

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

CORRECTED

FINDINGS: June 25, 2013

PROJECT ANALYST: Gene DePorter

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: F-10092-13/ Bio-Medical Applications of North Carolina, Inc d/b/a BMA Nations Ford/ Add 6 dialysis stations upon completion of Project I.D. # F-10052-12 (relocate six stations to FMC Southwest Charlotte) and this project for a total of 24 stations /Mecklenburg

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Bio-Medical Applications [BMA] of North Carolina, Inc. d/b/a BMA Nations Ford whose parent company is Fresenius Medical Care Holdings, Inc; proposes to add six dialysis stations to its existing dialysis facility located at 7901 England Street, Charlotte, for a total of 24 dialysis stations upon completion of this project and Project I.D. # F-10052-12 (relocation of six dialysis stations to FMC Southwest Charlotte dialysis facility).

The 2013 State Medical Facilities Plan [2013 SMFP] provides a county need methodology and a facility need methodology for determining the need for additional dialysis stations. According to the January 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of 6 stations and thus no need for an additional facility in Mecklenburg County. However, the applicant is eligible to apply for six additional stations in its existing facility based on the facility need methodology because the utilization rate reported for BMA Nations Ford in the January 2013 SDR is 106.82% or 4.27 patients per station. Application of the facility need

methodology indicates additional stations are needed for this facility, as illustrated in the following table;

Table 1
BMA Nations Ford
 ESRD Facility Need Methodology
 Semiannual Dialysis Facility Need

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/12		106.8%
Certified Stations		24
Pending Stations		0
Total Existing and Pending Stations		24
In-Center Patients as of (SDR2) (6/30/12)		94
In-Center Patients as of (SDR1) (12/31/11)		92
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	2
	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/11	4.3%
(ii)	Divide the result of step (i) by 12	0.0036
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January 2013 SDR (6) (6/30/12) until the end of calendar year 12/31/2012)	0.0217
(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 SDR1 [2.0398 + 94= 96.0398]	96.0435
(v)	Divide the result of step (iv) by 3.2 patients per station	6.0136
	and subtract the number of certified and pending stations as recorded in SDR2 [24] to determine the number of stations needed	6

As shown in the table above, based on the facility need methodology for dialysis stations there is a need for 6 additional dialysis stations. Step (c) of the facility need methodology, page 381 of the 2013 SMFP, states; “*The facility may apply to expand to meet the need established... up to a maximum of 10 stations.*” The applicant proposes to add six new stations and therefore, is consistent with the facility need determination of dialysis stations.

POLICY GEN-3: Basic Principles, page 42 of the 2013 SMFP is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State

Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

In Section II., page 23, the applicant describes how this proposal will promote safety and quality:

“BMA is a high quality health care provider. The Table at II.3D provides quality indicators for the BMA Nations Ford Dialysis facility. In addition, BMA’s parent company, Fresenius Medical Care encourages all BMA facilities to attain the FMC UltraCare certification. In addition, BMA’s parent company, Fresenius Medical Care, encourages all BMA facilities to attain the FMC UltraCare® certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for UltraCare certification.”

In Section II.3, page 33-34, the applicant provides BMA goals for quality that the applicant states are more stringent than national averages. Reference the following table;

**Table 2
BMA Core Indicators of Quality**

Core Indicator	Measuring	BMA Nations Ford
Dialysis Adequacy	% of patients with EKTv >1.2	94.7%
Nutrition	% of Patients with Albumin > 3.5	92.0%
Vascular Access	% of Patients with AV Fistula	68.0%
	% of Patients with Catheter	16.0%

The applicant identifies the following programs and methods it uses to insure and maintain quality care:

Table 3
Maintaining Quality Care Programs

Corporate Programs	Facility Programs
Technical Audits	Quality Improvement Program
Continuous Quality Improvement	Staff Orientation and Training
External Surveys-DFS Certification Surveys	In-Service Education
Core Indicators of Quality	
Single Use Dialyzers	

The applicant also discusses its safety measures in Section XI.6 (g), page 70. In addition, Exhibit 13 provides a copy of the applicant’s Quality Improvement program, Exhibit 14 contains a copy of the Training Manual, and Exhibit 15 contains a copy of the Staff In-service Training outline. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services at BMA Nations Ford.

