

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 5, 2014

PROJECT ANALYST: Gloria C. Hale

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: F-10249-14/ Bio-Medical Applications of North Carolina, Inc. d/b/a BMA North Charlotte/ Add two dialysis stations for a total of 32 dialysis stations upon completion of this project and Project I.D. #F-10091-13 (add three dialysis stations)/ Mecklenburg County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA North Charlotte proposes to add two in-center dialysis stations to the existing facility for a facility total of 32 in-center dialysis stations upon completion of this project and Project I.D. #F-10091-13 (add three dialysis stations).

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 dialysis facility or for any additional dialysis stations in Mecklenburg County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, BMA North Charlotte demonstrates a need for 14 additional stations in its existing facility based on the facility need methodology, because the utilization rate reported

in the January 2014 SDR is 4.41 patients per station, or 110.19%. This utilization rate was calculated based on 119 in-center dialysis patients and 27 certified dialysis stations as of June 30, 2013 (119 patients/27 stations = 4.41 patients per station). Effective July 15, 2013, BMA was approved to add three dialysis stations to BMA North Charlotte (Project I.D. #F-10091-13) for a total of 30 stations upon completion of the project.

Application of the facility need methodology indicates 14 additional stations are needed for this facility, as illustrated in the following table. However, BMA North Charlotte is seeking to add only two additional stations. Therefore, there will be a total of 32 stations at the completion of this project.

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		110.19%
Certified Stations		27
Pending Stations		3
<b>Total Existing and Pending Stations</b>		<b>30</b>
In-Center Patients as of 6/30/13 (SDR2, January 2014 SDR)		119
In-Center Patients as of 12/31/12 (SDR1, July 2013 SDR)		100
Difference (SDR2 - SDR1)		19
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	38
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12 (SDR1)	0.3800
(ii)	Divide the result of Step (i) by 12	0.0317
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the January 2014 SDR (6/30/13) until the end of calendar year 2013 (6 months)	0.1902
(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	141.6338
(v)	Divide the result of Step (iv) by 3.2 patients per station	44.2606
	and subtract the number of certified and pending stations as recorded in SDR2 [30] to determine the number of stations needed	14

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 14 stations, however Step (C) of the facility need methodology states, *“The facility may apply to expand to meet the need established..., up to a maximum of ten stations.”* The applicant proposes to add only two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: BASIC PRINCIPLES in the 2014 SMFP is also 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 (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A 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

The applicant, BMA North Charlotte, is a subsidiary of Fresenius Medical Care Holdings, Inc. (FMC). The applicant describes how its proposal will promote safety and quality in Section I, pages 4-8, and Section II, pages 12, 23-24, 26-28, and 31-32. The applicant states in Section I, pages 4-5,

*“FMC’s commitment to the quality and availability of dialysis services is evidenced in its organizational structure. The **Clinical Services Department**, within the Dialysis Division (Bio-Medical Applications, or BMA) serves as a central resource for the entire FMC network of health care providers. The department is devoted to assuring all FMC facilities are provided with the best procedures and equipment available and consistently meet the highest possible standards. Professional staff is available to assist facility managers and medical personnel with questions and concerns relative to clinical operations. Additionally, the department provides such services as an ongoing Clinical Review Program, guidelines for the comprehensive training of staff members, a Quality Assurance Program and a full range of services to support home care.*

*Another important resource for the provision of quality care is FMC’s **Technical Services Department**. The primary focus of this department is to oversee the technical and mechanical aspects of dialysis. The department is further supported by [sic] a research and quality control team that consistently leads the industry in dealing with technically complex issues facing dialysis providers.*

...

*The result of these services support the commitment and assurance that every patient receives care of the highest standards each time he or she is treated at an FMC facility.”*

In addition, in Section II, page 12, the applicant states it will provide all services in conformity with applicable laws and regulations, stating it consistently meets CMS and state guidelines for dialysis staffing. Furthermore, it states that all fire, water supply, and other relevant health and safety equipment will be appropriately maintained at the facility.

