

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 30, 2014

PROJECT ANALYST: Tanya S. Rupp

TEAM LEADER: Lisa J. Pittman

PROJECT I.D. NUMBER: N-10251-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lumberton / Add 2 dialysis stations to existing facility for a facility total of 35 stations upon completion of this project and Project ID# N-10195-13 / Robeson

### 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 Lumberton is currently certified for 30 in-center dialysis stations and provides in-center hemo-dialysis and home hemo-dialysis and peritoneal dialysis training and support services. In this application, the applicant proposes to add two (2) in-center dialysis stations to the existing facility for a facility total of 35 in-center dialysis stations upon completion of this project and Project ID# N-10195-13 (add three stations to existing facility for a total of 33).

The January 2014 SDR reports that as of June 30, 2013 there were 30 certified dialysis stations at BMA Lumberton, and three stations pending certification (the three stations approved in Project ID# N-10195-13). The January 2014 SDR also shows BMA Lumberton was dialyzing 104 in-center patients, which is an 87% utilization rate [104 patients / 30 certified stations = 3.467; 3.467 / 4 = 0.8667]. According to correspondence received by the Certificate of Need Section on April 16, 2014, the three pending stations were certified and dialyzing patients as of March 17, 2014.

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for any additional dialysis stations in Robeson County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, BMA Lumberton is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.47 patients per station, or 87%, as calculated above. See the following table, which illustrates the facility need methodology:

**APRIL 1 REVIEW-JANUARY SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		86.7%
Certified Stations		30
Pending Stations		3
<b>Total Existing and Pending Stations</b>		<b>33</b>
In-Center Patients as of 6/30/13 (SDR2)		104
In-Center Patients as of 12/31/12 (SDR1)		97
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	0.1443
(ii)	Divide the result of step (i) by 12	0.0120
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.0722
(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	111.5052
(v)	Divide the result of step (iv) by 3.2 patients per station	34.8454
	and subtract the number of certified and pending stations as recorded in SDR2 [33] to determine the number of stations needed	<b>2</b>

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.”* As shown in the table above, based on the facility need methodology for dialysis stations, the BMA Lumberton facility has a need for two additional stations. The applicant proposes to add two new stations and,

therefore, the application is consistent with the facility need methodology for dialysis stations. Thus, at the completion of this project, BMA Lumberton will be certified for 35 in-center dialysis stations.

Policy GEN-3 in the 2014 SMFP is also applicable to this review. Policy GEN-3 states:

*“A CON applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A CON 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 CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”*

#### Promote Safety and Quality

In Section I.13, pages 4 - 8, the applicant describes its corporate structure and how that structure contributes to the provision of quality dialysis services, specifically its Clinical Services Department, Technical Services Department, Regulatory Affairs and Law Departments as discussed below:

- Clinical Services Department
  - Serves as a clinical resource for the entire FMC network
  - Provides facilities with the best procedures and equipment available
  - Assists facility managers and medical personnel with questions and concerns on clinical operations
  - Provides ongoing Clinical Review Program, guidelines for comprehensive training, and Quality Assurance Program
- Technical Services Department
  - Oversees the technical and mechanical aspects of dialysis
  - Supported by a research and quality control team that leads the industry in dealing with technically complex issues facing dialysis providers
- Regulatory Affairs and Law Departments
  - Deals with legal and regulatory issues
  - Provides interpretation of legislation and government policy to ensure compliance
- Other Management Resources, including but not limited to:
  - Health, Safety and Risk Management - provides safety and risk management services to each facility

- Research – The Renal Research Institute involves dialysis facilities with strong ties to academic research institutions to ensure that all BMA dialysis facilities utilize the latest technology to deliver quality dialysis services to its patients.
- Regional Vice Presidents – provide operational direction and monitoring of daily operations

In addition, in Section II.1, on pages 27 - 28, the applicant describes the programs currently in place for staff training and orientation, such as a 10-week training program for each new employee, followed by continuous updates. The applicant states staff members are trained in all clinical aspects of their jobs, in facility and corporate policies and procedures, in safety precautions, regulations, and CPR. The applicant further states that training is part of a well-defined *Quality Improvement Program*, and is continually updated by the In-Service Instructor and Director of Nursing.

