

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 2, 2014
PROJECT ANALYST: Fatimah Wilson
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: F-10256-14/ Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Nations Ford / Add four dialysis stations for a total of 30 certified stations upon completion of this project, Project I.D. #F-10179-13 (add two stations), Project I.D. #F-10092-13 (add six stations) and Project I.D.# F-10052-12 (relocate six stations) / Mecklenburg County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

CA

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Nations Ford proposes to add four dialysis stations for a total of 30 certified dialysis stations upon completion of this project and Project I.D. #F-10179-13, Project I.D. #F-10092-13 and Project I.D. #F-10052-12.

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Mecklenburg County. 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 BMA Nations Ford in the January 2014 SDR is 4.25 patients per station. This utilization rate was calculated based on 102 in-center dialysis patients and 24 certified dialysis stations as of June 30, 2013 (102 patients / 24 stations = 4.25 patients per station).

On February 27, 2014, BMA was approved to add two dialysis stations to the BMA Nations Ford facility (Project I.D. # F-10179-13), for a total of 26 dialysis stations at BMA Nations Ford upon completion of the project. The certificate of need for that project was issued on April 3, 2014. Effective July 27, 2013, BMA was issued a certificate of need to add six stations to the BMA Nations Ford facility (Project I.D. #F-10092-13), for a total of 24 stations at BMA Nations Ford upon completion of the project. Also, effective March 1, 2013, BMA was issued a certificate of need to relocate six stations from BMA Nations Ford and four stations from BMA Charlotte to develop a new 10 station dialysis facility (Project I.D. #F-10052-12), FMC Southwest Charlotte. Both Project I.D. #F-10092-13 and F-10052-12 are still under development and scheduled for certification by July 2015. Project I.D. #F-10179-13 is also under development and scheduled for certification by June 30, 2015. Application of the facility need methodology indicates four additional stations are needed for this facility, as illustrated in the following table.

BMA Nations Ford APRIL 1 REVIEW – JANUARY 2014 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		106.3%
Certified Stations		24
Pending Stations		6
Total Existing and Pending Stations		30
In-Center Patients as of 6/30/13 (SDR2)		102
In-Center Patients as of 12/31/12 (SDR1)		97
Step	Description	
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12	0.1031
(ii)	Divide the result of Step (i) by 12	0.0086
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/11 until 12/31/12)	0.0515
(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	107.2577
(v)	Divide the result of Step (iv) by 3.2 patients per station	33.5180
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	4

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Step (C) of the facility need methodology states “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” However, the applicant received a CON (Project I.D. #F-10179-13) for two additional stations on April 3, 2014. Therefore the most stations that can be approved in this review are two. The applicant is conditioned to only develop two additional stations. See Condition # 2 in Criterion (4).

Policy GEN-3: Basic Principles, page 38, of the 2014 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.3, page 27, the applicant states,

“BMA Nations Ford will have a well-defined Quality Improvement program whose purpose is to establish an outcome focused review and evaluation of the quality, safety and effectiveness of patient care. The program’s work is conducted by the Continuous Quality Improvement Team and coordinated by the Clinical Manager and the Regional Quality Manager. The primary method of review is patient care audits and monitoring of critical patient indicators. Audits will be conducted monthly and results presented to the Quality Improvement Team for evaluation and recommendation. Other audits include Patient Satisfaction Surveys and chart audits. CQI membership includes the Medical Director, Area Manager, Clinical Manager, Chief Technician, Social Worker and Dietitian. The committee will meet monthly. Individual teams may be assigned to individual projects to gather data as needed to conduct the “Check, Plan, Do, and Check, Act” process for addressing the improvement opportunities.”

See Exhibit 8 for a copy of the “Quality Assessment and Performance Improvement” policy.

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

“BMA is a high quality health care provider. The Table at II.3 D 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. 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 I.13, pages 4-8, the applicant discusses the quality of services provided at BMA Nations Ford, attributing much of its success in providing quality services to its corporate structure, specifically its Clinical Services Department, Technical Services Department, Regulatory Affairs and Law Departments, and other management resources as discussed below.

