ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: November 24, 2015
Findings Date: November 24, 2015

Project Analyst: Julie Halatek
Assistant Chief: Martha J. Frisone

Project ID #: E-11094-15
Facility: BMA of Burke County
FID #: 955785
County: Burke
Applicant: Bio-Medical Applications of North Carolina, Inc.
Project: Add two dialysis stations for a total of 33 dialysis stations upon completion of this project and Project I.D. #E-11009-15 (relocate existing facility and add six 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. d/b/a BMA of Burke County ("BMA") proposes to add two dialysis stations for a total of 33 certified dialysis stations upon completion of this project and Project I.D. #E-11009-15 (relocate existing facility and add six stations). The approved site for the relocated facility is 814 West Union Street in Morganton.

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 July 2015 Semiannual Dialysis Report (SDR), the county need

methodology shows there is a deficit of only four stations in Burke County; therefore, it does not indicate additional stations are needed based on the county need methodology. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for BMA in the July 2015 SDR is 3.8 patients per station. This utilization rate was calculated based on 95 in-center dialysis patients and 25 certified dialysis stations (95 patients / 25 stations = 3.8 patients per station).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

October 1 Review – July 2015 SDR		
Required SDR Utilization		80.00%
Center Utilization Rate as of 12/31/14		95.00%
Certified Stations		25
Pending Stations		6
Total Existing and Pending Stations		**31**
In-Center Patients as of 12/31/14 (SDR2)		95
In-Center Patients as of 6/30/14 (SDR1)		90
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.1111
(ii)	Divide the result of Step (i) by 12	0.0093
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.1111
(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	105.5556
(v)	Divide the result of Step (iv) by 3.2 patients per station	32.9861
	and subtract the number of certified and pending stations to determine the number of stations needed	2

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two 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 two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2015 SMFP which is applicable to this review. **Policy GEN-3: Basic Principles** on page 38 of the 2015 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 12-13, and Section O, pages 65-70. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), pages 13-15; Section C.3, pages 22-23; Section I, pages 48-51; Section L, pages 58-62; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c), page 15, and Section N, page 64. 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.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need methodology in the July 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

BMA proposes to add two dialysis stations for a total of 33 certified dialysis stations upon completion of this project and Project I.D. #E-11009-15 (relocate existing facility and add six stations).

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Burke County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 27, BMA provides a table showing the historical patient origin for in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients served by BMA.

BMA – Patient Origin by County as of June 30, 2015			
County of Residence	**# IC Patients**	**# HH Patients***	**# PD Patients**
Burke	90	--	10
Caldwell	0	--	1
McDowell	1	--	0
Other States	1	--	0
Totals	**92**	**--**	**10**

*On page 27, BMA states that it is not currently certified to provide HH training for patients. The applicant was approved to add HH training services in Project I.D. #E-11009-15.

In Section C.1, page 19, the applicant provides a table showing the projected patient origin of the patients to be served at BMA for Operating Years (OY) 1 and 2 following completion of the project, as shown below.

BMA – Projected Patient Origin by County – Operating Years 1 & 2								
County	**Operating Year 1**			**Operating Year 2**			**County Patients as % of Total**	
	IC	**HH**	**PD**	**IC**	**HH**	**PD**	**OY 1**	**OY2**
Burke	106.7	2.0	12.1	113.0	4.2	13.0	98.4%	98.5%
Caldwell	0.0	0.0	1.0	0.0	0.0	1.0	0.8%	0.8%
McDowell	1.0	0.0	0.0	1.0	0.0	0.0	0.8%	0.8%
Total	**107.7**	**2.0**	**13.1**	**114.0**	**4.2**	**14.0**	**100.0%**	**100.0%**

Note: Totals may not foot due to rounding.

The applicant provides the assumptions and methodology for the above projections on pages 20-22. Exhibit C-1 includes a letter signed by 91 patients currently dialyzing at BMA pledging their support for the proposed project.

The applicant adequately identifies the population to be served.

Analysis of Need

BMA proposes to add two dialysis stations for a total of 33 certified dialysis stations upon completion of this project and Project I.D. #E-11009-15 (relocate existing facility and add six stations). In Section C.2, page 22, the applicant states the need for the proposed project is based on the following factors:

- ESRD patients require dialysis treatment on a regular and consistent basis in order to maintain life.

