

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 6, 2015

Findings Date: May 6, 2015

Project Analyst: Fatimah Wilson

Team Leader: Lisa Pittman

Project ID #: F-11007-15

Facility: BMA Beatties Ford

FID #: 960156

County: Mecklenburg

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Add four dialysis stations to the existing facility for a total of no more than 43 certified stations upon completion of this project and Project I.D. #F-10259-14 (add seven stations)

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. (BMA) d/b/a BMA Beatties Ford (“the applicant”), whose parent company is Fresenius Medical Care Holdings, Inc., proposes to add four dialysis stations to its existing facility for a total of 43 certified dialysis stations upon completion of the proposed project and Project I.D. #F-10259-14 (add seven stations).

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis

stations. According to the January 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of five (5) dialysis stations in Mecklenburg County. 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 for the BMA Beatties Ford facility in the January 2015 SDR is 3.8438 patients per station. This utilization rate was calculated based on 123 in-center dialysis patients and 32 certified dialysis stations (123 patients / 32 stations = 3.8438 patients per station). Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY 2015 SDR

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/14		96.09%
Certified Stations		32
Pending Stations		7
Total Existing and Pending Stations		39
In-Center Patients as of 6/30/14 (SDR2)		123
In-Center Patients as of 12/31/13 (SDR1)		108
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	15
	Multiply the difference by 2 for the projected net in-center change	30
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.2778
(ii)	Divide the result of step (i) by 12	0.0231
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.1389
(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	140.0833
(v)	Divide the result of step (iv) by 3.2 patients per station	43.7760
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	5

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five 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.*” The applicant proposes to add four new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: BASIC PRINCIPLES, page 47 of the 2015 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.”

The applicant addresses Policy GEN-3 beginning on page 4 of the application.

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section I.13, pages 4-8, Section II.1, page 19, Section II.3, pages 26-29, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section II, pages 20-21, Section VI.1, page 44, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section II.1, page 21. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 48 of the 2015 SMFP is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2015 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. (BMA) d/b/a BMA Beatties Ford (“the applicant”), whose parent company is Fresenius Medical Care Holdings, Inc., proposes to add four dialysis stations to its existing facility for a total of 43 certified dialysis stations upon completion of the proposed project and Project I.D. #F-10259-14 (add seven stations).

Population to be Served

In Section IV.1, page 37, the applicant identifies the population it served in-center, as of December 31, 2014, as illustrated in the table below.

BMA Beatties Ford Patient Origin

County of Residence	In-Center Patients	Home Patients
Mecklenburg	113	0
Total	113	0

In Section III.7, page 33, the applicant provides a table showing the projected patient origin of the patients to be served at BMA Beatties Ford for the first two years of operation following completion of the project, as shown below.

Projected BMA Beatties Ford Patient Origin

County	Operating Year 1	Operating Year 2	County Patients as a Percent of Total	
	In-Center	In-Center	Year 1	Year 2
Mecklenburg	138.8	148.8	100.0%	100.0%
Total	138.8	148.7	100.0%	100.0%

Note: On page 33, the applicant states that it recognizes that the CON Section has previously indicated that patients are not partial patients, but rather are whole. In financial projections and utilization projections for this application, BMA has rounded down to the whole number.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section III.1, page 30, the applicant states the application is filed pursuant to the Facility Need Methodology. The applicant utilizes data from the January 2015 SDR and proposes to add four (4) dialysis stations to BMA Beatties Ford upon completion of this project and Project I.D. #F-10259-14 (add seven stations).

In Section II, pages 12-14, and Section III.7, pages 31-33, the applicant provides the assumptions and methodology it uses to project utilization for the BMA Beatties Ford facility. The assumptions and methodology are summarized below:

- As of June 30, 2014 (January 2015 SDR) the utilization rate at BMA Beatties Ford was 96.09% or 3.8438 patients per station per week based on 123 patients utilizing 32 existing certified stations.
- The applicant projected growth for the patients residing in Mecklenburg County at the 7.1% Mecklenburg County Five Year Average Annual Change Rate published in the January 2015 Semiannual Dialysis Report (SDR).
- The project is scheduled to be completed December 31, 2016. Operating Year One is January 1, 2017 – December 31, 2017. Operating Year Two is January 1, 2018 – December 31, 2018.
- The applicant states that the facility has experienced a decline in patient utilization in the six months prior to December 31, 2014. The decline is based on a facility census of a 113 in-center Mecklenburg County patients December 31, 2014. This is a decline of 10 patients compared to the June 30, 2014 census of 123 patients. The applicant states that it is not uncommon for a dialysis facility census to decrease, even though the overall trend is an increase.