- Clinical Services Department
 - Serves as a clinical resource for the entire FMC network
 - Provides facilities with the best procedures and equipment available
 - Assist facility managers and medical personnel with questions and concerns on clinical operations
 - Provides ongoing Clinical Review Program, guidelines for comprehensive training, and Quality Assurance Program
- Technical Services Department
 - Oversees the technical and mechanical aspects of dialysis
 - Supported by a research and quality control team that leads the industry in dealing with technically complex issues facing dialysis providers
- Regulatory Affairs and Law Departments
 - Deal with legal and regulatory issues
 - Provides interpretation of legislation and government policy to ensure compliance
- Other Management Resources, including but not limited to:
 - Revenue Operations – draws experience through interaction with numerous Medicare intermediaries and third-party carriers
 - Accounting and Budget – tailored to ensure effective financial management of dialysis treatment centers
 - Facility Design and Maintenance – experienced architectural staff promotes development of efficiently designed facilities
 - Human Resources – develops productivity standards, job descriptions, staff performance review, personnel policies and procedures and employee relations.
 - Information Systems – develops comprehensive facility automation including enhanced software for clinical management to support delivery of high quality care
 - Marketing and Managed Care – responsible for competitive analysis and continuous development of dialysis services
 - Health, Safety, and Risk Management – provides regulatory information used to ensure compliance in the dialysis setting and provides risk management services.
 - Regional Vice Presidents – provide operational direction and monitoring of daily operations.

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

Promote Equitable Access

In Section II.2, page 21, 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 79.9% of the In-Center dialysis treatments will be covered by Medicare or Medicaid. Another 5.69% are expected to be covered by VA. Thus, 85.6% of the In-Center revenue is derived from government payors.”

On page 22, the applicant states:

“BMA is also keenly sensitive to the second element of “equitable access” – time and distance barriers. At this time Mecklenburg County has one [sic] operational dialysis facility. As the dialysis patient population of Mecklenburg County continues to increase, the need for dialysis stations will continue to increase. BMA will apply to develop new dialysis facilities when needed. In this case, BMA is applying for two [sic] additional stations to meet a growing need in Mecklenburg County.”

Also on page 22, the applicant states it has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, payor source, gender, or other considerations. The applicant further states, *“A patient in need of dialysis is always welcomed at a BMA facility; the only requirement is proper referral from a physician.”*

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

Maximize Healthcare Value

In Section VIII.1, page 55, the applicant projects a capital expenditure of \$36,000, and, in Section II.1, page 22, the applicant states that BMA is not seeking State or Federal monies or charitable contributions to develop the project. Rather, the applicant states, *“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 the patient homes.”* The applicant further states:

“As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. ... The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence BMA must work diligently to control costs of delivery for dialysis. BMA does.”

The applicant adequately demonstrates that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application, as conditioned, is consistent with the facility need determination in the January

2014 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion subject to Condition # 2 in Criterion (4).

- (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 four dialysis stations to its existing facility for a total of 30 certified stations upon completion of this project, Project I.D. #F-10179-13 (add two stations), Project I.D. #F-10052-12 (relocate six stations) and Project I.D. #F-10092-13 (add six stations). In Section IV.1, page 38, the applicant states that the number of in-center patients served at BMA Nations Ford is 104 as of December 31, 2013.

BMA Nations Ford	
County	In-center Patients
Mecklenburg	99
Iredell	1
Gaston	1
York, SC	3
Total	104

Population to be Served

In Section III.7, page 33, the applicant provides the projected patient origin for BMA Nations Ford for the first two years of operation following completion of the project, as follows:

BMA Nations Ford Projected Patient Origin				
County	Year 1 CY2016	Year 2 CY2017	County Patients as a Percent of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
Mecklenburg	95.8	102.1	95.0%	95.3%
Iredell	1.0	1.0	1.0%	0.9%
Gaston	1.0	1.0	1.0%	0.9%
York, SC	3.0	3.0	3.0%	2.8%
Total	100.8	107.1	100.0%	100.0%

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

Demonstration of Need

In Section II.9(b), page 15 and III.1, page 33, the applicant states the application is filed pursuant to the facility need methodology as indicated in the January 2014 SDR. It proposes to add four dialysis stations to BMA Nations Ford for a total of 30 stations at that facility. On pages 16-17, and 33-34, the applicant states the following assumptions:

1. *“The January 2014 SDR reports that BMA Nations Ford was operating at 106.25% utilization with a census of 102 in-center patients dialyzing on 24 certified dialysis stations as of June 30, 2013.*
2. *This project is scheduled to be completed December 31, 2016.*

*Operating Year 1 is the period from January 1, 2015 – December 31, 2016.
Operating Year 2 is the period from January 1, 2016 – December 31, 2017.*

3. *BMA assumes that the dialysis patient population utilizing BMA Nations Ford are a part of the Mecklenburg County ESRD patient population as a whole, and that this population will increase at a rate commensurate with the Mecklenburg County Five Year Average Annual Change Rate as published in the January 2014 SDR. That rate is 6.6%.*
4. *Within CON Project I.D. #F-10052-12, BMA projected that 22 patients dialyzing at BMA Nations Ford would transfer their care to the new FMC Southwest Charlotte facility as that facility was certified. FMC Southwest Charlotte is expected to be certified as of June 30, 2015. Thus, in projections of future patient populations for BMA Nations Ford, BMA will necessarily subtract 22 patients as of June 30, 2015.*
5. *As of December 31, 2013, BMA Nations Ford was serving 99 Mecklenburg County residents, three patients from York County, SC, one patient from Iredell County and one patient from Gaston County. BMA will project the five patients from other counties to continue dialysis at BMA Nations Ford as a function of patient choice. All other future patients are projected to residents of Mecklenburg County.”*

As on pages 17 and 34, the applicant’s methodology is provided in the following table.

BMA Nations Ford	In-Center
BMA begins with facility census of Mecklenburg County as of December 31, 2013.	99
Growth of the census is projected by the Mecklenburg County Five Year Average Annual Change Rate for one year to December 31, 2014.	$(99 \times .066) + 99 = 105.5$
Growth of the census is increased by one half the Five Year Average Annual Change Rate to June 30, 2015. This is the projected certification date for FMC Southwest Charlotte.	$[105.5 \times (.066 / 12 \times 6)] + 105.5 = 109.0$
BMA subtracts 22 patients projected to transfer to the FMC Southwest Charlotte facility.	$109.0 - 22 = 87.0$
The census is again increased, using one half the Five Year Average Annual Change Rate, for six months to December 31, 2015.	$[87.0 \times (.066 / 12 \times 6)] + 87.0 = 89.9$
BMA adds the five patients from other counties. This is the beginning census for this project	$89.9 + 5 = 94.9$
The Mecklenburg County patient census is increased by the Five Year Average Annual Change Rate for one year to December 31, 2016.	$(89.9 \times .066) + 89.9 = 95.8$
BMA adds the five patients from other counties. This is the ending census for Operating Year 1.	$95.8 + 5 = 100.8$
The Mecklenburg County patient census is increased by the Calculated Average Annual Change Rate for one year to December 31, 2017.	$(95.8 \times .066) + 95.8 = 102.1$
BMA adds the five patients from other counties. This is the ending census for Operating Year 2.	$102.1 + 5 = 107.1$

The applicant projects to serve 100 in-center patients or 3.36 patients per station ($100 / 30 = 3.33$) by the end of Year 1 and 107 in-center patients or 3.57 patients per station ($107 / 30 = 3.57$) by the end of Year 2 for the proposed 30-station facility. However, the applicant is being conditioned to develop only two additional stations. See Criterion 4 for conditions. Based on the approval of only two additional stations, the census for operating years one and two would be as follows:

Operating Year 1

100 patients dialyzing on 28 stations = 3.60 patients per station
 $100 / (4 \times 28) = 0.8926$, or 89.26%

Operating Year 2

107 patients dialyzing on 28 stations = 3.82 patients per station
 $107 / (4 \times 28) = 0.9553$, or 95.53%

This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access

In Section VI, page 46, the applicant states that each of BMA's 100 facilities in 42 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. On page 47, the applicant projects 85.59% of its patients will be covered by Medicare or Medicaid. The applicant demonstrates adequate access for the underserved to its services.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for two additional 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. The applicant received a CON (Project I.D. #F-10179-13) on April 3, 2014 to add two additional stations to the facility, thus, the need demonstrated in this application is for two stations and not four. An approval of four stations would result in an excess of stations at BMA Nations Ford upon completion of this project and Project I.D. #F-10179-13. Therefore, the application is conforming to this criterion subject to Condition # 2 in Criterion (4).