In Section II, pages 23-24, the applicant states BMA's parent company, FMC, "*encourages all BMA facilities to attain the FMC UltraCare® certification*", an ongoing quality care program focused on delivering optimum care to patients through "*Clinical Leadership ▪ Continuous Quality Improvement ▪ Superior Customer Service Team Approach to Care ▪ Innovative Technology ▪ Patient-Centered Care.*"

Moreover, in Section II, pages 31-32, the applicant discusses its various programs used to ensure quality of care. These include: a quality improvement program, staff orientation and training, in-service education, technical audits, continuous quality improvement, external surveys, and single use dialyzers. In addition, BMA North Charlotte participates in the "*Core Indicators Project*" which includes goals for quality indicators that are more stringent than those of the Federal Centers for Medicare and Medicaid Services for assessing the quality of dialysis treatment outcomes. The following table is provided, on page 32, to illustrate BMA North Charlotte's averages on three quality indicators,

<b>Core Indicator</b>	<b>Measurement</b>	<b>Result</b>
Dialysis Adequacy	% of patients with Ekt/V > 1.2	92.2%
Nutrition	% of patients with Albumin > 3.5	53.0%
Vascular Access	% of patients with AV Fistula	60.5%
	% of patients with Catheter	15.3%

The applicant notes that the higher the number of patients with AV Fistula and the lower the number of patients with catheters "*are a positive indication.*"

#### Promote Equitable Access

The applicant describes how its proposal will promote equitable access in Section II, pages 24-25, and in Section VI, pages 51-52. The applicant states in Section II, pages 24-25, that the majority of its dialysis patients are covered by Medicare and Medicaid and projects that 76.69% of its in-center dialysis treatments will be covered by these two payors. The applicant projects that an additional 3.36% of in-center dialysis treatments will be covered by VA, bringing the projected total for government payors up to 80.0%. In Section VI, page 49, the applicant states,

*"BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age, or any other grouping/category or basis for being an underserved person."*

In addition, the applicant states, on page 52, that there are some patients who do not have sufficient financial resources to pay for the services rendered and that “*BMA allocates these un-collectables to a ‘Bad Debt’ account.*” The applicant reports that the amount of bad debt for BMA North Charlotte was \$1,190,202 for FY 2013. Although BMA’s admission policy requires some type of insurance prior to receiving dialysis services, the applicant states on page 51, “*...the Regional Vice President does have the authority to override the policy. The Social Worker and Business office staff will assist the patient by identifying available sources of funding and completing the required information necessary to obtain assistance.*”

Moreover, the applicant states in Section II, page 25, that it is sensitive to time and distance barriers and that it will “*apply to develop new dialysis facilities when needed*” to address the growing dialysis population in Mecklenburg County. By applying for two additional dialysis stations at BMA North Charlotte, it is addressing a growing need for dialysis services in the county.

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

#### Maximize Healthcare Value

The applicant describes how its proposal will maximize health care value for resources expended in Section II, page 25. The applicant states that its parent company, FMC, “*is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment close to the patient homes.*” Since the majority of BMA North Charlotte’s patients are covered by government payors using fixed rates of reimbursement, BMA “*must work diligently to control costs of delivery for dialysis. BMA does.*”

The applicant adequately demonstrates how its 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 patients to be served. The application is consistent with the facility need determination in the January 2014 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

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA North Charlotte proposes to add two in-center dialysis stations to the existing facility, pursuant to a Facility Need

Determination, for a facility total of 32 stations upon completion of this project and Project I.D. #F-10091-13 (add three stations).

Population to be Served

In Section III.7, page 37, the applicant provides BMA North Charlotte’s projected patient origin during the first two operating years as illustrated below:

COUNTY	OPERATING YEAR 1 CY 2016		OPERATING YEAR 2 CY 2017		COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CENTER PATIENTS	HOME DIALYSIS	IN-CENTER PATIENTS	HOME DIALYSIS	YEAR 1 (CY 2016)	YEAR 2 (CY 2017)
Mecklenburg	148.0	8.3	153.8	12.8	100.0%	100.0%
<b>Total*</b>	<b>148.0</b>	<b>8.3</b>	<b>153.8</b>	<b>12.8</b>	<b>100.0%</b>	<b>100.0%</b>

\*Totals may not foot due to rounding.

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III, pages 33-38, the applicant provides the assumptions and methodology used to project patient utilization and the need for two additional dialysis stations, summarized as follows:

- Based on the data reported in Table A, page 15 of the January 2014 SDR, BMA North Charlotte had 119 in-center patients as of June 30, 2013. There are 27 certified dialysis stations at the facility and a utilization rate of 110.19%.
- Based on information provided by the applicant in Section III.2, page 33, and illustrated in a table provided by the analyst (see Criterion 1), the facility demonstrates a need for 14 additional stations based on facility need methodology.
- The applicant assumes that the number of patients utilizing the facility will increase by 6.6%, equal to the Five Year Average Annual Change Rate (AACR) for Mecklenburg County as stated in the January 2014 SDR.
- The applicant projects to serve home training patients at BMA North Charlotte, projecting as it did in Project I.D. #F-10091-13, that four patients would change to home dialysis each year. *“BMA maintains that projection within this application.”*
- BMA North Charlotte is projected to have 148.0 in-center patients by the end of Operating Year One (January 1, 2016 - December 31, 2016) and 153.8 in-center patients by the end of Operating Year Two (January 1, 2017