Additionally, in Exhibit 8, the applicant provides a copy of Fresenius Medical Care's (FMC) corporate *Quality Assessment and Performance Improvement for FMS Inpatient Services Programs*, which details FMC's procedures regarding safety and quality in its dialysis facilities. In Section II.1, on page 21, the applicant describes the *UltraCare*® certification for which all BMA facilities strive. In Section II.3, on pages 27 - 30, the applicant describes additional corporately mandated measures for all BMA facilities to ensure the provision of quality services in its dialysis facilities.

In Section V.7, page 44, the applicant states that all BMA facilities continue to find ways to contain operating costs while providing quality care to its patients. The applicant further states that the proposed project will not adversely affect quality, but will enhance the quality of life for ESRD patients in Robeson County.

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

#### Promote Equitable Access

In Section II.1, page 22, the applicant states:

*“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, BMA is projecting that 87.1% of the In-Center dialysis treatments will be covered by Medicare or Medicaid. An additional 2.63% of the treatments will be reimbursed by VA. Thus, 89.8% of the In-Center revenue is derived from government payors.*

...

*BMA is also keenly sensitive to the second element of 'equitable access' – time and distance barriers. ... As the dialysis patient population of Robeson County continues to increase, the need for dialysis stations will continue to increase. BMA will apply*

*to develop new dialysis facilities when needed. In this case, BMA is applying for two additional stations to meet a growing need in Robeson County.”*

In addition, in Section VI.1, on page 45, the applicant states that BMA has a long history of providing dialysis services to the underserved populations in North Carolina. The applicant states that in North Carolina BMA facilities in FY 2013, Medicare represented 83.97% of dialysis treatments, and Medicaid represented an additional 4.82% of treatments.

The applicant provides a table on page 45 to illustrate the payor mix of BMA Lumberton, as shown below:

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65 +)	MEDICARE	WOMEN	RACIAL MINORITIES
BMA Lumberton	49.2%	25.0%	65.3%	56.5%	67.7%

The applicant adequately demonstrates that the proposal will promote equitable access to dialysis services in Robeson County.

#### Maximize Healthcare Value

In Section II.1, on page 22, the applicant states:

*“BMA is not projecting any capital expenditure for this project. BMA is not seeking State or Federal monies to develop the CON application or the additional dialysis stations at the facility; BMA is not seeking charitable contributions. Rather, BMA, through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment close to the patient homes. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. For example, within this application, BMA projects that 87.1% of the treatments are covered by Medicare and Medicaid, and an additional 2.63% are covered by VA. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence BMA must work diligently to control costs of delivery for dialysis. BMA does.”*

The applicant adequately demonstrates that the proposal will maximize healthcare value.

Consequently, the applicant demonstrates that the proposed services incorporate *Policy GEN-3: Basic Principles* in meeting the needs of the patients to be served. The application is also consistent with the facility need determination in the 2014 SMFP. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lumberton proposes to add two in-center dialysis stations to the existing facility, pursuant to the facility need determination, for a facility total of 35 stations upon completion of this project and Project ID# N-10195-13 (add three stations to existing facility for a total of 33). The January 2014 SDR reports that as of June 30, 2013 there were 30 certified dialysis stations at BMA Lumberton, and three stations pending certification (the three stations approved in Project ID# N-10195-13). [According to correspondence received by the Certificate of Need Section on April 16, 2014, the three stations previously approved in Project ID# N-10195-13 were certified and dialyzing patients as of March 17, 2014.] The January 2014 SDR also shows that as of June 30, 2013, BMA Lumberton was dialyzing 104 in-center patients, which is an 87% utilization rate [104 patients / 30 certified stations = 3.467; 3.467 / 4 = 0.8667].