- Failure to add the proposed stations will lead to higher utilization rates at the existing facility.

- Regarding the facility census, the applicant states:

> *"The BMA of Burke County facility census has been increasing at a rate greater than the Five Year Average Annual Change Rate of Burke County. The Facility Need Methodology calculates a growth rate of 11.1%."*

Projected Utilization

The applicant projects to serve 107 in-center dialysis patients on 33 dialysis stations at the end of the first operating year. This is 3.24 patients per station or an 81 percent utilization rate.

In Section C.1, pages 20-22, BMA provides the assumptions and methodology it uses to determine the need for additional dialysis stations at the facility. The applicant's assumptions and methodology are summarized below:

- The Burke County patient population will grow at a rate of 7.8 percent (the Five Year AACR for Burke County as published in the July 2015 SDR) through the end of the second year of operation.

- In each of the first two operating years after project completion, two in-center patients will switch to home hemodialysis.

- The applicant assumes no increase for residents of other counties who utilize the facility but assumes those patients will continue to dialyze at BMA and are added to the calculations when appropriate.

- The facility was providing dialysis care for one patient from another state on June 30, 2015. The applicant assumes this one patient was a transient patient and will not be dialyzing at BMA for purposes of projecting utilization.

- The project is scheduled for completion on December 31, 2016. Operating Year 1 is CY 2017. Operating Year 2 is CY 2018.

In Section C.1, page 21, the applicant provides the calculations used to arrive at the projected in-center patient census for Operating Year 1 and Operating Year 2 as summarized in the table below.

BMA	In-Center Dialysis
Starting point of calculations is Burke County patients dialyzing at BMA on June 30, 2015.	90
Burke County patient population is projected forward by six months to December 31, 2015. Projection is based on one-half of the AACR for Burke County (7.8%).	[90 X (.078 / 12 X 6)] + 90 = 93.5
Burke County patient population is projected forward by one year to December 31, 2016, using the Five Year AACR (7.8%).	(93.5 X .078) + 93.5 = 100.8
The one McDowell County patient is added. This is the projected starting census for January 1, 2017.	100.8 + 1 = 101.8
Burke County patient population is projected forward by one year to December 31, 2017, using the Five Year AACR (7.8%).	(100.8 X .078) + 100.8 = 108.7
The two patients projected to change to HH dialysis are subtracted.	108.7 – 2 = 106.7
The one McDowell County patient is added. This is the projected census for the end of Operating Year 1 (December 31, 2017).	106.7 + 1 = 107.7
Burke County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (7.8%).	(106.7 X .078) + 106. 7 = 115
The two patients projected to change to HH dialysis are subtracted.	115 – 2 = 113
The one McDowell County patient is added. This is the projected census for the end of Operating Year 2 (December 31, 2018).	113 + 1 = 114

As shown in the previous table, at the end of Operating Year 1, BMA projects an in-center patient census of 107.7 patients, which the applicant rounds down to 107, for a utilization

rate of 81 percent or 3.24 patients per station (107 patients / 33 stations = 3.24 / 4 = .81). At the end of Operating Year 2, BMA projects an in-center patient census of 114, for a utilization rate of 86.25 percent or 3.45 patients per station (114 patients / 33 stations = 3.45 / 4 = .8625). The projected utilization of 3.24 patients per station per week for Operating Year 1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The following tables summarize peritoneal and home hemodialysis projections at the end of Operating Years 1 and 2, based on BMA's assumptions.

BMA	PD
Starting point of calculations is Burke County PD patients dialyzing at BMA on June 30, 2015.	10
Burke County patient population is projected forward by six months to December 31, 2015. Projection is based on one-half of the AACR for Burke County (7.8%).	[10 X (.078 / 12 X 6)] + 10 = 10.4
Burke County patient population is projected forward by one year to December 31, 2016, using the Five Year AACR (7.8%).	(10.4 X .078) + 10.4 = 11.2
The one Caldwell County patient is added. This is the projected starting census for January 1, 2017.	11.2 + 1 = 12.2
Burke County patient population is projected forward by one year to December 31, 2017, using the Five Year AACR (7.8%).	(11.2 X .078) + 11.2 = 12.1
The one Caldwell County patient is added. This is the projected census for the end of Operating Year 1 (December 31, 2017).	12.1 + 1 = 13.1
Burke County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (7.8%).	(12.1 X .078) + 12.1 = 13
The one Caldwell County patient is added. This is the projected census for the end of Operating Year 2 (December 31, 2018).	13 + 1 = 14