– December 31, 2017). The applicant illustrates this in Section III, pages 36-37, applying the Five Year AACR of 6.6% for Mecklenburg County as follows:

- BMA North Charlotte census as of December 31, 2013 = 129 in-center patients
- January 1, 2014 – December 31, 2014 -  $(129 \times .066) + 129 = 137.5$  in-center patients
- January 1, 2015 – December 31, 2015 –  $(137.5 \times .066) + 137.5 = 146.6$  in-center patients for the projected completion date for Project I.D. #F-10091-13
- Four patients are projected to change to home dialysis in CY 2015 as stated in Project I.D. #F-10091-13, therefore the number of in-center patients will be 142.6  $(146.6 - 4 = 142.6)$
- January 1, 2016 – December 31, 2016 –  $(142.6 \times .066) + 142.6 = 152.0$  in-center patients
- Four patients will change to home dialysis in CY 2016 as projected in Project I.D. #F-10091-13, therefore the number of in-center patients will be 148.0  $(152.0 - 4 = 148.0)$  at the end of Operating Year One
- January 1, 2017 – December 31, 2017 –  $(148.0 \times .066) + 148.0 = 157.8$  in-center patients
- Four patients will change to home dialysis in CY 2017 as projected in Project I.D. #F-10091-13, therefore the number of in-center patients will be 153.8  $(157.8 - 4 = 153.8)$  at the end of Operating Year Two

Next, the applicant provides further clarification regarding its projections for the number of home dialysis patients for Operating Years One and Two as follows:

- For the year ending December 31, 2015, the end of the first operating year for Project I.D. #F-10091-13, there will be four home trained patients
- The applicant applies the Five Year AACR for Mecklenburg County, 6.6%, to the number of home trained patients to project growth for CY 2016, resulting in 4.3 home trained patients  $[(4 \times .066) + 4 = 4.3]$
- The 4.3 home trained patients resulting from growth in CY 2016 are added to the four in-center patients expected to change to home dialysis by the end

of CY 2016, resulting in 8.3 home trained patients ( $4.3 + 4 = 8.3$ ) for Operating Year One

- The applicant applies the Five Year AACR for Mecklenburg County, 6.6%, to the number of home trained patients in Operating Year One to project growth for CY 2017, resulting in 8.8 home trained patients [ $(8.3 \times .066) + 8.3 = 8.8$ ]
- The 8.8 home trained patients resulting from growth in CY 2017 are added to the four in-center patients expected to change to home dialysis by the end of CY 2017, resulting in 12.8 home trained patients ( $8.8 + 4 = 12.8$ ) for Operating Year Two

The applicant states, on page 37, “*In financial projections and utilization projections for this application, BMA has rounded down to the whole number.*” Therefore, for Operating Year One, 148 patients would be dialyzing on 32 stations for a total of 4.63 patients per station ( $148/32 = 4.63$ ) which exceeds the minimum of 3.2 patients per station per week as required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need for two additional dialysis stations at the BMA North Charlotte facility. Consequently, 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

The applicant proposes to add two in-center dialysis stations to its existing facility, for a facility total of 32 in-center dialysis stations following completion of this project and Project I.D. #F-10091-13 (add three stations). In Section III.9, page 40, the applicant states that it considered the alternative of applying for fewer additional stations at the facility, however the patient census is growing at the facility and at other BMA facilities in Mecklenburg County. In fact, the applicant states, “*The Facility Need Calculations*

*demonstrate that the facility is growing at 38.9% annually, significantly more than the Mecklenburg County Five Year Average Annual Change Rate.”*