- (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, pages 35-37, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Apply for fewer stations - but the applicant rejected this alternative because it would not meet the growing demand for dialysis services at BMA Nations Ford, which projects 83.34% utilization at the end of PY1.
- 2) Do Nothing - but the applicant rejected this alternative because it would remove choice from the patient options. The growth rate for the facility seems likely to continue. The facility is projected to exceed 80% utilization, therefore, failure to expand potentially denies patients a choice of dialysis at BMA Nations Ford.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the BMA Nations Ford proposal is the least costly or most effective alternative to meet the need. 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 the certificate of need application.**
 2. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Nations Ford shall develop and operate no more than two additional dialysis stations for a total of no more than 28 certified stations upon completion of this project, Project I.D. #F-10179-13 (add two stations), Project I.D. #F-10092-13 (add six stations), and Project I.D. #F-10052-12 (relocate six stations) which shall include any 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 no more than two additional dialysis stations for a total of no more than 28 dialysis 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 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

In Section VIII.1, page 55, the applicant projects a capital cost of \$36,000 for the proposed project. In Section IX, page 59, the applicant also states there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 24 includes a letter dated March 17, 2014 from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

“This is to inform you that Fresenius Medical Care Holdings, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.

“BMA is submitting a Certificate of Need Application to add four dialysis stations to its BMA Nations Ford facility in Mecklenburg County. The project calls for the following capital expenditure:

Capital Expense \$36,000

As Vice President, I am authorized and do hereby authorize the addition of four dialysis stations, for capital costs as identified above. Further, I am authorized and hereby authorize and commit cash reserves for the capital cost of \$36,000 as may be needed for this project.”

In Exhibit 4, the applicant provides the audited financial statements for FMC and Subsidiaries for the years ended December 31, 2011 and 2012. As of December 31, 2012, FMC and Subsidiaries had cash and cash equivalents totaling \$341 million with \$17.8 billion in total assets and \$9.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the proposed project.

In Section X.1, page 60, the applicant projects the following charge per treatment for each payment source:

BMA Nations Ford	
Payor	In-Center Charge
Commercial	\$1,425.00
Medicare	\$239.00
Medicaid	\$137.29
VA	\$146.79
Private Pay	\$1,425.00

The applicant states the commercial charge listed does not reflect actual reimbursement. The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

In 2010, Medicare began the “Bundling” reimbursement program that provides one basic fee for dialysis treatment. This fee includes all ancillary services which were previously billed separately. In Section X.1, page 61, the applicant states:

“BMA historically projected additional revenues for ancillary services provided with each dialysis treatment. Financial projections included in this application will reflect those same additional revenues except for the Medicare treatment volumes. The Medicare treatment volumes (including Medicare Advantage) have been subtracted from the total number of treatments within the ancillary projections.

In November 2013, Medicare announced further cuts to reimbursement for dialysis treatment. These cuts amount to a 12% reduction in revenues and will be phased in over several years. The following table demonstrates the projected Medicare reimbursement by calendar year. BMA will use these rates within the application and its projections of revenues.

*Table X.1-2
Anticipated Medicare Reimbursement by Year*

<i>Year</i>	<i>Medicare Rate</i>
2014	\$239.02
2014	\$239.02
2016	\$229.46
2017	\$220.28
2018	\$211.47
2019	\$211.47

In Section X.2, page 62 and X.4, page 67, the applicant reports projected revenues and expenses as follows:

BMA Nations Ford		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$4,881,545	\$5,102,307
Total Operating Costs	\$4,371,394	\$4,555,616
Net Profit	\$510,151	\$546,691

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the Pro Forma financial statements, including the number of projected treatments, are reasonable. See Section X, page 63, for the applicant's assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the operating expenses of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues (charges) 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.