BMA	HH
BMA projects two patients will change to HH during Operating Year 1. This is the projected census for the end of Operating Year 1 (December 31, 2017).	2
Burke County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (7.8%).	(2 X .078) + 2 = 2.2
The two patients projected to change to HH during the year are added. This is the projected census for the end of Operating Year 2 (December 31, 2018).	2.2 + 2 = 4.2

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

Access

In Section C.3, pages 22-23, BMA 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 applicant states that the patient population of the proposed facility is expected to be comprised of the following:

BMA – Projected Populations of Traditionally Underserved Groups					
	Medicaid/Low Income	**Elderly (65+)**	**Medicare***	**Women**	**Racial Minorities**
BMA	4.9%	44.1%	64.7%	46.1%	48.0%

*BMA states on page 23 that the Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit and does not mean that 64.7% of the facility treatment reimbursement is from Medicare.

The applicant states on page 23 that the above projections are based on the current demographics of the patients dialyzing at BMA. The applicant also states that Medicare and Medicaid payments represented 82.54 percent and 4.63 percent, respectively, of dialysis treatments in BMA facilities in Fiscal Year 2014. The applicant states that low income and medically underinsured persons will continue to have access to all services provided by BMA and that the facility will conform to all codes and standards for handicapped access.

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 E.1, page 31, BMA discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – The applicant states that this option ignores the utilization of BMA at a rate of above 80 percent and could potentially restrict patient admissions.

2. Develop One Additional Dialysis Station – The applicant states that this option is not the most effective alternative because even with the proposed additional two stations, BMA will see utilization rates greater than 80 percent at the end of Operating Year 1, and fewer stations will result in higher utilization rates.

After considering the above alternatives, BMA states that developing two additional stations is the most effective alternative to meet the needs of dialysis patients.

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, BMA 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 of Burke County 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 of Burke County shall develop and operate no more than two additional dialysis stations for a total of no more than 33 certified stations following completion of this project and Project I.D. E-11009-15 (relocate existing facility and add six stations), which shall include any home hemodialysis training or isolation stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Burke County shall install plumbing and electrical wiring through the walls for no more than 33 dialysis stations at the replacement facility, which shall include any isolation or home hemodialysis stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Burke County shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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

BMA proposes to add two dialysis stations for a total of 33 certified dialysis stations upon completion of this project and Project I.D. #E-11009-15 (relocate existing facility and add six stations).

Capital and Working Capital Costs

In the table in Section F.1, page 32, BMA states dialysis machines will be leased and the only capital cost of the project is $9,000 for equipment and furniture. In Section F.10-11, page 36, the applicant states it does not project any working capital needs related to this project.

Availability of Funds

In Section F.5, page 34, BMA states that it is using accumulated reserve funds to complete the project. Exhibit F-1 contains a letter dated September 15, 2015 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of BMA, committing sufficient cash reserves for development of the project.

In Section F.7, page 35, Applicant refers to Exhibit F-2 for a copy of the most recent Fresenius Medical Care Holdings, Inc. balance sheet. As of December 31, 2014, Fresenius Medical Care Holdings, Inc. and subsidiaries had $195,280,000 in cash and cash equivalents, $18,507,042,000 in total assets and $9,460,268,000 in net assets (total assets less total liabilities).

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

Financial Feasibility

In Section R, Form C, pages 89-94, BMA provides its allowable charge per treatment for each payment source for in-center, peritoneal, and home hemodialysis patients, along with its revenue assumptions.

The applicant provides the following assumptions regarding patient treatments:

- Treatments = Number of Patients x 156 Treatments per Year
- Treatments Missed by Patients = 5%
- CY2015 is considered an interim year with the June 30, 2015 in-patient census of 91 (as well as 11 PD patients) considered to be average census for the year.

BMA projects revenues and summarizes operating expenses in Section R, Form B on page 87, as presented in the table below.