Promote Equitable Access

In Section II, page 25, the applicant describes how the proposal will promote equitable access for medically underserved groups, as follows:

“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 fourteen operational dialysis facilities and two facilities CON approved and at various stages of development. The January 2013 SDR reports that Mecklenburg County has the largest ESRD patient population in North Carolina and that population is growing at an Average Annual Change Rate of 5.6%. As the dialysis patient population of Mecklenburg County continues to increase, the need for dialysis stations will continue to increase.

Over the years, BMA has sought to develop new facilities and new dialysis stations in an effort to make dialysis convenient to the patient. This application to add six dialysis stations to FMC Nations Ford is another example of BMA efforts to meet the needs of the ESRD patient population of Mecklenburg County.”

As noted in Section VI.1 (a), page 48 of this application:

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

In Section VI 1. (a) page 48; the current patient population profile for BMA Nations Ford is as follows:

Table 4
BMA Nations Ford Facility Demographics

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Nations Ford	16.5%	23.7%	71.1%	46.4%	63.9%

In Section VI.2, page 51, the applicant states:

“The design of the facility is such that handicapped persons have easy access to the facility; the facility complies 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 52, the applicant indicates that the BMA admission policy states the following;

“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 an acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.” [Reference Exhibit 8-FMC Business and Admission Policy and Exhibit 9, Appendix IV]

The applicant adequately demonstrates the proposal will promote access to medically underserved groups.

Maximize Healthcare Value

In Section II, page 25, 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 station at the facility; BMA is not seeking charitable contributions. Rather, BMA, through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment closer to patient homes. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. For example, within this application, BMA

projects that 78.8% of the treatments are covered by Medicare and Medicaid, and an additional 4% are covered by VA. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence BMA must work diligently to control costs of delivery for dialysis. BMA does.”

The applicant adequately demonstrates the proposal will maximize healthcare value. Additionally, the applicant demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the January 2013 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

The applicant, BMA Nations Ford, proposes to add six dialysis stations upon completion of Project I.D. # F-10052-12 (relocate six stations to FMC Southwest Charlotte) and this project for a total of 24 stations.

Population to Be Served

In Section IV.1, page 40, the applicant indicated that it served 97 in-center patients from Mecklenburg County as of December 31, 2012. Mecklenburg County has an Average Annual Change Rate for the past five years of 5.6%.

In Section II, page 18, the applicant identifies the in-center population it proposes to serve during the first two operating years following project completion, as follows:

Table 5
BMA Nations Ford In-Center Patient Projections
Operating Years 1 and 2

County	Operating YR 1 7/1/15-6-30/16	Operating YR 2 7/1/16-6/30/17	County Patients as a Percentage of Total	
	In-Center Patients	In-Center Patients	Year 1	Year 2
Mecklenburg	94.2	99.5	100.0%	100.0%
Total	94.2	99.5	100.0%	100.0%

The applicant adequately identified the population BMA Nations Ford proposes to serve.

Demonstration of Need

BMA Nations Ford assumes the patient population of the facility will continue to increase. The applicant has applied the Average Annual Change Rate for the past five years (5.6%) for projecting future dialysis station need calculations in the BMA Nations Ford service area.

In Section III.7, pages 37-38, the applicant states the following assumptions in support of adding six dialysis stations at BMA Nations Ford:

- The January 2013 SDR reports that BMA Nations Ford was operating at 106.82% capacity with a census of 94 patients dialyzing on 22 certified dialysis stations as of June 30, 2012.
- BMA Nations Ford operates a nocturnal dialysis shift. This shift is a function of patient choice. BMA assumes that patients will continue to dialyze on the nocturnal dialysis shift. BMA has estimated that 12 patients will continue on the nocturnal dialysis shift.
- The Facility Need Methodology indicated a need for 6 additional stations at BMA Nations Ford. The applicant has applied for 6 stations.
- Calculations in this application are based upon completion and certification of stations as of June 30, 2015.
- At the present time, BMA Nations Ford is not serving patients from other counties.