CA

BMA Nations Ford proposes to add four in-center dialysis stations for a total of 30 dialysis stations upon project completion. However, the applicant received a CON (Project I.D. #F-10179-13) for two additional stations on April 3, 2014, therefore this application is conditioned to only develop two additional stations. See Condition # 2 in Criterion (4).

BMA Nations Ford was serving 102 patients weekly on 24 stations, which is 4.25 patients per station or 106.25% of capacity, as of June 30, 2013. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 33-35 of the application. The growth projections are based on a projected 6.6% average annual growth rate in the number of dialysis patients at the BMA Nations Ford facility.

According to the January 2014 North Carolina Semiannual Dialysis Report there are 17 ESRD facilities in Mecklenburg County; 15 of those facilities are operational and operating a total of 377 available stations. Of those facilities located in Mecklenburg County, 13 of those facilities (one facility is not currently operational) are located in Charlotte along with BMA Nations Ford for a total of 14 facilities in Charlotte that provide ESRD services. Those facilities are briefly discussed below:

Name of facility	# of Certified dialysis stations as of 6/30/2013	# of Stations approved per CON conditional approval*	# of In-center patients	Utilization by % as of 6/30/2013	Distance to BMA Nations Ford
BMA Beatties Ford*	32		120	93.75%	13.2 miles
BMA Nations Ford*	24	2	102	106.25%	
BMA East Charlotte*	24	9	83	86.46%	11.1 miles
BMA North Charlotte*	27	3	119	110.19%	15.0 miles
BMA West Charlotte*	29		83	71.55%	11.3 miles
CMC	9		13	36.11%	7.6 miles
Charlotte Dialysis	34	2	120	88.24%	9.0 miles
Charlotte East Dialysis	16		77	120.31%	14.8 miles
DSI Latrobe Dialysis	24		60	62.50%	9.6 miles
DSI Glenwater Dialysis	42		116	69.05%	18.4 miles
FMC Charlotte*	40		130	81.25%	7.2 miles
FMC Matthews*	21		90	104.14%	13.0 miles
FMC Southwest Charlotte***		10 Stations Pending			
Huntersville Dialysis**		10 Stations Pending			
Mint Hill Dialysis	10		32	80.00%	19.1 miles
North Charlotte Dialysis	25		120	120.00%	14.9 miles
South Charlotte Dialysis	20		63	78.75%	6.1 miles

Source: January 2014 SDR; Distance data source: Google Map. *BMA entities. **Approved new site.

As illustrated in the table above, the closest facility to BMA Nations Ford is South Charlotte Dialysis at 6.1 miles driving distance and the facility furthest away is DSI Glenwater Dialysis at 18.4 miles. Twelve of the 14 facilities listed above are operational. Nine of the 12 facilities have a utilization rate above 70%. DSI Charlotte Latrobe Dialysis has a utilization rate of 62.5%, Carolinas Medical Center a utilization rate of 36.11%, and DSI Glenwater a utilization rate of 69.05%. Additionally, according to the US Census Bureau 2012 Population Estimates¹, Charlotte is ranked as the fastest growing city in North Carolina and the 17th ranked city nationally.

The January 2014 SDR identifies a deficit of zero dialysis stations in Mecklenburg County. The county need methodology requires that there be a deficit of at least 10 stations and that

¹US Census Bureau <http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk>
http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2013_PEP_CUMCHG.ST05&prodType=table

all existing facilities operate at or above 80% capacity. However, the applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported is 106.25%. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. At the end of Operating Year One, BMA Nations Ford projects the utilization will be 3.57 in-center patients per station (100 patients / 28 stations = 3.57), which is 89.26% of capacity (3.57 patients per station / 4 patients per station = 0.8926). This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). At the end of Operating Year Two, BMA Nations Ford projects the utilization will be 3.82 in-center patients per station (107 patients / 28 dialysis stations = 3.82), which is 95.53% of capacity (3.82 patients per station / 4 patients per station = 0.9553). Based on the conditional approval of only two additional stations, the census for operating years one and two would be as follows:

Operating Year 1

100 patients dialyzing on 28 stations = 3.60 patients per station
 $100 / (4 \times 28) = 0.8926$, or 89.26%

Operating Year 2

107 patients dialyzing on 28 stations = 3.82 patients per station
 $107 / (4 \times 28) = 0.9553$, or 95.53%

Additionally, the January 2014 SDR reports that as of June 30, 2013, home dialysis patients accounted for 11.7% of Mecklenburg County patients receiving ESRD services. Therefore, projected utilization is based on reasonable and supported assumptions regarding continued growth.