Projected Revenues and Operating Expenses		
BMA	**Operating Year 1 CY 2017**	**Operating Year 2 CY 2018**
Gross Patient Revenue	$68,071,117	$73,902,504
Deductions from Gross Patient Revenue	$62,668,200	$67,959,182
Net Patient Revenue	$5,402,918	$5,943,322
Total Operating Expenses	$4,889,989	$5,259,516
Net Income/Profit	**$512,929**	**$683,805**

Note: Totals may not foot due to rounding.

On Form B in Section R, page 87, the number of in-center patients appears to be 123 and 132, respectively, for Operating Years 1 and 2. These numbers are higher than those reported in Section C (107 and 114, respectively). The Project Analyst was able to confirm that the number of in-center patients listed on Form B is the total number of patients projected in the first two operating years (including in-center, HH, and PD patients), by adding the total number of patients from each treatment modality that are projected in each operating year.

BMA projects that revenues will exceed operating expenses in each of the first two operating years. The applicant's projections of treatments and revenues are reasonable based on the number of 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 H.1, page 57, BMA provides projected staffing and salaries. Form A in Section R, page 94, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, BMA adequately demonstrates the availability of sufficient funds for the capital needs of the project and 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

BMA proposes to add two dialysis stations for a total of 33 certified dialysis stations upon completion of this project and Project I.D. #E-11009-15 (relocate existing facility and add six stations). According to the July 2015 SDR, Burke County has a deficit of four stations. In this application, BMA is applying for additional stations based on the facility need methodology.

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Burke County. Facilities may also serve residents of counties not included in their service area.

BMA operates the only existing dialysis facility located in Burke County and there are no other approved facilities. As of December 31, 2014, BMA was serving 95 in-center patients weekly on 25 stations, which is 3.8 patients per station or 95 percent of capacity (95 patients / 25 stations = 3.8; 3.8 / 4 = 0.95 or 95%). At the end of Operating Year One, after completion of this project and Project I.D. #E-11009-15, the applicant projects that it will serve 107 in-center patients weekly on 33 stations, which is 3.24 in-center patients per station or 81 percent of capacity (107 patients / 33 stations = 3.24; 3.24 / 4 = 0.81 or 81%). This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

BMA adequately demonstrates the need for two additional stations based on the number of in-center patients it currently serves and proposes to serve. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

BMA adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved dialysis services or facilities in Burke 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 H.1, page 44, BMA provides information on projected staffing in Full Time Equivalents (FTEs). The replacement facility is not yet developed, so the staffing table illustrates projected staff following relocation of the facility and completion of this project. BMA states the Medical Director is a contracted position and so is not reflected in the projected staffing numbers in the table below.

BMA – Projected Staffing in FTEs	
Position	**FTE Positions**
Registered Nurse	4.50
Patient Care Techs	13.15
Home Training Nurse	2.00
Dietary Consultant	1.00
Social Services	1.00
Clinical Manager	1.00
Director of Operations	0.15
In-Service	0.25
Clerical	1.50
Chief Tech	0.25
Equipment Tech	1.00
Total	**25.80**

In Section H.7, page 59, BMA projects the number of direct care staff in Operating Year 2, as shown in the table below.

BMA – Projected Direct Care Staff – Operating Year 2 (CY 2018)					
Direct Care Positions	**# FTEs** [a]	**Hours / Year / FTE** [b]	**Total Annual FTE Hours** [c] = [a] x [b]	**Total Annual Hours of Operation** [d]	**FTE Hours / Hours of Operation** [e] = [c] ÷ [d]
RN	4.50	2,080	9,360	3,120	3.00
Patient Care Tech	13.15	2,080	27,352	3,120	8.77
Total	17.15	2,080	36,712	3,120	11.77

In Section H.6, page 46, the applicant states the projected hours of operation are the same as BMA's current operating hours and there is no anticipated change in hours.

In Section I.3, page 49, BMA identifies Dr. Michele Higerd as the Medical Director of the facility. In Exhibit I-6, the applicant provides a September 1, 2015 letter signed by Dr. Higerd of Piedmont Nephrology and Hypertension Associates, P.A., supporting the project and confirming his commitment to continue serving as Medical Director. Exhibit I-7 contains Dr. Higerd's curriculum vitae. In Section H.3, page 58, BMA states that it anticipates no difficulties in filling staff positions. In Section I.3, pages 49-50, the applicant lists six nephrologists who have agreed to provide medical coverage at BMA.