The following methodology illustrates the calculation of in-center hemodialysis patients and growth.

Table 6
 BMA Nations Ford In-Center Methodology for Projected Patient Volume
 December 31, 2012 through June 30, 2017

BMA begins with facility census as of December 31, 2012	97
BMA projects this population forward to December 31, 2013	$(97 \times .056) + 97 = 102.4$
BMA projects this population forward to December 31, 2014	$(102.4 \times .056) + 102.4 = 108.2$
BMA projects this population forward to June 30, 2015	$[108.2 \times (.056/12 \times 6)] + 108.2 = 111.2$
BMA subtracts 22 patients projected to transfer to FMC Southwest Charlotte. This is the beginning census for this project	$111.2 - 22 = 89.2$
BMA projects this population forward to June 30, 2016. This is the ending of Operating Year 1	$(89.2 \times .056) + 89.2 = 94.2$
BMA projects the patient population to June 30, 2017. This is the end of Operating Year 2.	$(94.2 \times .056) + 94.2 = 99.5$

Consequently, in the second year of operations the applicant projects it will serve 4.125 in-center dialysis patients per station per week [99 patients/24 certified stations = 4.125 patients per station]. This exceeds the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding

the historical growth which is expected to continue. Therefore, the applicant adequately demonstrates the need for six additional stations.

Access

In Section II, page 24, BMA indicates that it has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments at BMA Nations Ford (78.9%) are covered by Medicare and Medicaid. The applicant demonstrates adequate access for medically underserved groups at BMA Nations Ford.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population has for six additional dialysis stations at BMA Nations Ford, and demonstrates all residents of the area, and in particular, underserved groups are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section III.9, page 39, the applicant states:

“BMA of North Carolina has chosen the most effective and least costly alternative for meeting the needs of the patients choosing to receive treatment at the BMA Nations Ford facility.

- a) BMA considered asking patients to transfer to other facilities in the Mecklenburg County area. This option removes patient choice and is the least likely option, short of a major catastrophe which would remove the facility from operation*
- b) BMA could apply for fewer expansion stations. This option seems to ignore the growing patient census at BMA Nations Ford. ...The growth rate for the facility seems likely to continue. The facility is already projected to exceed 100% utilization.*

Considering the alternatives, BMA has only one viable option: apply to expand.”

The applicant adequately demonstrated the need for six additional stations based on the number of in-center patients it now serves and proposes to serve. See Criterion (3) for discussion on need which is hereby incorporated by reference as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria and thus is approvable. The applicant adequately demonstrates that this project is its least costly or most effective alternative to meet the need for additional dialysis stations at this facility. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Nations Ford shall materially comply with all representations made in its certificate of need application.**
 2. **Bio-Medical Applications of North Carolina, Inc., d/b/a BMA Nations Ford shall add no more than six additional dialysis stations for a total of no more than 24 certified dialysis stations at BMA Nations Ford following completion of the project and Project I.D. # F-10052-12, which shall include any home hemodialysis training or isolation stations.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Nations Ford shall install plumbing and electrical wiring through the walls for six additional dialysis stations for a total of 24 stations, which shall include any home hemodialysis training or isolation stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Nations Ford shall not offer or develop peritoneal or home dialysis training.**
 5. **Bio-Medical Applications of North Carolina, Inc. 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.

C

This project does not require any capital cost on behalf of BMA. Please refer to Exhibit 10 for a copy of the most recent audited FMC Holdings, Inc., Consolidated Balance Sheet. The 2011 Consolidated Balance Sheet reflects more than \$204 million in cash, and current assets exceeding \$13 billion. The applicant states that FMC has the resources necessary for all projects. There are no associated start-up or initial operating expenses involved.