Projected Utilization

In Section II, page 14 and Section III.7, page 33, the applicant provides the calculations used to arrive at the projected patient census for Operating Year One, as of December 31, 2017 and Operating Year Two, as of December 31, 2018, as shown below.

BMA Beatties Ford	In-Center Dialysis
<i>BMA begins with facility census of Mecklenburg County patients as of December 31, 2014.</i>	113
<i>Growth of the census projected by the Mecklenburg County Five Year Average Annual Change Rate for one year to December 31, 2015.</i>	$(113 \times .071) + 113 = 121.0$
<i>Growth of the census is projected by the Mecklenburg County Five Year Average Annual Change Rate for one year to December 31, 2016. This is the beginning census for this project.</i>	$(121.0 \times .071) + 121.0 = 129.6$
<i>The Mecklenburg County patient census is increased by the Five Year Average Annual Change Rate for one year to December 31, 2017. This is the ending census for Operating Year 1.</i>	$(129.6 \times .071) + 129.6 = 138.8$
<i>The Mecklenburg County patient census is increased by the Five Year Average Annual Change Rate for one year to December 31, 2018. This is the ending census for Operating Year 2.</i>	$(138.8 \times .071) + 138.8 = 148.7$

As shown in the previous table, at the end of Operating Year One, BMA Beatties Ford is projecting an in-center patient census of 138 patients for a utilization rate of 80.23% or 3.21 patients per station (138 patients / 43 stations = 3.21 / 4 = .8023). At the end of Operating Year Two, the applicant is projecting an in-center patient census of 148, for a utilization rate of 86.05% or 3.44 patients per station (148 / 43 = 3.44 / 4 = .8605). The projected utilization of 3.21 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section VI.1, page 44, the applicant states:

“It is clear that BMA Beatties 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.”

On page 44, the applicant states that the patient population of the BMA Beatties Ford facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
BMA Beatties Ford	9.7%	45.1%	72.6%	37.2%	98.2%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 72.0% of the facility treatment reimbursement is from Medicare.

On page 45, the applicant projects that approximately 94.53% of its in-center patients will be covered by some form of Medicare or Medicaid, including Medicare/Commercial insurance. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section III.9, pages 34-36, the applicant discusses the alternatives considered, which include:

- 1) Apply for fewer stations. This alternative was not considered viable because BMA Beatties Ford is highly utilized. As of June 30, 2014, the facility served 123 patients on 32 certified stations for a utilization rate of 3.84 patients per station, or 96.09%. Within this application, BMA projects utilization to exceed 80% at the end of the first year of operations of this project.
- 2) Relocation of dialysis stations from another BMA facility in Mecklenburg County to BMA Beatties Ford. The applicant determined that the existing facilities within Mecklenburg County are all highly utilized. The lowest utilization rate of a BMA facility in Mecklenburg County is BMA West Charlotte with a utilization rate of 78.45% as of December 31, 2014. All other BMA facilities in the county were utilized at a rate higher than 80%.

After considering the above alternatives, the applicant states that the alternative represented in the application, to add four stations to BMA Beatties Ford, is the most effective alternative.

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 this proposal is the least costly or most effective alternative to meet the identified 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 Beatties 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 Beatties Ford shall develop and operate no more than four additional dialysis stations for a total of no more than 43 certified stations following completion of this project and Project I.D. #F-10259-14 (add seven stations), which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Beatties Ford shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations for a total of no more than 43 dialysis stations following completion of this project and Project I.D. #F-10259-14, which shall include any home hemodialysis training or isolation stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Beatties Ford shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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 the table in Section VIII, page 53, the applicant shows the capital cost of the project as summarized in the following table.