Population to be Served

In Section III.7, page 34 of the application, the applicant projects the following patient origin:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS A % OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Robeson	110.2	19.4	113.0	19.9	97.0%	97.0%
Bladen	3.0	0	3.0	0	2.2%	2.2%
Columbus	1.0	0	1.0	0	0.7%	0.7%
Total	114.2	19.4	117.0	19.9	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.1, on page 31, the applicant states the application is filed pursuant to the Facility Need Methodology in the 2014 SMFP. In Section II.1, on pages 12 – 17, and Section III.7, on pages 32 – 35, the applicant provides the following assumptions and methodology it used to project the need for two additional stations at BMA Lumberton:

1. *“The January 2014 SDR reports that BMA Lumberton was operating at 86.67% utilization with a census of 104 in-center patients dialyzing on 30 certified dialysis stations as of June 30, 2013.*
2. *This project is scheduled to be completed December 31, 2015.*

*Operating Year 1 is the period from January 1, 2015 [sic] - December 31, 2016.  
 Operating Year 2 is the period from January 1, 2016 [sic] - December 31, 2017.*

3. *BMA assumes that the patient population of BMA Lumberton will increase at a rate commensurate with the Robeson County Five Year Average Annual Change Rate as published in the January 2014 SDR. The Robeson County growth rate is 2.6%.*
4. *As of December 31, 2013 the facility was providing dialysis treatment for three patients residing in Bladen County and one patient residing in Columbus County. BMA will not demonstrate growth of the population from Bladen and Columbus County. BMA will only demonstrate an increase in the patient population residing in Robeson County. The patients from Bladen and Columbus County will be added to the projected census at appropriate points in time.*
5. *BMA will demonstrate growth of the home patient population in similar manner.”*

On page 33, the applicant provides a table, reproduced below, to illustrate projected growth of the Robeson County in-center patient population through the second project year:

Begin with Robeson County patient census as of 12/31/13	102
Increase one year to 12/31/14 using Robeson County AACR	$102 \times 1.026 = 104.7$
Increase one year to 12/31/15 using Robeson County AACR	$104.7 \times 1.026 = 107.4$
Add four Bladen and Columbus County patients.	$107.4 + 4 = 111.4$
Beginning census for facility: 1/1/16	111.4
Increase Robeson County patient census one year to 12/31/16 using Robeson County AACR	$107.4 \times 1.026 = 110.2$
Add four Bladen and Columbus County patients; Year 1 Census	$110.2 + 4 = 114.2$
Increase Robeson County patient census one year to 12/31/17	$110.2 \times 1.026 = 113.0$
Add four Bladen and Columbus County patients; Year 2 Census	$113.0 + 4 = 117.0$

In its methodology on pages 12, 16, and 33, the applicant states the January 2014 SDR reported 104 in-center patients were dialyzing at BMA Lumberton as of June 30, 2013. Furthermore, the applicant states it will utilize only Robeson County patients in its calculation of growth projections for in-center patients. Thus, the applicant states it will subtract four patients from the census who are residents of either Bladen or Columbus Counties.

In the table above, reproduced from page 33, the applicant begins its calculations with 102 in-center patients from Robeson County as of December 31, 2013. In Section IV.1, on page 38, the applicant states the patient origin for BMA Lumberton as of December 31, 2013 was 102 Robeson County patients, three Bladen County patients, and one Columbus County patient, for a facility total of 106 in-center patients.

The applicant’s projections for the number of home dialysis patients are provided in the following table, from page 34 of the application:

Begin with facility census for home patients as of 12/31/13	18
Increase by Robeson County AACR to 12/31/14	18 x 1.026 = 18.5
Increase by Robeson County AACR to 12/31/15	18.5 x 1.026 = 18.9
Increase by Robeson County AACR to 12/31/16	18.9 x 1.026 = 19.4
Increase by Robeson County AACR to 12/31/17	19.4 x 1.026 = 19.9

In Section III.7, on page 34, the applicant states it projects that one patient in each of Operating Years One and Two will change his or her modality from in-center to home dialysis.

The applicant projects the following mix of in-center and home dialysis patients for BMA Lumberton following the addition of two stations:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS % OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Robeson	110.2	19.4	113.0	19.9	97.0%	97.1%
Bladen	3.0	0	3.0	0	2.2%	2.2%
Columbus	1.0	0	1.0	0	0.7%	0.07%
Total	113.0	20.0	116.0	21.0	100.0%	100.0%

Therefore, in Operating Year One, the applicant projects to serve 113 in-center patients on 35 dialysis stations, which is 3.23 patients per station, or 80.75% of capacity [ $113 / 35 = 3.23$ ;  $3.23 / 4 = 0.875$ ]. Likewise, in Operating Year Two, the applicant projects to serve 116 in-center patients on 35 stations, which is 3.3 patients per station, or 83% of capacity [ $116 / 35 = 3.31$ ;  $3.31 / 4 = 0.8275$ ]. Thus, in the first operating year, the applicant projects to serve at least 3.2 patients per station per day, as required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and supported assumptions regarding continued growth of dialysis patients at BMA Lumberton.