In Exhibit 24 of the application, the Vice President of Fresenius Medical Care Holdings states the following in a letter dated March 15, 2013:

“BMA proposes to add six dialysis stations to the BMA Nations Ford dialysis facility. The project does not call for any capital expense on behalf of BMA. As Vice President, I am authorized and do hereby authorize the addition of six new dialysis stations.”

The applicant adequately demonstrates availability of sufficient funds for the capital needs of the project.

The rates in the following table were provided by the applicant in application Section X.1, page 62 and are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services

**Table 7
 In-Center Medicare/Medicaid Rates**

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

In the revenue and expense statements in Section X. 2, page 63 and Section X.4, page 66, the applicant projects that revenues will exceed operating costs in each of the first two years of operation. The following table illustrates projected revenues and expenses during the first two years after project completion.

**Table 8
 BMA Nations Ford
 Current and Projected
 Revenue, Deductions from Revenue, Operating Costs and Difference**

Cash Flow	Current Year Operating Revenue	Year 1 Operating Revenue	Year. 2. Operating Revenue
Gross Patient Service Revenue	\$6,386,598	\$5,879,365	\$6,212,020
Contractual Allowances	\$1,358,253	\$1,248,495	\$1,317,094
Net Revenue	\$5,028,337	\$4,630,870	\$4,894,926
Total Operating Costs	\$4,235,447	\$4,017,474	\$4,235,896
Difference	\$ 792,890	\$ 613,396	\$ 659,030

The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X, pages 63-65, for the applicant’s assumptions. In summary, the applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable projections regarding revenues and operating costs. Therefore, the application is conforming to this criterion.

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

The applicant proposes to add six dialysis stations to the existing BMA Nations Ford facility for a total of 24 dialysis stations upon completion of this project and Project ID # F-10052-12 (relocation of six stations from BMA Nations Ford to FMC Southwest Charlotte dialysis facility).

There are 14 dialysis facilities in Mecklenburg County with utilization rates ranging from 66.67% to 106.82%. As of June 30, 2012, the 22 station BMA Nations Ford was operating at 106.82% capacity ($94/22 = 4.27$; $4.27/4 = 1.0682$). The target utilization is 80%. The applicant therefore is eligible to expand its facility and may apply for additional stations. Upon completion of this project and Project I.D. # F-10052-12, the facility will have 25 stations serving 94 patients at the end of Year 1, which is a utilization of 97.9% ($94/24 = 3.92$; $3.92/4 = .98$). Therefore the applicant is conforming with the requirement in 10A NCAC 14C. 2203. The applicant adequately demonstrates the need to develop six additional dialysis stations at 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 application is conforming to this criterion.

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

C

In Section VII.1, page 53, the applicant provides the current and projected staffing for BMA Nations Ford as shown in the following table:

Table 9
BMA Nations Ford Current and Projected Staffing

	# of Current	# of (FTE)	# of Projected
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	(FTE) Positions	Positions to be added	(FTE) Positions
RN	4.00	0.00	4.00
Tech.	9.00	0.00	9.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract Position not a facility FTE.		
Administrator	0.20	0.00	0.20
Dietitian	0.60	0.00	0.60
Social Worker	0.60	0.00	0.60
Chief Tech	0.10	0.00	0.10
Equipment Tech	0.50	0.00	0.50
In-Service	0.20	0.00	0.20
Clerical	1.00	0.00	1.00
Total	17.20	0.00	17.20

The applicant indicates that no additional staffing is required. The facility will operate with a total of 17.20 FTE staff. The applicant indicates in Section VII.4, page 54; that it does not expect any difficulty in recruiting staff. The information regarding staffing provided in application Section VII and the estimated annual salaries and revenues are reasonable and credible.