Project Capital Costs

Water Treatment Equipment	\$ 1,500
Equipment/Furniture	\$ 14,000
Total Capital Cost	\$ 15,500

In Section IX, page 57, the applicant states BMA Beatties Ford is an existing facility, therefore there are no associated start up or initial operating expenses.

In Section VIII.5, page 55, the applicant states, “*BMA is utilizing accumulated reserves to finance this project.*” The applicant further states:

“Please refer to Exhibit 24 for letter of commitment from Mark Fawcett, Vice President and Assistant Treasurer, Fresenius Medical Care Holdings, Inc. This letter will verify the availability of the FMC funds necessary for the project.”

Exhibit 24 contains a March 16, 2015 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states,

“BMA is submitting a Certificate of Need Application to add four dialysis stations to its BMA Beatties Ford facility in Mecklenburg County. Upon completion of this project and Project I.D. #F-10259-14 the facility will have a total of 43 dialysis stations. The project calls for following capital expenditure:

Capital Expenditure \$ 15,500

As Vice President, I am authorized and do hereby authorize the addition of four dialysis stations, for capital costs identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$15,500 as may be needed for this project.”

In Section VIII.7, page 55, the applicant refers to Exhibit 4 for a copy of the most recent audited FMC Holdings, Inc., financial statements (years ended December 31, 2013 and 2012). As of December 31, 2013, Fresenius Medical Care Holdings, Inc. and Subsidiaries had \$275,719,000 in cash and cash equivalents with \$16,597,314,000 in total assets and \$8,521,824,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

In Section X.1, page 58, the applicant provides its allowable charges per treatment for each payment source, as illustrated below:

Allowable Charge Per Treatment

Payment Source	In-Center
Private Pay	\$ 1,425.00
Commercial Insurance	\$ 1,425.00
Medicare	\$ 239.02
Medicaid	\$ 140.23
Medicare/Medicaid	\$ 239.02
Medicare/Commercial	\$ 239.02
State Kidney Program	\$ 100.00
VA	\$ 231.12
Other: Self/Indigent	\$ 1,425.00

The applicant provides the following explanations for the costs and charges on pages 58-59,

“The commercial charges above do not reflect actual reimbursement rates, and should not be taken as absolute. It is industry standard for providers to have contractual relationships with various payors, resulting in less reimbursement than the stated charge.

...

BMA also notes that Medicare began the “Bundling” reimbursement program in 2010. The Bundling program provides one basic fee for the dialysis treatment; this fee includes all ancillary services which were previously billed separately. As a consequence of this, the basic rate for Medicare reimbursement has been approximately \$240 per treatment. Medicare will provide additional reimbursement for some co-morbid conditions. BMA has reflected a Medicare rate of \$239 in the above table.”

The applicant projects revenues in Section X.2-4, pages 59-64, and operating expenses in Section X.4, page 64, as summarized in the table below:

BMA Beatties Ford	Operating Year 1 1/1/17 – 12/31/17	Operating Year 2 1/1/18 – 12/31/18
Total Net Revenue	\$ 5,950,172	\$ 6,371,050
Total Operating Expenses	\$ 5,005,979	\$ 5,276,141
Net Profit	\$ 944,192	\$ 1,094,909

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. See Section X.3, pages 60-62 for the applicant’s assumptions, including number of treatments (3 treatments/week, 52 weeks/year, and 6.5% missed treatments) for in-center patients. The applicant’s projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section VII.1, page 49, the applicant provides projected staffing and salaries. The financials in Sections X.4 and X.5, pages 63-65, show budgeted operating costs adequate to cover the projected staffing.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project 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. (BMA) d/b/a BMA Beatties Ford (“the applicant”), whose parent company is Fresenius Medical Care Holdings, Inc., proposes to add four dialysis stations to its existing facility for a total of 43 certified dialysis stations upon completion of the proposed project and Project I.D. #F-10259-14 (add seven stations).