The applicant adequately demonstrates the need to develop two 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

The following table illustrates current and projected staffing for BMA Nations Ford, as provided by the applicant in Section VII.1, page 51:

BMA Nations Ford			
Position	Current FTEs	# of FTE Positions to be Added	Total FTE Positions
RN	4.00	2.00	6.00
Tech.	11.00	2.00	13.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract		
Admin. (FMC Dir. Ops)	0.15	0.00	0.15
Dietician	1.00	0.00	1.00
Social Worker	1.00	0.00	1.00
Medical Records	0.50	0.00	0.50
Chief Tech.	0.25	0.00	0.25
Equipment Tech.	1.00	0.00	1.00
In-Service	0.25	0.00	0.25
Clerical	0.50	0.00	0.50
Total	20.65	4.00	24.65

As shown in the above table, the applicant proposes to employ a total of 24.65 full-time equivalent (FTE) positions to staff BMA Nations Ford upon completion of the proposed project. In Section V.4(c), page 43, the applicant states that Greg Merten, M.D., a nephrologist with Metrolina Nephrology, will serve as medical director of the facility. Exhibit 21 contains a letter from Dr. Merten stating his intention to continue as the medical director for BMA Nations Ford.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. 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.

C

In Section V.1, page 40, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit 21 contains a letter from the medical director of the facility and other physicians expressing their support for the proposed project, and Exhibit 22 contains a patient petition of support for the project. 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.

- (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(b), page 47, the applicant reports that 82.76.% 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 sources of the facility:

BMA Nations Ford	
Source of Payment	Percentage
Commercial Insurance	9.86%
Medicare	68.71%
Medicaid	11.19%
VA	5.69%
Medicare/Medicaid	0.00%
Medicare/Commercial	2.86%
State Kidney Program	0.00%
Other: Self/Indigent	1.70%
Total	100.00%

Table does not foot due to rounding.

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.

County	2010 Total # of Medicaid Eligibles as % of Total Population*	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population*	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Mecklenburg	15%	5.1%	20.1%
Statewide	17%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by BMA Nations Ford. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012, page 74*).

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*² (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%

² www.usrds.org/adr.aspx

Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6.
 Table includes North Carolina statistics only.³

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
TOTAL	\$49.2	100.0%

*Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 327.

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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 48, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status.”

In Section VI.6 (a), page 49, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

³ www.esrdnetwork6.org/publications/reports.html

- (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 47, the applicant provides the projected payer mix for the proposed services at BMA Nations Ford as shown in the following table.

PAYOR	IN-CENTER
Commercial Insurance	9.86%
Medicare	68.71%
Medicaid	11.19%
Medicare/Medicaid	5.69%
Medicare/Commercial	0.00%
State Kidney Program	2.86%
VA	0.00%
Other: Self/Indigent	1.70%
TOTAL	100.00%

The project analyst notes that the historical and the projected payer mix tables provided by the applicant are slightly different. Specifically, the projected Medicare/Medicaid, Medicare/Commercial, State Kidney Program and VA payor mixes are different compared to the historical payor mix for the same payor category. Based on the pro formas provided by the applicant in Section X.3, page 64, the applicant used the historical payor mix to project revenue. Use of the historical payor mix to project revenue is consistent with applications submitted by the applicant in the past. Therefore, the project analyst will assume that 79.9% (68.71% Medicare and 11.19% Medicaid) of the projected payer mix for dialysis visits at the facility for project years one and two will be Medicare/Medicaid. 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, page 49, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA Nations Ford will have an open policy, which means that any nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

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

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

C

In Section V.3, page 41 the applicant states,

“All health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. ...”