The applicant adequately documents the availability of resources, including health manpower and management personnel, for the provision of the services to be provided. Therefore, the application is conforming to 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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BMA Nations Ford is an existing kidney disease treatment center certified by the Centers for Medicare and Medicaid. The facility meets all conditions of participation, including any requirements for the provision of ancillary and support services. In Section V. 1, page 42, the applicant includes a list of providers for the necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

Exhibits 16 & 17 contain copies of a “*Patient Transfer Agreement*” and “*Transplant Center Evaluation Services Agreement*” between BMA Nations Ford and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center. Section V.4, page 45 contains two tables listing physicians; a) who support this application and b) those physicians who have expressed a willingness to provide medical coverage for ESRD patients. Exhibit 21 contains a letter from Dr. Gregory Merten, who is and will continue to serve, as the Medical

Director for the facility. 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;

C

In Section VI.1 (a), page 48, the applicant states the following;

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc., parent company to BMA currently operates 93 facilities in 40 North Carolina Counties (includes our affiliations with RRI facilities); in addition BMA has seven facilities under development or pending CON approval. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly or other traditionally underserved persons. The patient population of the BMA Nations Ford facility is comprised of the following:

Table 10
BMA Nations Ford Patient Profile

<i>Facility</i>	<i>Medicaid/Lo w Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>BMA Nations Ford</i>	16.5%	23.7%	71.1%	46.4%	63.9%

“Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 71.1% of the facility treatment reimbursement is from Medicare.”

It is clear that BMA Nations Ford provides service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved...For example, Medicare represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities for FY 2012, Low income and medically underinsured persons will continue to have access to all services provided by BMA.

The facility will conform to the North Carolina 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.”

As shown in the following table, 89.20% of BMA Nations Ford current in-center patients have some or all of their care paid for by Medicare, Medicaid or VA.

In Section VI.1 (b) & (c), page 49, the applicant provides the current and projected payer mix for BMA Nations Ford. The applicant projects no change in reimbursement, between current and projected reimbursement, as shown in the following table:

Table 11
BMA Nations Ford
Current and Projected Payor Mix

Payor Source	Current/Projected
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	Percent of Total
Private	0.0%
Commercial Insurance	10.6%
Medicare	73.1%
Medicaid	5.8%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
State Kidney Program	0.0%
VA	4.0%
Other: Self Pay/Indigent	6.5%
Total	100.0%

The applicant demonstrated that medically underserved populations currently have adequate access to dialysis services provided at BMA Nations Ford. Therefore, the application is conforming to this criterion.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Mecklenburg County and statewide. More current data, particularly with regard to the estimated uninsured percentages, was not available.

Table 12
Percent of Medicaid Eligible
By County and State

County	Total # of Medicaid Eligible as % of Total Population^①	Total # of Medicaid Eligible Age 21 and older as % of Total Population^②	% Uninsured CY 08-09 (Estimate by Cecil G. Sheps Center)
Mecklenburg	15.0%	5.1%	20.1%
Statewide	17.0%	6.7%	19.7%

Source: www.ncdhhs.gov/dema-Medicaid-Eligible-Mecklenburg-County June 2010.

^① Medicaid Eligible by Age for Mecklenburg County, June 2010,

^② Medicaid Eligible Age 21+ for Mecklenburg County and State, 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 older segments of the population, particularly the services offered by BMA Nations Ford. In fact, in 2011 only 5.8% of all newly diagnosed

ESRD patients (Incident ESRD patients) in North Carolina's Network 6 were under the age of 35. ③

The Office of Budget and Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition data are available by race, age or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do 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.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

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

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.” ④

In addition, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides the following national statistics for FY 2010:

Table 13
The 2012 United States Renal Data System Report
Selected National Statistics as of December 31, 2010

Patients Receiving Hemodialysis	376,000
White Dialysis Patients	55.38%
African American Dialysis Patients	38.23%
Male Dialysis Patients	55.65%
65+ Dialysis Patients	44.65%

③ Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16

④ Source: <http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>.