According to the January 2015 Semiannual Dialysis Report, including BMA Beatties Ford, there are 17 dialysis facilities in Mecklenburg County, as follows:

Mecklenburg County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/14	% Utilization	Patients Per Station
BMA Beatties Ford (BMA)	32	96.09%	3.84
BMA Nations Ford (BMA)	24	113.54%	4.54
BMA East Charlotte (BMA)	24	69.79%	2.79
BMA North Charlotte (BMA)	28	110.71%	4.42
BMA West Charlotte (BMA)	29	70.69%	2.82
Carolinas Medical Center (CMC)	9	47.22%	1.88
Charlotte Dialysis (DaVita)	35	80.00%	3.20
Charlotte East Dialysis (DaVita)	24	84.38%	3.37
DSI Charlotte Latrobe (TRC)	24	67.71%	2.70
DSI Glenwater (TRC)	42	73.21%	2.92
FMC Charlotte (BMA)	40	86.88%	3.47
FMC Matthews (BMA)	21	100.00%	4.00
FMC Southwest Charlotte (BMA)*	0	0.00%	0.00
Huntersville Dialysis (DaVita)*	0	0.00%	0.00
Mint Hill Dialysis (DaVita)	10	87.50%	3.50
North Charlotte Dialysis (DaVita)	35	88.57%	3.54
South Charlotte Dialysis (DaVita)	20	73.75%	2.95

Source: January 2015 SDR, Table A.

*New Site, no data reported

The applicant operates eight (8) of the 17 dialysis facilities in Mecklenburg County. DaVita, DSI Renal, Total Renal Care (TRC) and Carolinas Medical Center (CMC) are the other providers of dialysis services in Mecklenburg County, as shown in the table above. Nine of the seventeen Mecklenburg County dialysis facilities are operating above 80% utilization (3.2 patients per station), two of the seventeen facilities are operating at or above 70% utilization, three of the seventeen facilities are operating below 70% utilization and two of the seventeen facilities were not operational at the time of the report.

In Section III.9, page 35, the applicant explains why it did not propose to relocate existing stations from any other BMA facility in Mecklenburg County. The applicant states,

“BMA considered relocation of dialysis stations from another of the BMA facilities in Mecklenburg County, to the BMA Beatties Ford facility. However, the existing facilities are highly utilized.

...

The overall utilization for all BMA facilities in Mecklenburg County has increased over the six months ended December 31, 2014. Only the BMA West Charlotte facility was utilized less than 80%, and its utilization was nearly 80%.”

On page 35, the applicant provides the following table of Mecklenburg County BMA facilities:

	June 30, 2014			December 31, 2014		
	Stations	Patients	Utilization	Stations	Patients	Utilization
BMA Beatties Ford (BMA)	32	123	96.09%	32	113	88.28%
BMA Nations Ford (BMA)	24	109	113.54%	24	110	114.58%
BMA East Charlotte (BMA)	24	67	69.79%	25	84	84.00%
BMA North Charlotte (BMA)	28	124	110.71%	28	117	104.46%
BMA West Charlotte (BMA)	29	82	70.69%	29	91	78.45%
FMC Charlotte (BMA)	40	139	86.88%	40	132	82.50%
FMC Matthews (BMA)	21	84	100.00%	21	96	114.29%
Total	198	728	91.92%	199	743	93.34%

As shown in the table above, only one of the seven Mecklenburg County BMA facilities, BMA West Charlotte, operated at less than 80% as of December 31, 2014. However, the facility was close to the 80% threshold with a utilization rate of 78.45%. All other BMA facilities, including BMA Beatties Ford operated at a utilization rate of 80% or more.

The applicant adequately demonstrates the need to add dialysis stations to the existing BMA Beatties Ford 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 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 49, the applicant states that BMA Beatties Ford currently employs 20.75 full time equivalent (FTE) positions. The applicant further states on page 49 that, that BMA Beatties Ford proposes to hire 6.75 additional FTEs upon project completion, which are illustrated in the table below.