Exhibit 19 contains a letter from the FMC Area Manager to Central Piedmont Community College inviting the school to include the facility in its clinical rotations for nursing students. The information the applicant provides in Section V.3 is reasonable and credible and supports a finding of conformity to this criterion.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Nations Ford proposes to add four dialysis stations for a total of 30 certified dialysis stations upon completion of this project and Project I.D. #F-10179-13 (add two stations), Project I.D. #F-10092-13 (add six stations) and Project I.D. #F-10052-12 (relocate six stations). The applicant operates eight dialysis centers in Mecklenburg County. The applicant has an additional facility that has been CON approved, but is not yet operational. There are nine other dialysis centers with various providers of dialysis services in Mecklenburg County. The following table shows the dialysis facilities in Mecklenburg County, their number of certified stations, utilization and number of patients per station.

Name of	# of Certified	%	Patients per
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facility	dialysis stations as of 6/30/2013	Utilization	Station
BMA Beatties Ford*	32	93.75%	3.75
BMA Nations Ford*	24	106.25%	4.25
BMA East Charlotte*	24	86.46%	3.45
BMA North Charlotte*	27	110.19%	4.40
BMA West Charlotte*	29	71.55%	2.86
CMC	9	36.11%	1.44
Charlotte Dialysis	34	88.24%	3.52
Charlotte East Dialysis	16	120.31%	4.81
DSI Latrobe Dialysis	24	62.50%	2.50
DSI Glenwater Dialysis	42	69.05%	2.76
FMC Charlotte*	40	81.25%	3.25
FMC Matthews*	21	104.14%	4.28
FMC Southwest Charlotte***			
Huntersville Dialysis**			
Mint Hill Dialysis	10	80.00%	3.20
North Charlotte Dialysis	25	120.00%	4.80
South Charlotte Dialysis	20	78.75%	3.15

Source: January 2014 SDR; Distance data source: Google Map. *BMA entities. **Approved new site.

As shown in the table above, 11 of the 15 operational Mecklenburg County dialysis facilities are operating at or above 80% utilization (3.2 patients per station), and four of the 15 facilities are operating below 80% utilization. Six of the seven operational BMA facilities are operating at or above 80% utilization.

The January 2014 SDR shows no deficit of dialysis stations in Mecklenburg County, however, in this proposal the applicant is applying for additional stations based on the facility need methodology. According to the January 2014 SDR there are 15 ESRD facilities (including BMA Nations Ford), that are currently operational in Mecklenburg County. The January 2014 SDR reports that as of June 30, 2013, the 24 stations at BMA Nations Ford were operating at 106.25% of capacity ($102 / 24 = 4.25$; $4.25 / 4 = 1.0625$ or 106.25). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility.

In Section V.7, page 45, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states,

“BMA does not expect this proposal to have effect on the competitive climate in Mecklenburg County. According to the January 2014 SDR there were 17 dialysis facilities operating (or planned) within Mecklenburg County. These facilities offer 424 dialysis stations to the more than 1,400 ESRD patients of Mecklenburg County. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who choose dialysis at a BMA facility.

This facility also has added value stemming from the strength of our relationship with Metrolina Nephrology Associates. Metrolina Nephrology Associates is a premier group of nephrologists practicing across south central North Carolina. As evidence by the physician letters of support, the practice brings together the collaborative efforts of 31 very qualified nephrologists to provide care for the patients choosing to dialyze at BMA Nations Ford.

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ... In this application, BMA projects that 79.9% of the In-center patients will be relying upon either Medicare or Medicaid. The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ...

This proposal will ... enhance the quality of the ESRD patients' lives."

See Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding two dialysis stations to the existing BMA Nations Ford facility will have a positive impact on cost-effectiveness, quality and access to the proposed service based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to add two additional stations to the existing facility based on facility need methodology. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to BMA Nations Ford patients;
- The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 (pages 40-44), and VII (pages 51-54), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.
- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 46, the applicant states:

"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."

The applicant provides the following table in Section VI.1(a), page 46, to demonstrate that medically underserved populations will continue to have adequate access to BMA services, as illustrated below.

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Nations Ford	36.5%	25.0%	68.2%	41.3%	73.1%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 68.2% of facility treatment reimbursement is from Medicare.

The applicant further states on page 46,

“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.”

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. 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 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 promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable regulatory review criteria. The specific criteria are discussed below:

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

-C- See Section III.1, page 31, which indicates the facility had a 106.25% utilization rate as of the January 2014 SDR.