The applicant further states, in Section III.9, page 40, that patient choice would be adversely affected if the stations were not added, and that the facility is projected to exceed 80% utilization. The applicant adequately explains why it chose the selected alternative over the status quo. Furthermore, the application is conforming to all other applicable statutory review criteria. Therefore, the applicant adequately demonstrates that the selected proposal is its least costly or most effective alternative to meet the identified facility need for two additional dialysis stations at BMA North Charlotte. Consequently, the application is conforming to this criterion and is approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA North Charlotte 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 North Charlotte shall develop and operate no more than two additional dialysis stations for a total of 32 certified stations upon completion of this project and Project I.D. #F-10091-13 (add three stations) which shall include any home hemodialysis training or isolation stations.**
  3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA North Charlotte shall install plumbing and electrical wiring through the walls for two additional dialysis stations for a total of 32 dialysis stations which shall include any home hemodialysis training or isolation stations.**
  4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA North Charlotte 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(b), page 59, the applicant states that the capital cost is projected to be \$112,250, including \$98,550 for construction contract fees, \$8,500 for (RO) water treatment equipment, and \$5,200 for equipment/furniture. In Section IX, page 63, the applicant states that there are no start-up or initial operating expenses since BMA North Charlotte is an existing facility.

In Section VIII.2, page 60, the applicant indicates that this project will be funded from accumulated reserves. Exhibit 24 includes a letter dated March 17, 2013 from the Vice President of Fresenius Medical Care Holdings, Inc. verifying the availability of funds for the project, which states in part,

*“As Vice President, I am authorized and do hereby authorize the addition of two dialysis stations, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$112,250 as may be needed for this project.”*

In Exhibit 4, the applicant provides a copy of the most recent audited financial reports for FMC, Inc. and Subsidiaries. As of December 31, 2012, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$341,071,000 with \$17,841,509,000 in total assets and \$9,469,431,000 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 64, the applicant lists the following charges per treatment for each payment source,

**BMA North Charlotte Projected  
Allowable  
In-Center Charges per Treatment**

<b>SOURCE OF PAYMENT</b>	<b>IN-CENTER CHARGE</b>
Private Pay	\$1,425.00
Commercial Insurance*	\$1,425.00
Medicare**	\$239.00
Medicaid	\$137.29
VA	\$146.79
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.00
State Kidney Program	\$100.00
Other: Self/Indigent	\$1,425.00

\*Includes Blue Cross/Blue Shield

\*\*Includes Medicare Advantage program

The applicant states, on pages 64-65, that it is using a Medicare rate of \$239 to reflect Medicare’s ‘*Bundling*’ of the dialysis treatment with all ancillary services and to account for additional reimbursement due to some co-morbid conditions. The applicant states, on page 64, that “...*the basic rate for Medicare reimbursement has been approximately \$240 per treatment.*” Further, the applicant notes, on page 65, that there will be cuts to Medicare reimbursement for dialysis treatment which will be phased in over several years, amounting to a 12% reduction in revenues. The applicant provides the following projected Medicare reimbursement by calendar year, stating, “*BMA will use these rates within in [sic] the application and its projections of revenues.*”

**BMA North Charlotte  
 Anticipated Medicare Reimbursement by Year**

Year	Medicare Rate
2014	\$239.02
2015	\$239.02
2016	\$229.46
2017	\$220.28
2018	\$211.47
2019	\$211.47

In Sections X.2 through X.4, pages 66-73, the applicant reports projected revenues and expenses as follows:

	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
Total Net Revenue	\$7,749,871	\$8,245,672
Total Operating Costs	\$6,383,931	\$6,737,998
Net Profit	\$1,365,940	\$1,507,674

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X, pages 67-72 of the application, for the applicant's assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of 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.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA North Charlotte proposes to add two in-center dialysis stations to the existing facility. As reported by the applicant in Section II, page 14, as of December 31, 2013, BMA North Charlotte was serving 129 patients, six days a week, with 27 certified stations. Three additional dialysis stations are pending certification based on completion of Project I.D. #F-10091-13. Dialysis facilities that operate two shifts per week (2 patients dialyzing per day at each station on alternate days) have a capacity of four patients per station. This equates to 4.78 patients per station, which is 119.50% of capacity (129 patients/27 stations = 4.78; 4.78 patients per station/4 patients per station = 119.50%). 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 as discussed in Section II, page 15 of the application. At the end of

operating year one, with 32 dialysis stations (includes three stations added upon completion of Project I.D. #F-10091-13) and 148 in-center patients projected, the applicant's projected utilization will be 4.62 patients per station (148 patients/32 stations = 4.62). The applicant states, in Section VII.10, page 58, that it has a third shift available from 5:00pm – 10:00pm, three evenings per week. Therefore, five patients can be served at each station on alternate days which equates to a utilization rate of 92.4% (4.62 patients per station/5 patients per station = 0.924). The target utilization rate is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility required by 10A NCAC 14C .2203(b). Therefore, BMA North Charlotte proposes to exceed the minimum target utilization.