**BMA Beatties Ford
Proposed New FTE Positions**

Position	Projected # of FTEs
RN	2.00
Technician	4.00
Dietitian	0.15
Social Worker	0.10
Equipment Technician	0.50
Total Proposed FTEs	6.75

The applicant projects a total of 27.50 FTE positions upon project completion and states on page 50 that there is no difficulty expected in filling staff positions. In Section VII.9, page 52, the applicant provides a chart showing that the facility will offer two shifts (7am to 12pm and 12PM to 5PM) Monday through Saturday. In Section V.4(c), page 41, and Exhibit 21 the applicant identifies Dr. John Dashiell as the Medical Director for the facility. In Exhibit 21, the applicant provides a letter from Dr. Dashiell indicating his willingness to continue serving as the Medical Director for the facility.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed 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 39, the applicant lists the providers of the necessary ancillary and support services to be provided for the proposed facility. The applicant discusses coordination with the existing health care system on pages 40-42. Exhibits 15, 21 and 26 contain documents from SPECTRA, Metrolina Nephrology and Carolinas HealthCare System, respectively, which demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section V.1 and Exhibits 15, 21 and 26 is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.

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

NA

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

C

In Section VI.1(a), page 44, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 100 dialysis facilities in 42 North Carolina counties (including affiliations with Renal Research Institute facilities). The applicant further states, *“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 proposed patient population of the BMA Beatties Ford facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
BMA Beatties Ford	9.7%	45.1%	72.6%	37.2%	98.2%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say that 72% of the facility treatment reimbursement is from Medicare.

On pages 44-45, the applicant further states:

“BMA notes that the historical performance as reported here is a function of the payor mix for BMA Beatties Ford as of December 30, 2014. The historical performance does change as new patients are admitted. Commercial insurance for patients generally covers the patient for a period of 30 months from the beginning of treatment; thereafter, Medicare provides coverage for the patient. The commercial insurance population is therefore constantly changing. In addition, not every patient beginning dialysis has commercial insurance. Thus, the payor mix should be considered dynamic and not fixed.”

In Section VI.1(b), page 45, the applicant reports that as of December 30, 2014, 94.53% of the patients who were receiving treatments at BMA Beatties Ford, respectively, had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical payment source for those facilities.

HISTORICAL PAYOR MIX

SOURCE OF PAYMENT	BMA Beatties Ford
Private	0.00%
Commercial Insurance	2.93%
Medicare	74.46%
Medicaid	8.04%
Medicare/Medicaid	0.00%
Medicare/Commercial	12.03%
State Kidney Program	0.00%
VA	1.81%
Self/Indigent	0.73%
Total	100.00%

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.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Mecklenburg County	14.7%	5.1%	20.1%
Statewide	16.5%	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 dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99.*)¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted 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 do not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

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

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

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

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which shows 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 2013 USRDS Annual Data Report (p. 332) 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%

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

The applicant demonstrates that it currently 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 applicants;

C

In Section VI.1(f), page 46, 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 facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section VI.6, page 47, the applicant states, *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”*

The application is conforming to this criterion.

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

C

In Section VI.1(d), page 46, 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.”

On page 45, the applicant reports that it expects over 94.53% of the in-center patients who receive treatments at BMA Beatties Ford to have all or part of their services paid for by Medicare or Medicaid, as indicated below.

PROJECTED PAYOR MIX

SOURCE OF PAYMENT	BMA Beatties Ford
Private	0.00%
Commercial Insurance	2.93%
Medicare	74.46%
Medicaid	8.04%
Medicare/Medicaid	0.00%
Medicare/Commercial	12.03%
State Kidney Program	0.00%
VA	1.81%
Self/Indigent	0.73%
Total	100.00%

On page 45, the applicant states,

“Projections of future in-center reimbursement are presented the same as historical facility in-center performance. BMA has projected the payor mix as noted above; however, the payor mix is dynamic and not fixed.”

The applicant demonstrates that medically underserved populations will 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 47, 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 Beatties 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.

Patients cannot self-refer for dialysis and dialysis treatment does require orders from an attending physician with staff privileges at the facility. Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed 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, pages 40-41, the applicant states,

“Exhibit 19 contains a letter from FMC to Central Piedmont Community College encouraging the school to include the BMA Beatties Ford facility in their clinical rotations for nursing students.

...

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. This experience enhances the clinical experience of the

students enrolled in these programs enabling them to learn about the disease, prognosis and treatment for the patient with end stage renal disease.”