.2202(a)(2) Mortality rates;

-C- In Section IV.2, page 38, the applicant reports 2011, 2012 and 2013 facility mortality rates of 10.7%, 8.2% and 5.0%, respectively.

.2202(a)(3) The number of patients that are home trained and the number of patients on Home dialysis;

-NA- In Section IV.3, page 38, the applicant states that BMA Nations Ford does not have any home-trained patients. Patients who are candidates for home dialysis are referred to BMA Charlotte.

.2202(a)(4) The number of transplants performed or referred;

-C- In Section IV.4, page 38, the applicant states BMA Nations Ford referred 15 patients for transplant evaluation in 2013. BMA Nations Ford had five patients receive transplants in 2013.

.2202(a)(5) The number of patients currently on the transplant waiting list;

-C- In Section IV.5, page 38, the applicant states that BMA Nations Ford has five patients on the transplant waiting list.

.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

-C- See Section IV.6, page 39, the applicant reports a total of 201 hospital admissions in 2013; 142 are non-dialysis related and 59 are 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- In Section IV.7, page 39, the applicant reports that in 2013 there were no patients with an infectious disease, and no patients converted to infectious status in 2013.

(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:

.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- Exhibit 12 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.

.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, water supply, and other relevant health and safety requirements.*

-C- See Sections II.1(b)(6), page 12, VII.2, page 52 and XI.6(g), page 73.

.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- In Sections II.7, page 14 and III.7, pages 33-34, BMA Nations Ford provides projected patient origin based on historical experience, assumptions and methodology. The first two years of operation following completion of the project are as follows:

County	Year 1	Year 2	Patients as a Percent of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
Mecklenburg	95.8	102.1	95.0%	95.3%
Iredell	1	1	1.0%	0.9%
Gaston	1	1	1.0%	0.9%
York, SC	3	3	3.0%	2.8%
Total	100.8	107.1	100.0%	100.0%

.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 for such services.*
- C- In Section II.1, page 15, 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.”

10 NCAC 14C .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 station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- BMA 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 Sections II.1, pages 15-16 and III.7, pages 33-35, the applicant projects to serve 100 in-center patients by the end of Year 1, which is 3.57 patients per station ($100 / 28 = 3.57$).
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 15-16 and Section III.7, pages 33-35, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

10 NCAC 14C .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- These services are provided by patient facility of choice and provided by Carolinas Medical Center. See Section V.1, page 40.
- .2204(2) *Maintenance dialysis;*
- C- Provided at BMA Nations Ford. See Section V.1, page 40.
- .2204(3) *Accessible self-care training;*
- C- Provided by BMA Charlotte. See Section V.1, page 40.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- Provided by BMA Charlotte. See Section V.1, page 40 and V.2(d), page 41.
- .2204(5) *X-ray services;*
- C- Provided by patient facility of choice and provided by Carolinas Medical Center. See Section V.1, page 40.
- .2204(6) *Laboratory services;*

- C- Provided by SPECTRA Laboratories, Inc. See Section V.1, page 40, and Exhibit 15.
- .2204(7) *Blood bank services;*
- C- Provided by Carolinas Medical Center. See Section V.1, page 40.
- .2204(8) *Emergency care;*
- C- Provided by BMA Nations Ford facility staff and the hospitals. See Section V.1, page 40.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- Provided by Carolinas Medical Center. See Section V.1, page 40.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- Provided by CMC; Metrolina Nephrology Associates Access Center; Piedmont Surgical or Sanger Heart and Vascular. See Section V.1, page 40.
- .2204(11) *Transplantation services;*
- C- Provided by Carolinas Medical Center. See Section V.1, page 40.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- Provided by referral to Charlotte-Mecklenburg Vocational Rehabilitation services. See Section V.1, page 40.
- .2204(13) *Transportation*
- C- Provided by Charlotte Area Transportation (CATS), A-1 Wheelchair Transport, or area taxi services. See Section V.1, page 40.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
- C- In Section VII.1, page 51, the applicant provides the proposed staffing. In Section VII.2, page 52, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.
- .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, page 52 and Exhibits 9 and 10.