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39% covered solely by Medicare, and 32% covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in

2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients respectively.”⁵

The report provides 2010 ESRD spending, by payor as follows:

Table 14
ESRD Spending Nationally by Payor

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

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

The Southeastern Kidney Council (SKC) provides Network 6, 2011 Incident ESRD patient data by age, race and gender, as shown below:

Table 15
Number and 2011 Percent of Dialysis Patients
By Age, Race, and Gender

Age	# of ESRD Patients	% of Dialysis Population
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.30%
Total	9,342	100.00%

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.

⁵Source: United States Renal Data System 2012 USRDS Report, Chapter 1, and page 225: http://www.usrds.org/2012/Pdf/v2_ch1_12.pdf.

The applicant demonstrates that it provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In application Section VI.1 (f), page 50, 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 52, the applicant states, “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*”

The application is conforming to this criterion.

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

C

In Section VI.1(c), page 49, the applicant provides the projected payor mix for the proposed services at BMA Nations Ford. The applicant projects no change from the current payor mix for dialysis visits as shown in the table in Criteria (13a) above. The applicant projects that 78.9% of the patients will be Medicare or Medicaid beneficiaries. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.5 (a), page 51, the applicant states,

“BMA Nations Ford will have an open policy, which means that any Nephrologist may apply to admit patients at the facility.” Further, in Section VI.5 (b), page 51, the applicant states, “*... all patients will be admitted to the facility through one of the Nephrologists on the staff of BMA Nations Ford Center.*”

The applicant adequately demonstrates that BMA Nations Ford offers a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In application Section V.3 (a), page 44, the applicant states: “*Exhibit 19 contains letters ...encouraging the school to include the BMA Nations Ford facility in their clinical rotations for nursing students.*”

In Section V. 3(c), the applicant states:

“BMA has communicated with the local student nursing programs encouraging those programs to utilize the resources of the BMA Nations Ford facility to enhance the educational opportunities for the nursing student. Copies of the letters are included in Exhibit 19.”

The information provided in application Section V 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

The applicant proposes to add six dialysis stations for a total of 24 stations upon completion of this project and project I.D. # F-10052-12.

According to the January 2013 SDR, BMA Nations Ford is one of 14 existing dialysis facilities in Mecklenburg County with utilization rates ranging from 66.67% to 106.82%. See Table below for a list of Mecklenburg County dialysis facilities by stations:

Facility	Number of Dialysis Stations as of December 21, 2012				Total
	Certified	CON Issued/ Not Certified	Decision Rendered-CA	Decision Pending	
BMA West Charlotte	27		2		29
BMA of Beaties Ford	32				32
BMA of North Charlotte	27				27
CMC	9				9

DSI Charlotte Latrobe Dialysis	24				24
DSI Glenwater Dialysis	34	8			42
South Charlotte Dialysis	17	3			20
Charlotte Dialysis	34				34
Charlotte East Dialysis	16	4			20
North Charlotte Dialysis	25			10	35
BMA of Charlotte	40		-4		36
BMA of East Charlotte	24				24
BMA of Nations Ford	24		-6		18
FMC of Matthews	21				21
FMC of Southwest Charlotte	Proposed new site consisting of existing stations				
Mint Hill Dialysis Center	Proposed new site consisting of existing stations				

Source: January 2013 SDR

In Section V.7, page 46, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access.

According to the applicant, adding six stations will reduce utilization measures to more acceptable levels and support positive outcomes related to cost-efficiency, quality and access. See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality, and access to services in Mecklenburg County. This determination is base on information in the application and the following analysis:

- The applicant adequately demonstrates the need to add six dialysis stations, and that it is a cost-effective alternative to meet the patient volume at BMA Nations Ford dialysis center;
- The applicant adequately demonstrates that it will continue to provide quality services;
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this application.

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

C

The applicant currently provides dialysis services at several facilities in North Carolina. According to files of 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

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 regulatory review criteria. The specific findings are discussed below.