BMA 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.

In Section I, pages 48-50, BMA describes the necessary ancillary and support services and explains how they will be provided. Exhibit I contains copies of agreements between providers of specified services and BMA. The applicant discusses coordination with the existing health care system on pages 48-50. BMA 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. The information in Section I and referenced Exhibits is reasonable 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.

C

In Project I.D. #E-11009-15, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.

(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 L.1, pages 58-59, BMA states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 100[1] dialysis facilities in 42 North Carolina counties (including affiliations with Renal Research Institute facilities). 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 applicant states that BMA and Fresenius-related facilities have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. BMA further states in Section C.3, page 23, that during FY 2014, Medicare and Medicaid represented 82.54 percent and 4.63 percent, respectively, of North Carolina dialysis treatments in Fresenius' facilities.

In Section L.7, page 62, BMA reports that during calendar year 2014, 82.5 percent of the patients who were receiving treatments at the facility had some or all of their services paid for by Medicare or Medicaid, as shown in the table below.

BMA Historical Payor Mix – CY 2014

Source of Payment	% of IC Patients	% of PD Patients
Self Pay / Indigent / Charity	3.51%	0.00%
Medicare	66.67%	57.14%
Medicaid	3.51%	14.29%
Commercial Insurance	3.51%	7.14%
Medicare/Commercial	14.04%	21.43%
VA	8.77%	0.00%
Total	**100.00%**	**100.00%**

Note: HH patients are not included because BMA is not currently certified to serve HH patients.

[1]Section C.3, page 22, states that Fresenius currently operates 102 dialysis facilities in North Carolina counties.

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Burke, Caldwell, and McDowell counties and statewide.

County	Total # of Medicaid Eligibles as % of Total Population*	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population*	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Burke	18.3%	7.7%	17.7%
Caldwell	19.4%	8.6%	18.1%
McDowell	20.4%	9.5%	17.4%
Statewide	16.5%	6.7%	19.7%

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

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. *(Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59).* [2]

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. But it does not include information on the number of elderly, handicapped, minorities, or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

[2]http://www.esrdnetwork6.org/utils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	**% of Dialysis Population**
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.[3]

BMA 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 L.3(e), pages 60-61, BMA 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 requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act."*

[3]http://www.esrdnetwork6.org/utils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf

In Section L.6, page 61, BMA 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 C.3, page 23, BMA states that the patient population is expected to be comprised of the following:

BMA – Projected Populations of Traditionally Underserved Groups					
	Medicaid/Low Income	**Elderly (65+)**	**Medicare***	**Women**	**Racial Minorities**
BMA	4.9%	44.1%	64.7%	46.1%	48.0%

*BMA states on page 23 that the Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit and does not mean that 64.7% of the facility treatment reimbursement is from Medicare.

In Section L.3(b), page 60, BMA 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 59, BMA reports that it expects over 84.8 percent of the patients who receive treatments at the facility to have all or part of their services paid for by Medicare or Medicaid, as indicated below.

BMA Projected Payor Mix – Operating Year 2				
Source of Payment	**% of Total Patients**	**% of IC Patients**	**% of HH Patients**	**% of PD Patients**
Self Pay / Indigent / Charity	3.00%	3.51%	0.00%	0.00%
Medicare	65.90%	66.67%	75.00%	57.14%
Medicaid	4.50%	3.51%	0.00%	14.29%
Commercial Insurance	4.50%	3.51%	25.00%	7.14%
Medicare/Commercial	14.40%	14.04%	0.00%	21.43%
VA	7.60%	8.77%	0.00%	0.00%
Total	**100.00%**	**100.00%**	**100.00%**	**100.00%**

BMA states on page 59 that its payor mix is normally calculated based on treatments, which are the projections used in revenue calculations. The applicant states that since the question in Section L asks for payor mix by number of patients, the numbers above differ from those used in other calculations.

