year 1	Year 2
Operating Costs	\$4,398,157	\$4,619,619
Net Revenue	\$5,350,858	\$5,626,697
Profit/(Loss)	\$952,701	\$1,007,078

The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X of the application for the applicant's assumptions.

In Section X.1, page 54, the applicant provides the dialysis facility’s allowable charge per treatment for each payment source as shown in the following table:

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

The charges for treatment are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of 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 proposes to add two dialysis stations to the existing BMA Nations Ford facility for a total of 24 dialysis stations upon completion of this project. BMA Nations Ford is currently serving 99 patients weekly at 4.5 patients per station. Dialysis facilities that operate four shifts per week (2 / day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant discusses projections for the in-center patient population on pages 12-13, 15-16 and page 31 of the application. At the end of Operating Year One, with 24 dialysis stations and 108 dialysis patients after the two-station addition, BMA Nations Ford projects the utilization will be 4.5 in-center patients per station (108 patients / 24 dialysis stations = 4.5). The growth projections are based on Mecklenburg County projected Average Annual Growth Rate in the number of dialysis patients. It is also noted that with no growth in utilization, the current population of 99 in-center patients utilizing 24 stations would exceed four patients per station.

The applicant adequately demonstrates the need to add two dialysis stations to the existing facility based on the number of in-center patients it proposes to serve. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the applicant 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 46, the applicant provides a table which shows that no additional full-time equivalent (FTE) positions will be required as a result of this project. Exhibit 21

contains a letter from Gregory Merten, MD stating that he is the current Medical Director of BMA Nations Ford and supports the proposed expansion of 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 35, the applicant lists the providers of the necessary ancillary and support services, and in Sections V.2, page 36, V.4, page 38, and V.5, pages 38-39, illustrates how the project will be coordinated with the existing health care system. The information provided in Section V 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 V1.1(b), page 42, the applicant reports that 82.2% of the patients who received treatments at BMA Nations Ford had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source of the facility:

IC Payor Source	%
Private Pay	0.0%
Commercial Insurance	14.1%
Medicare	71.7%
Medicaid	10.5%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
State Kidney Program	0.0%
VA	3.4%
Other: Self/Indigent	0.2%
Total	100.0%

The applicant states that BMA currently operates 86 facilities in 40 North Carolina Counties, each with 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 Nations Ford facility is comprised of the following:

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Nations Ford	14.1%	19.2%	80.7%	36.4%	74.7%

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 as of June 2010 and CY2009, respectively. The data in the table was obtained May 7, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2005 (Estimate by Cecil G. Sheps Center)
Mecklenburg County	15.0%	5.1%	20.1%
Statewide	17.0%	6.7%	19.7%

*Source: DMA Website: <http://www.ncdhhs.gov/dma/pub/index.htm>

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 dialysis services to be offered at BMA Nations Ford. 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 or 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 applicant demonstrated that medically underserved populations currently have adequate access to BMA Nations' Ford existing services. 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;

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In Section VI.1(f) page 43, the applicant states “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.*” In Section VI.6(a), page 44, 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 with 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

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In Section VI.1(a), page 41, the applicant states,

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina.

It is BMA policy to provide 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.

BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, 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(c), page 42, the applicant provides the projected payor mix for in-center dialysis patients.

IC Payor Source	%
Private Pay	0.0%
Commercial Insurance	14.1%
Medicare	71.7%
Medicaid	10.5%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
State Kidney Program	0.0%
VA	3.4%
Other: Self/Indigent	0.2%
Total	100.0%

The applicant demonstrated that

medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming with 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.