.2202 INFORMATION REQUIRED OF APPLICANT

(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- Utilization-January 2013 SDR-106.82% or 4.27 patients per station,
- .2202(a)(2) Mortality rates;*
-C- In Section IV.2, page 40 the applicant provides the following mortality rates-Year 2010-15.5%, 2011-10.2%, and 2012-8.2%.
- .2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*
-C- See Section IV.3, page 40, Home dialysis training is provided at BMA Charlotte.
- .2202(a)(4) The number of transplants performed or referred;*
-C- See Section IV.4, page 40, In 2011, 40 transplants were referred and 3 transplants were performed. In 2012 11 transplants were referred and 2 transplants were performed.
- .2202(a)(5) The number of patients currently on the transplant waiting list;*
-C- See Section IV.5, page 40, 11 patients are on the waiting list.
- .2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related-65.*
-C- See Section IV.6, page 40. total admissions were 187 with 59 related to dialysis and 128 non-dialysis related.

- .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 Section IV.7, page 41-There were no infectious disease cases in 2011 or 2012.

(b) An applicant that proposed develop 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- BMA Nations Ford 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- BMA Nations Ford is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
-NA- BMA Nations Ford 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), page 70 and Exhibit 12 regarding back-up capabilities.
- .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- BMA Nations Ford 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 Section II.1, page 13, Section XI.6 (g), page 70 and Exhibits 11 and 12.
- .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 Section III.7, pages 36-38, and discussion in Criterion (3).
- .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- BMA Nations Ford is an existing facility.
- .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 Section II, page 17.

.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 Nations Ford is an existing facility.
- .2203(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 III.7, pages 36-37 the applicant projects to serve 94 in-center patients by the end of Year 1, which equates to 3.92 patients per station per week [94 / 24 = 3.92]. Further, the applicant projects to serve 99 in-center patients by the end of Year 2, which equates to 4.125 patients per station per week [99 / 24 = 4.125]. See Criterion (3) for discussion which is hereby incorporated by reference as if fully set forth herein.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
-C- See Section II (7), pages 13-15, In Section III.7, pages 36-38, the applicant provides the assumptions and methodology used

to project utilization of the additional stations. See Criterion (3) for discussion which is hereby incorporated by reference as if fully set forth herein.

.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 Section V.1 (e), page 42. Carolinas Healthcare System
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1 (c), page 42. On Site
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1 (d), page 42. BMA Charlotte
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- Provided at BMA Charlotte, page 42.
- .2204(5) *X-ray services;*
 - C- See Section V.1 (g), page 42. Carolinas Healthcare System
- .2204(6) *Laboratory services;*
 - C- See Section V.1 (h), page 42. Spectra (Exhibit 18).
- .2204(7) *Blood bank services;*
 - C- See Section V.1, page 42. Carolinas Healthcare System
- .2204(8) *Emergency care;*
 - C- See Section V.1 (b), page 42. All staff is trained to respond, a fully stocked crash cart is maintained, and ambulance transport to hospital is accessible.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1 (a), page 42. Carolinas Healthcare System.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
 - C- See Section V.1 (p), page 42. Referral to Metrolina Nephrology Associates Access Center; Dilworth Surgical Group; or Sanger Clinic.
- .2204(11) *Transplantation services;*
 - C- See Section V.1 (f), page 42. Carolinas Medical Center
- .2204(12) *Vocational rehabilitation counseling and services; and*
 - C- See Section V. 1 (o), page 42. Charlotte-Mecklenburg Vocational Rehabilitation Services.
- .2204(13) *Transportation*
 - C- See Section V.1 (q), page 42. Prestige Cabs, Crown Cab, Red Cross.

.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 494 (formerly 405.2100)*

- C- See Section VII.1, page 53 the applicant provides the proposed staffing. In Section VII 2, page 54 the applicant states, the proposed facility will comply with all staffing requirements set forth in the Federal code. The applicant

adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein

- .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 Section VII.5, pages 54-55 and Exhibits 14 and 15 for outline of continuing education programs.