BMA 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 L.4, page 61, BMA states:

> *"Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA of Burke County has 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."*

BMA 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 M, page 61, BMA states:

> *"All health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. 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 M-1 contains a copy of a letter from Fresenius Medical Care to the Dean of the School of Health Sciences at Western Piedmont Community College, inviting the school to include BMA in the clinical rotation for its nursing students. The information provided in Section M is reasonable 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

BMA proposes to add two dialysis stations for a total of 33 certified dialysis stations upon completion of this project and Project I.D. #E-11009-15 (relocate existing facility and add six stations). According to the July 2015 SDR, Burke County has a deficit of four stations. In this application, BMA is applying for additional stations based on the facility need methodology.

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Burke County. Facilities may also serve residents of counties not included in their service area.

BMA operates the only existing dialysis facility located in Burke County and there are no other approved facilities. As of December 31, 2014, BMA was serving 95 in-center patients weekly on 25 stations, which is 3.8 patients per station or 95 percent of capacity (95 patients / 25 stations = 3.8; 3.8 / 4 = 0.95 or 95%). At the end of Operating Year One, after completion of this project and Project I.D. #E-11009-15, the applicant projects that BMA will be serving 107 in-center patients weekly on 33 stations, which is 3.24 in-center patients per station or 81 percent of capacity (107 patients / 33 stations = 3.24; 3.24 / 4 = 0.81 or 81%). This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

In Section N.1, page 64, BMA discusses how any enhanced competition in the service area will promote cost-effectiveness, quality, and access to the proposed services. BMA states:

> *"BMA does not expect this proposal to have effect on the competitive climate in Burke County. At the present time, BMA is the only provider of dialysis services in Burke County. BMA does not project to serve dialysis patients currently being served by another provider. ...*

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 93% of the In-center patients will be relying upon government payors (Medicare / Medicaid / VA). 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 proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."

See also Sections C, F, G, H, L, and P where BMA discusses the impact of the project on cost-effectiveness, quality, and access.

The information provided by BMA in the sections above and referenced exhibits is reasonable 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:

- BMA 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.

- BMA adequately demonstrates it will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.

- BMA demonstrates it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (3) 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.

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by BMA or an affiliated company.

In Section O, beginning on page 65, BMA discusses the methods it uses to insure and maintain quality. In Section O.3, pages 69-70, the applicant states:

> *"BMA* [Fresenius-related facilities] *has incurred two Immediate Jeopardy citations within the recent 18 month period.*
>
> *a. BMA Lumberton dialysis facility on May 6, 2015;*
> *b. BMA East Charlotte dialysis facility on August 11, 2015."*

BMA further states:

> *"BMA Lumberton is back in full compliance with all CMS Guidelines.*
> *BMA East Charlotte is back in full compliance with all CMS Guidelines."*

Based on a review of the certificate of need application and publicly available data, BMA adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

(1) Utilization rates;

-C- In Exhibit G-1 (copy of the July 2015 SDR, Tables A and B), BMA provides the utilization rates for the facility. The December 31, 2014 utilization is 3.8 patients per station or 95 percent with 95 patients dialyzing on 25 stations.

(2) Mortality rates;

-C- In Section P, page 72, BMA provides the mortality rates for the facility from 2012 through 2014.

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

-C- In Section P, page 72, BMA states that it currently has 11 dialysis patients who are home trained and dialyzing at home.

(4) The number of transplants performed or referred;

-C- In Section P, page 73, BMA reports that it referred 16 patients for transplant evaluation in 2014.

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

-C- In Section P, page 73, BMA states that it has six patients on the transplant waiting list.

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

-C- In Section P, page 73, BMA reports a total of 124 hospital admissions in 2014 with 5 (4.0%) being dialysis related.

(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.

-C- In Section P, page 73, BMA reports that it has two patients dialyzing in isolation due to hepatitis. There were no conversions to infectious status 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:

(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 is an existing facility.

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with 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 is an existing facility.

(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

-NA- BMA is an existing facility.

(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.

-C- Exhibit K-3 contains written policies and procedures for back up electrical service in the event of a power outage.

(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 is an existing facility.

(6) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety

equipment, physical environment, water supply, and other relevant health and safety requirements.

-C- In Section P, page 74, BMA states that it *"...provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements."* See also Section B.4 and B.5, pages 12-18; Section H.2, page 45; Section K.1(g), page 55; and Exhibits K-2 and K-3.