Exhibit 19 contains a copy of a letter from Fresenius Medical Care to the Director of Health & Human Services at Central Piedmont Community College inviting the college to include BMA Beatties Ford in the clinical rotation for its nursing students. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Beatties Ford (“the applicant”), whose parent company is Fresenius Medical Care Holdings, Inc., proposes to add four dialysis stations to its existing facility for a total of 43 certified dialysis stations upon completion of the proposed project and Project I.D. #F-10259-14 (add seven stations). According to the January 2015 SDR, there are 17 dialysis facilities in Mecklenburg County, listed as follows:

Mecklenburg County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/14	% Utilization
BMA Beatties Ford (BMA)	32	96.09%
BMA Nations Ford (BMA)	24	113.54%
BMA East Charlotte (BMA)	24	69.79%
BMA North Charlotte (BMA)	28	110.71%
BMA West Charlotte (BMA)	29	70.69%
Carolinas Medical Center (CMC)	9	47.22%
Charlotte Dialysis (DaVita)	35	80.00%
Charlotte East Dialysis (DaVita)	24	84.38%
DSI Charlotte Latrobe (TRC)	24	67.71%
DSI Glenwater (TRC)	42	73.21%
FMC Charlotte (BMA)	40	86.88%
FMC Matthews (BMA)	21	100.00%
FMC Southwest Charlotte (BMA)*	0	0.00%
Huntersville Dialysis (DaVita)*	0	0.00%
Mint Hill Dialysis (DaVita)	10	87.50%
North Charlotte Dialysis (DaVita)	35	88.57%
South Charlotte Dialysis (DaVita)	20	73.75%

Source: January 2015 SDR, Table A.

*New Site, no data reported

As the table above illustrates, the eight BMA Mecklenburg facilities, on average, are highly utilized.

In Section V.7, page 43, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. 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.

...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 94% 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. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This facility is no different.”

See also 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 any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively are incorporated herein by reference.
- The applicant adequately demonstrates BMA will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates BMA will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add stations in its existing facility based on the application of the facility need methodology. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Beatties Ford has operated in compliance with all Medicare Conditions of Participation within the eighteen 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.

CA

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 criteria, as 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- In Section II.1, page 10, and Exhibit 5 (copy of the January 2015 SDR, Tables A and B), the applicant provides the utilization rates for BMA Beatties Ford, which was 96.09% ($123 / 32 = 3.84$; $3.84 / 4 = 0.9609$ or 96.09%).

.2202(a)(2) Mortality rates;

- C- In Section II.1, page 10, the applicant reports 2012, 2013 and 2014 facility mortality rates for BMA Beatties Ford as 7.9%, 14.3% and 8.1%, respectively.

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

- C- In Section II.1, page 10, the applicant states that BMA Beatties Ford is not certified to provide home dialysis therapies. 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 II.1, page 10, the applicant reports that BMA Beatties Ford referred 19 patients for transplant evaluation in 2014, and four patients received transplants in

2014.

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

-C- In Section II.1, page 10, the applicant states that BMA Beatties Ford has eight patients on the transplant waiting list.

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

-C- In Section II.1, page 11, the applicant states that BMA Beatties Ford had a total of 108 hospital admissions in 2014; 23 or 21% were dialysis related and 85 or 79% 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 II.1, page 11, the applicant states that there were no patients with infectious disease or infectious status at the facility during the last calendar year.

(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 (Replaced with 42 CFR Part 494).*

-NA- BMA Beatties Ford is an existing facility applying for additional stations based on the facility need methodology.

.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 Beatties Ford is an existing facility applying for additional stations based on the facility need methodology.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- BMA Beatties Ford is an existing facility applying for additional stations based on the facility need methodology.
- .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 excerpts from Fresenius' Clinical Services Integrated Policy and Procedure Manual Volume II which includes Guidelines for Use of Emergency Generators Policy.
- .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 Beatties Ford is an existing facility applying for additional stations based on the facility need methodology.
- .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 states, in Section II, page 12, that “BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations.” See also Sections I, pages 4-7, VII.2, page 50, and Exhibits 12 and 13.
- .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.1, page 14, the applicant provides the projected patient origin for BMA Beatties Ford. The applicant's assumptions and methodology for its projections are provided on pages 12-14 of the application.