At the end of operating year two, with 32 dialysis stations and 153 in-center patients projected, the applicant's projected utilization will be 4.78 patients per station, operating at 95.6% of capacity (153 patients/32 stations = 4.78; 4.78 patients per station/5 patients per station = 0.956). These utilization projections are based on applying the Five Year AACR for Mecklenburg County of 6.60% in dialysis patients utilizing BMA North Charlotte. In addition, some of BMA North Charlotte's in-center patients will convert to home dialysis at the rate of four per year. Reasonable projections for home dialysis patients are provided by the applicant in Section III, pages 35-37. 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.

According to the January 2014 SDR there are 17 dialysis facilities in Mecklenburg County; 15 of those facilities are operational with a total of 377 certified stations. Of those facilities located in Mecklenburg County, 13 of those facilities (including one that is not currently operational and one that is pending a CON decision) are located in Charlotte along with BMA North Charlotte. Each of the 17 facilities in Mecklenburg County is discussed below:

Name of facility	# of Certified dialysis stations as of 6/30/13	# of Stations approved per CON conditional approval	# of In-center patients	Utilization by % as of 6/30/13	Distance to BMA North Charlotte
BMA Nations Ford*	24	0	102	106.25%	14.78 miles
BMA Beatties Ford*	32	0	120	93.75%	8.16 miles
BMA East Charlotte*	24	0	83	86.46%	3.95 miles
BMA North Charlotte*	27	3	119	110.19%	
BMA West Charlotte*	29	0	83	71.55%	10.92 miles
Carolinas Medical Center	9	0	13	36.11%	6.05 miles
Charlotte Dialysis*	34	1	120	88.24%	7.59 miles
Charlotte East Dialysis	16	0	77	120.31%	4.76 miles
DSI Charlotte Latrobe Dialysis	24	0	60	62.50%	5.53 miles
DSI Glenwater Dialysis	42	0	116	69.05%	4.58 miles
FMC Charlotte*	40	-4	130	81.25%	5.65 miles
FMC Matthews*	21	0	90	107.14%	12.18 miles
FMC of Southwest Charlotte**	0	10	0	0.00%	15.63 miles
Huntersville Dialysis***	0	0	0	0.00%	5.42 miles
Mint Hill Dialysis	10	0	32	80.00%	11.57 miles
North Charlotte Dialysis Center	25	0	120	120.00%	9.83 miles
South Charlotte Dialysis	20	0	63	78.75%	16.65 miles

Source: January 2014 SDR; Distance data source: MapQuest. \*BMA entities. \*\*Approved new site. \*\*\*CON decision pending.

As illustrated in the table above, the closest facility to BMA North Charlotte is BMA East Charlotte at approximately four miles driving distance, however its utilization rate is over 85%. The facility that is furthest away is South Charlotte Dialysis at 16.65 miles. Fifteen of the 17 facilities listed above are operational. Ten of the 15 operational facilities have a utilization rate above 80% and five of those are operating at above 100%. According to estimates from the U.S. Census Bureau, Mecklenburg County's population grew 2.38% from July 1, 2012 to July 1, 2013, had 990,977 residents as of July 1, 2013, and was the most populous county in the state<sup>1</sup>.

<sup>1</sup> Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2013, U.S. Census Bureau, Population Division, <http://factfinder2.census.gov>

The applicant adequately demonstrates the need to add two dialysis stations to the existing facility based on the number of in-center patients it proposes to serve. The applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved dialysis facilities in Mecklenburg County. 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 55, the applicant provides current and projected staffing for the BMA North Charlotte facility following the addition of two stations, as illustrated in the following table:

POSITION	CURRENT FTES	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
Registered Nurse	7.00	1.00	8.00
Technician	10.00	3.00	13.00
Clinical Manager/ Director of Nursing	1.00	0	1.00
Administrator (FMC Director of Operations)	0.15	0	0.15
Dietician	1.00	0	1.00
Social Worker	1.00	0	1.00
Home Training Nurse	0.50	1.50	2.00
Medical Records	0.50	0	0.50
Chief Technician	0.25	0	0.25
Equipment Technician	1.00	0	1.00
In-Service	0.25	0	0.25
Clerical	1.00	0.50	1.50
<b>Totals</b>	<b>23.65</b>	<b>6.00</b>	<b>29.65</b>