(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 C.1, page 19, BMA provides projected patient origin by county for BMA, based on the facility's existing patient origin. The applicant's assumptions and methodology used for projections are provided on pages 20-22 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

(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 is an existing facility.

(9) A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.

-C- In Section P, page 75, 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."*

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- BMA is an existing facility.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the

beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- BMA proposes to serve 107 in-center patients at the end of Operating Year 1 on 33 dialysis stations, which is 3.24 patients per station per week (107 / 33 = 3.24).

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

-C- In Section C.1, pages 20-22, BMA 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.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

(1) diagnostic and evaluation services;

-C- In Section P, page 75, and Section I.1, page 48, BMA states that diagnostic and evaluation services will be referred to Carolinas HealthCare System – Blue Ridge Morganton Hospital.

(2) maintenance dialysis;

-C- In Section P, page 75, and Section I.1, page 48, BMA states it will provide in-center dialysis maintenance.

(3) accessible self-care training;

-C- In Section P, page 76, and Section I.1, page 48, BMA states candidates for self-care are referred to the facility home training department and trained on-site.

(4) accessible follow-up program for support of patients dialyzing at home;

-C- In Section P, page 76, and Section I.1, page 48, BMA states the facility will provide follow-up services to its patients.

(5) x-ray services;

-C- In Section P, page 76, and Section I.1, page 48, BMA states that x-ray services will be referred to Carolinas HealthCare System – Blue Ridge Morganton Hospital or other local providers.

(6) laboratory services;

-C- In Section P, page 76, and Section I.1, page 48, BMA states that laboratory services will be provided on-site by Applicant through a contract with Spectra Labs. Exhibit I-3 contains a letter from the Vice President at Spectra Laboratories and an agreement documenting its ongoing provision of the above services to the BMA.

(7) blood bank services;

-C- In Section P, page 76, and Section I.1, page 48, BMA states that blood bank services will be referred to Carolinas HealthCare System – Blue Ridge Morganton Hospital. Exhibit I-4 contains an affiliation agreement stating Carolinas HealthCare System – Blue Ridge Morganton Hospital (formerly Grace Hospital) will provide services to the facility's dialysis patients.

(8) emergency care;

-C- In Section P, page 76, and Section I.1, page 48, BMA states that facility staff will provide emergency care on site until emergency responders arrive and that a fully stocked 'crash cart' will be available for use at the proposed facility. Patients in need of emergency care at a hospital are transported via emergency services.

(9) acute dialysis in an acute care setting;

-C- In Section P, page 76, and Section I.1, page 48, BMA states that acute dialysis services will be referred to Carolinas HealthCare System – Blue Ridge Morganton Hospital. Exhibit I-4 contains an affiliation agreement stating Carolinas HealthCare System – Blue Ridge Morganton Hospital (formerly Grace Hospital) will provide services to the facility's dialysis patients.

(10) vascular surgery for dialysis treatment patients;

-C- In Section P, page 76, and Section I.1, page 48, BMA states that vascular surgery patients will be referred to Dr. Randall Bast or Horizon Surgical in Lenoir.

(11) transplantation services;

-C- In Section P, page 77, and Section I.1, page 48, BMA states that transplantation services will be referred to UNC Hospitals. Exhibit I-5 contains an agreement, documenting that UNC Hospitals will provide transplantation services for the facility's dialysis patients.

(12) vocational rehabilitation counseling and services; and

-C- In Section P, page 77, and Section I.1, page 48, BMA states that patients will be referred to the North Carolina Division of Vocational Rehabilitation Services in Burke County for vocational rehabilitation counseling and services.

(13) transportation.

-C- In Section P, page 77, and Section I.1, page 48, BMA states that transportation services will be provided by Greenway Transportation, Specialized Transport, or Medical Transport.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 [494].

-C- In Section H.1, page 44, BMA provides current and proposed staffing. In Section H.2, page 45, BMA states the facility will comply with all staffing requirements set forth in the Code of Federal Regulations. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

(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 P, page 77, BMA discusses the required training for staff and states that training is continually updated, as needed, by the In-Service Instructor and Director of Nursing. In Section H.4, page 45, BMA further discusses its ongoing training program. Exhibit H-1 contains an outline of the training program and an example of one of the training modules. Exhibit H-2 contains a training checklist and a list annual training requirements.