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In Section VI.5, page 44, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity 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

In Section V.3(a), page 37, the applicant states “*Exhibit 19 contains a letter from Jim Swann, FMC Director of Market Development and Certificate of Need, encouraging the school to include the BMA Nations Ford facility in their clinical rotations for nursing students.*” The information provided in Section V.3 is reasonable and credible and supports a 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, III, V, VI and VII in the BMA Nations Ford application. In particular, see Section V.7 pages 39-40 in which BMA Nations Ford discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the proposal would have a positive impact on cost-effectiveness, quality and access to dialysis services in Mecklenburg County. This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to add two dialysis stations and that it is a cost-effective alternative;
- The applicant has and will continue to provide quality services, and
- The applicant has and will continue to provide adequate access to medically underserved populations as shown in the tables below. The proposed project improves geographic access to patients who wish to transfer their care to a closer facility.

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Nations Ford	14.1%	19.2%	80.7%	36.4%	74.7%

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, BMA Nations Ford operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

BMA Nations' Ford application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .2200. See discussion below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.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- See Section II.I, page 10, Section IV.2, page 33 and the January 2012 SDR.
 - (2) *Mortality rates;*
-C- See Section II.I, page 10, Section IV.2, page 33.
 - (3) *The number of patients that are home trained and the number of patients on home dialysis;*
-C- In Section II.I, page 10, the applicant states, “*BMA Nations Ford does not have a home training program. Patients who are candidates for home training are referred to BMA Charlotte.*”
 - (4) *The number of transplants performed or referred;*
-C- See Section II.I, page 10 and Section IV.4, page 33.
 - (5) *The number of patients currently on the transplant waiting list;*
-C- See Section II.I, page 10 and Section IV.5, page 33.
 - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-C- See Section II.I, pages 10 and Section IV.6, page 33.
 - (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
-C- See Section II.I, page 11 and Section IV.7, page 34.
- (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- The applicant does not propose to develop a new 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- The applicant does not propose to develop a new facility.

- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
-NA- The applicant does not propose to develop a new or replacement facility.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
-C- See Section IX.6(f), page 62, Exhibit 11 and Exhibit 29.
- (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- The applicant does not propose to develop a new 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- See Section II.I, page 10, Section XI.6(g), page 62 and Exhibits 11 and 29. The applicant does not propose to develop a new facility. The existing facility operated in conformity with Medicare Conditions of Participation during the 18 months immediately preceding the date of this decision.
- (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 II.7, page 12 and Section III.7, page 31.
- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
-NA- The applicant does not propose to develop a new 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.9, page 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.”

.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- The applicant does not propose to develop a new 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- In Section II, page 15 and Section III.7, pages 30-32, the applicant projects to serve 108 in-center patients or 4.5 patients per station per week [$108 / 24 = 4.5$] by the end of the first operating year of the additional stations.
- (c) *An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected.*
- C- In Section II, pages 15-16 and Section III.7, pages 31-32, the applicant provides the assumptions and methodology used to project utilization of the proposed additional stations. See Criterion (3) for discussion.

.2204 SCOPE OF SERVICES

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

- (1) *Diagnostic and evaluation services;*
-C- See Section V.1, page 35.
- (2) *Maintenance dialysis;*
-C- See Section V.1, page 35.
- (3) *Accessible self-care training;*
-C- See Section V.1, page 35.
- (4) *Accessible follow-up program for support of patients dialyzing at home;*
-C- See Section V.1, page 35.
- (5) *X-ray services;*
-C- See Section V.1, page 35.
- (6) *Laboratory services;*
-C- See Section V.1, page 35.
- (7) *Blood bank services;*
-C- See Section V.1, page 35.
- (8) *Emergency care;*
-C- See Section V.1, page 35.
- (9) *Acute dialysis in an acute care setting;*
-C- See Section V.1, page 35.
- (10) *Vascular surgery for dialysis treatment patients;*
-C- See Section V.1, page 35.
- (11) *Transplantation services;*
-C- See Section V.1, page 35.
- (12) *Vocational rehabilitation counseling and services; and*
-C- See Section V.1, page 35.
- (13) *Transportation.*
-C- See Section V.1, page 35.

.2205 STAFFING AND STAFF TRAINING

- (a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*
 - C- See Section VII.1 & 2, pages 46-47, and Section VII.10, pages 48-49.
- (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 Section VII.5, page 47, and Exhibits 14 and 15.