Projected BMA Beatties Ford Patient Origin

County	Operating Year 1	Operating Year 2	County Patients as a Percent of Total	
	In-Center	In-Center	Year 1	Year 2
Mecklenburg	138.8	148.8	100.0%	100.0%
Total	138.8	148.7	100.0%	100.0%

Note: On page 33, the applicant states that it recognizes that the CON Section has previously indicated that patients are not partial patients, but rather are whole. In financial projections and utilization projections for this application, BMA has rounded down to the whole number.

The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

.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 Beatties Ford is an existing facility applying for additional stations based on the facility need methodology.

.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 Beatties Ford is an existing facility applying for additional stations based on the facility need methodology.

.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- BMA Beatties Ford projects to serve 138 in-center patients or 3.21 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 12-13 and Section III.7, pages 32-33.

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

- C- In Section II.1, pages 12-14 and Section III.7, pages 32-33, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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- The applicant states, in Section II, page 17, and Section V, page 39, that diagnostic and evaluation services will be referred to Carolinas Medical Center.

.2204(2) Maintenance dialysis;

- C- The applicant states, in Section II, page 17, and Section V, page 39, that the facility will provide in-center maintenance dialysis.

.2204(3) Accessible self-care training;

- C- The applicant states, in Section II, page 17, and Section V, page 39, that patients who candidates for self-care will be referred to BMA Charlotte home training department.

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

- C- The applicant states, in Section II, page 17, and Section V, page 39, that patients who candidates for home dialysis will be referred to BMA Charlotte home training department.

.2204(5) X-ray services;

- C- The applicant states, in Section II, page 17 and Section V, page 39 that x-ray services will be provided by Carolinas Medical Center.

.2204(6) Laboratory services;

- C- Laboratory services will be provided on-site by the applicant through a contract with Spectra Labs, as stated by the applicant in Section II, page 17, Section V, page 39 and an agreement in Exhibit 15.

.2204(7) Blood bank services;

- C- The applicant states, in Section II, page 17, and Section V, page 39, that blood bank services will be provided by Carolinas Medical Center.

.2204(8) Emergency care;

- C- The applicant states, in Section II, page 17 and Section V, page 39, that facility staff provide emergency care on site until emergency responders arrive and that a fully stocked 'crash cart' is available for use at the facility. Patients in need of emergency care at a hospital are transported via emergency services.

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

- C- The applicant states, in Section II, page 17 and Section V, page 39, that acute dialysis in an acute care setting will be provided by Carolinas Medical Center.

.2204(10) Vascular surgery for dialysis treatment patients;

- C- The applicant states, in Section II, page 17, that patients needing vascular surgery will be referred to Metrolina Nephrology Associates (MNA) Access Center, Southeast Surgical or Sanger Heart and Vascular. In Section V, page 39, the applicant lists Carolinas Medical Center, Sanger Heart and Vascular, and MNA Vascular Access Center as providing vascular surgery services.

.2204(11) Transplantation services;

- CA- In Section II, page 18, and Section V, page 39, the applicant states that candidates for transplantation services will be referred to Carolinas Medical Center. Exhibit 26 contains a copy of an agreement with Carolinas Medical Center to provide these services.

.2204(12) Vocational rehabilitation counseling and services; and

- C- Vocational rehabilitation counseling and services will be referred to the Division of Vocational Rehabilitation of Mecklenburg County, as stated by the applicant in Section II, page 18, and Section V, page 39.

.2204(13) Transportation

- C- The applicant states, in Section II, page 18, and Section V, page 39, that transportation services will be provided by Charlotte Area Transportation (CATS), A-1 Wheelchair Transport and 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 (Replaced with 42 CFR Part 494).

- C- In Section VII.1, page 49, the applicant provides a proposed staffing chart. In Section VII.2, page 50, the applicant states the proposed facility will comply with all staffing requirements set forth in the Federal code. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

.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- In Section II.1, page 18, the applicant discusses the required training for staff and states that training at BMA facilities is continually updated by the In-Service Instructor and Director of Nursing. Exhibit 9 contains an outline of the training program and Exhibit 10 contains an outline of continuing education programs.