In Exhibit 21 of the application, the applicant provides a letter from Dr. Daniel J. Tierney, Metrolina Nephrology Associates, PA, stating that he will continue to serve as the Medical Director of BMA North Charlotte. The information provided in Section VII is reasonable and credible. The applicant adequately demonstrates the availability of adequate health manpower and management personnel, including a 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 43, the applicant provides a table listing all ancillary and support services, indicating whether they are provided on the premises or off site, and if off site, by whom. Carolinas Medical Center will provide acute dialysis services when needed, diagnostic evaluation services, transplantation services, x-ray services, blood bank services, pediatric nephrology, and vascular surgical services to BMA North Charlotte patients. Vascular surgery will also be provided by Sanger Heart and Vascular and MNA Vascular Access Center. Psychological counseling will be provided by Carolinas Medical Center, Randolph Road and isolation for hepatitis is provided by referral to BMA Charlotte. Dialysis/maintenance, nutritional counseling, and social work services will be provided onsite. Self care training for hemodialysis, intermittent peritoneal dialysis, CAPD, and CCPD will be referred to BMA Charlotte until BMA North Charlotte's home training program becomes operational. All laboratory services will be provided on site by SPECTRA Laboratories. All other ancillary services will be provided by stated providers.

The applicant states, on page 45, that it has existing professional relationships with local physicians for referrals and that it does not expect referral patterns to change. In addition, the applicant states, in Section V.6(a), page 47,

*“As an active facility in Mecklenburg County, BMA North Charlotte enjoys the support of the medical community and community leadership. The applicant keeps the medical community apprised of developments through the relationship with Nephrology physicians who refer patients to the facility.”*

In addition, the applicant provides a patient petition of support in Exhibit 22.

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 care 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(a), page 49, the applicant states,

*“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 100 facilities in 42 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has eight 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.*

...

*It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”*

In addition, in Section VI.1(b), page 50, the applicant provides the current in-center dialysis payor mix at BMA North Charlotte as of December 31, 2013, as shown in the table below:

<b>BMA NORTH CHARLOTTE PAYOR SOURCE</b>	<b>PERCENT OF TOTAL</b>
Medicare	70.38%
Medicaid	6.31%
Medicare/Medicaid	0%
Commercial Insurance	12.32%
VA	3.36%
Medicare/Commercial	7.04%
Private Pay	0%
Other: Self/Indigent	0.60%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Mecklenburg County and statewide.

<b>COUNTY</b>	<b>2010 TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION</b>	<b>2010 TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION</b>	<b>2008-2009 % UNINSURED (ESTIMATE BY CECIL G. SHEPS CENTER)</b>
Mecklenburg	14.7%	5.1%	20.1%
Statewide	17.0%	6.7%	19.7%

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 with respect to dialysis services offered by BMA North Charlotte. 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 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 does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

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

*"The December 31, 2011 prevalent population included 430,273 patients on dialysis ..."*<sup>2</sup> (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. 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:

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<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

<b>Number and Percent of Dialysis Patients by Age, Race and Gender 2012</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
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%
<b>Gender</b>		
Female	6,692	44.9%
Male	8,226	55.1%
<b>Race</b>		
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.<sup>3</sup>

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

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

C

In Section VI.6 (a), page 53, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facilities within the last five years. Therefore, the application is conforming to this criterion.

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

<sup>3</sup> [www.esrdnetwork6.org/publications/reports.html](http://www.esrdnetwork6.org/publications/reports.html)

C

In Section VI.1(c), page 50, the applicant provides the projected payor mix for the proposed services at BMA North Charlotte. The applicant projects no change from the current payor mix for dialysis visits, however it states “*the payor mix is dynamic and not fixed.*” In addition, the facility is approved for the provision of home dialysis training and support, however there were no patients receiving home dialysis in 2013. Its proposed payor mix is illustrated in the table below:

**BMA NORTH CHARLOTTE  
 PROJECTED PAYOR MIX**

<b>PAYOR SOURCE</b>	<b>IN-CENTER</b>	<b>HOME</b>
Private Pay	0%	0%
Commercial Insurance	12.32%	25.0%
Medicare	70.38%	55.8%
Medicaid	6.31%	0.7%
Medicare/Medicaid	0%	0%
Medicare/Commercial	7.04%	15.0%
State Kidney Program	0%	0%
VA	3.36%	2.1%
Other: Self/Indigent	0.60%	1.4%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

In Section VI.1(c), pages 50-51, the applicant states,

*“BMA expects the percentage of home dialysis patients with commercial insurance to increase as more patients choose home dialysis.*

...

*BMA has noted...that while the ESRD patient population of North Carolina continues to increase at a rate of approximately 3% annually, the home patient population is increasing at significantly higher rates.”*

In addition, the applicant states, on page 51,

*‘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.’*

The applicant demonstrates it will provide adequate access to medically underserved populations, including the elderly. 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 Sections VI.5(a) and (b), page 53, the applicant states that patients have access to dialysis services through Nephrologists who apply for and receive medical staff privileges to admit patients to the facility. Further, the applicant states,

*“BMA North Charlotte will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.*

...

*The Nephrologists expect to continue receiving referrals from the local physician community, home health agencies, and acute care facilities.”*

The applicant adequately demonstrates that BMA North Charlotte 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(a), pages 44-45, the applicant states that all health related training programs are welcome to learn about the facility and receive instruction on ESRD, its prognosis and treatment. Exhibit 19 contains a letter from the FMC Director of Operations to Carolinas College of Health Sciences inviting the school to participate in clinical rotations for its nursing students at the BMA North Charlotte facility. The information provided in Section V.3 and Exhibit 19 is reasonable and credible for an existing facility 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

The applicant proposes to add two dialysis stations to its existing dialysis facility for a total of 32 certified stations upon completion of the proposed project. The January 2014 SDR shows that there is no need for additional dialysis stations in Mecklenburg County, however, the applicant demonstrates a need for 14 additional dialysis stations based on the facility need methodology in the 2014 SMFP. The utilization rate for BMA North Charlotte currently exceeds 110%. BMA North Charlotte is one of 17 in-center dialysis services facilities currently operating, conditionally approved but not yet certified, or pending a CON decision in Mecklenburg County.

In Section V.7, page 48, 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 that it *“has added value”* due to its relationship with Metrolina Nephrology Associates which is a large group of nephrologists practicing in south central North Carolina. In addition, the facility is compelled to operate efficiently since it relies heavily on Medicare and Medicaid payors to cover treatment expenses at fixed rates. Moreover, the applicant states that its combined efforts to contain operating costs and to provide outstanding care to patients contribute to the overall success of the facility and that its proposal to add two dialysis stations will *“enhance the quality of the ESRD patients’ lives.”*

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

- The applicant adequately demonstrates the need, based on ‘Facility Need,’ to add two dialysis stations for a total of 32 certified dialysis stations following completion of this project and Project I.D. #F-10091-13. The applicant also demonstrates that the proposed project will provide additional access to Mecklenburg County residents and is a cost-effective alternative;
- The applicant adequately demonstrates it 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 and VII is reasonable and credible and demonstrates the provision of quality services.

- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations. In Section VI.1, page 49, the applicant states,

*“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 100 facilities in 42 North Carolina Counties...*

*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 applicant provides the following table from Section VI.1(a), page 49, to demonstrate that medically underserved populations will continue to have adequate access to BMA North Charlotte’s dialysis services, as illustrated below:

<b>Facility</b>	<b>Medicaid/ Low Income</b>	<b>Elderly (65+)</b>	<b>Medicare</b>	<b>Women</b>	<b>Racial Minorities</b>
BMA North Charlotte	10.9%	53.5%	82.9%	31.8%	92.2%

*“Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 82.9% of the facility treatment reimbursement is from Medicare.”*

The applicant further states on page 49,

*“It is clear that BMA North Charlotte 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 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. Therefore, the application is conforming to this criterion.

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

C

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, BMA North Charlotte 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 proposal 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- The utilization rate as of June 30, 2013 as shown in the January 2014 SDR is 110.19%. See Exhibit 5 (copy of the January 2014 SDR, Table A, page 8).

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

-C- In Section IV.2, page 41, the applicant reports the 2011, 2012 and 2013 facility mortality rates, which were 4.8%, 13.4%, and 9.5%, respectively.

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

-NA- The applicant states, in Section IV.3, page 41, that it is not yet certified to provide home therapies. It proposed to add home therapies in Project I.D. #F-10091-13 and expects to do so once the project is complete.

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

- C- In Section IV.4, page 41, the applicant states that BMA North Charlotte referred five patients for transplant evaluation in 2013. One patient received a transplant in 2013.

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

- C- In Section IV.5, page 41, the applicant states that BMA North Charlotte has two patients on the transplant waiting list.

*Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

.2202(a)(6)

- C- The applicant reports, in Section IV.6, page 42, that there were a total of 146 hospital admissions in 2013; 6.9% were dialysis-related and 93.2% were 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- In Section IV.7, page 42, the applicant reports that in 2013 there were no patients with Hepatitis B and no patients who converted to infectious status with Hepatitis B in 2013. The applicant states, “BMA does not identify patients with AIDS or other infectious disease. All other patients with infectious disease such as AIDS will receive their dialysis care and treatment in the in-center treatment area.”

*(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 North Charlotte 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 North Charlotte 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 North Charlotte 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 excerpts from Fresenius Medical Care’s written policies and procedures which includes back up for electrical service in the event of a power outage. Fresenius Medical Care (FMC) is the parent company of Bio-Medical Applications of North Carolina, Inc. d/b/a BMA North Charlotte.

.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 North Charlotte 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- The applicant provides documentation that it provides its services in conformity with all applicable laws and regulations in Sections VII.2, page 56, XI.6(e), page 79, and XI.6(g), page 79.

.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 Section II, page 15, BMA North Charlotte provides its projected patient origin. The projected patient origin for the first two years of operation following completion of the project is provided as follows:

County	Operating Year One 1/01/2016 – 12/31/2016		Operating Year Two 1/01/2017 – 12/31/2017	
	IN-CENTER PATIENTS	HOME PATIENTS	IN-CENTER PATIENTS	HOME PATIENTS
Mecklenburg	148.0	8.3	153.8	12.8
<b>Total*</b>	<b>148.0</b>	<b>8.3</b>	<b>153.8</b>	<b>12.8</b>

Assumptions and methodology are provided in Section II, pages 12-15.

.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 North Charlotte 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(a)(9), page 16, 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 North Charlotte 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, page 38, the applicant states it projects to serve 148 in-center patients by the end of Operating Year 1, which is 4.63 patients per station ( $148/32 = 4.63$ ) or 92.6% of capacity ( $4.63/5 = .926$ ).

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

-C- In Section II, pages 12-15 and Section III.7, pages 35-38, 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- See Section V.1, page 43. Diagnostic evaluation services are provided by Carolinas Medical Center.
- .2204(2) *Maintenance dialysis;*
  - C- See Section V.1, page 43. BMA North Charlotte provides maintenance dialysis.
- .2204(3) *Accessible self-care training;*
  - C- See Section V.1, page 43. Self-care training in hemodialysis, intermittent peritoneal dialysis, CAPD, and CCPD is provided through referral to BMA [FMC] Charlotte.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
  - C- See Section V.2(d), page 44. The applicant states that patients dialyzing at home are followed by the BMA [FMC] Charlotte training program.
- .2204(5) *X-ray services;*
  - C- See Section V.1, page 43. X-ray services are provided by Carolinas Medical Center.
- .2204(6) *Laboratory services;*
  - C- See Section V.1, page 43 and Exhibit 15. All laboratory services are provided on the premises by SPECTRA Laboratories.
- .2204(7) *Blood bank services;*
  - C- See Section V.1, page 43. Blood bank services are provided by Carolinas Medical Center.
- .2204(8) *Emergency care;*
  - C- See Section V.1, page 43. Emergency care is provided by fully trained BMA North Charlotte staff and ambulance transport is available to the nearest hospital.
- .2204(9) *Acute dialysis in an acute care setting;*
  - C- See Section V.1, page 43. Acute dialysis in an acute care setting is provided by Carolinas Medical Center.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
  - C- See Section V.1, page 43. Vascular surgery for dialysis treatment patients is provided by Carolinas Medical Center, Sanger Heart and Vascular, and MNA Vascular Access Center.
- .2204(11) *Transplantation services;*
  - C- See Section V.1, page 43. Transplantation services are provided by Carolinas Medical Center.
- .2204(12) *Vocational rehabilitation counseling and services; and*
  - C- See Section V.1, page 43. Vocational rehabilitation counseling and services are provided by the North Carolina Division of Vocational Rehabilitation Services Branch Office.
- .2204(13) *Transportation*

- C- See Section V.1, page 43. Transportation is provided by Charlotte Area Transportation (CATS), A-1 Wheelchair Transport, or area taxi services.

**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 55, the applicant provides the proposed staffing. In Section VII.2, page 56, the applicant states the proposed facility does and will comply with all staffing requirements set forth in 42 C.F.R. Section 494. 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.3, page 56, for discussion of training and certifications held or required for the BMA North Charlotte direct patient care staff. In addition, the applicant states that BMA North Charlotte continually updates its training and corporate staff monitors policies and procedures to keep up to date with federal and state regulations. Moreover, see Exhibit 9 for FMC's Core Curriculum for the Dialysis Technician Training Program Outline and Exhibit 10 for FMC's continuing education programs outlines and requirements.