Access to Services

In Section VI.1, pages 45 - 46, the applicant states that BMA currently operates 100 facilities in 42 North Carolina counties, all of which include low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The applicant projects that 89.8% of its patients will be covered by Medicare and Medicaid. The applicant adequately demonstrates the need that this population has for the dialysis services proposed. Furthermore, the applicant adequately demonstrates the extent to which all residents of the area; 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 dialysis services proposed.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for two additional in-center dialysis stations and the extent to which all

residents of the area are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section III.9, pages 36 - 37, the applicant describes the alternatives it considered prior to the submission of this application, which include:

- 1) Apply for fewer than two stations: The applicant states that this alternative is not consistent with the increasing demand for dialysis services in Robeson County; in particular, at BMA Lumberton. The applicant states the facility need methodology calculations demonstrate a 14.4% annual growth rate at this facility, which is more than the Five Year AACR of 2.6% from the January 2014 SDR.
- 2) Maintain the status quo: The applicant states that this alternative is not an option because failure to apply for these stations eventually removes patient choice from patients seeking dialysis treatment in Robeson County. The applicant provides a table on page 36, reproduced below, that shows all the dialysis facilities in Robeson County are operating at or above 80% utilization as of February 28, 2014:

FACILITY	# CERTIFIED STATIONS	# CON APPROVED STATIONS	# IN-CENTER PATIENTS	UTILIZATION RATE
BMA Red Springs	12	0	43	89.58%
FMC Robeson County	23	0	74	80.43%
FMC Pembroke	13	6	51	98.08%
FMC St. Pauls	15	0	49	81.67%
BMA Lumberton	30	3	110	91.67%
Total	93	9	327	87.90%

\*The applicant states this data is taken from each facility as of February 28, 2014, when this application was being prepared.

- 3) Add two stations: BMA chose this alternative as most effective and least costly to meet the growing demand for dialysis services at BMA Lumberton.

The applicant adequately demonstrates the need for two additional dialysis stations based on the continued growth of the ESRD patient population in Robeson County and the facility's projected utilization. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, 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 Lumberton 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 Lumberton shall develop and operate no more than two additional stations for a total of no more than 35 certified in-center dialysis stations, which shall include any home hemodialysis training and isolation stations, following completion of this project.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lumberton shall install plumbing and electrical wiring through the walls for no more than two additional dialysis stations for a total of no more than 35 dialysis stations which shall include any home hemodialysis training and isolation stations**
  - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lumberton shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII, pages 53 - 55, the applicant states that BMA will not incur a capital cost to develop this project. In Section IX, page 56, the applicant likewise projects no working capital (start-up and initial operating expenses) associated with the proposed project.

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

*“BMA is submitting a Certificate of Need Application to add two dialysis stations to its BMA Lumberton facility in Robeson County. The project does not require any capital expenditure on behalf of BMA.”*

In Exhibit 4, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. for the fiscal year ended December 31, 2011 and December 31, 2012. As of December 31, 2012, FMC had \$341,071,000 in cash and cash equivalents, \$17,841,509,000 in total assets and \$9,469,431,000 in net assets (total assets less total liabilities).

In Section X.1, page 57, the applicant provides the allowable charges per treatment for each payment source for BMA Lumberton as follows:

PAYOR	ALLOWABLE CHARGE
Private Pay	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$ 239.00
Medicaid	\$ 137.29
Medicare/Medicaid	\$ 239.00
Medicare/Commercial	\$ 239.00
State Kidney Program	\$ 100.00
VA	\$ 146.79
Other: Self/Indigent	\$1,425.00

On page 57, the applicant states that the commercial charges listed do not reflect actual reimbursement rates. In addition, the applicant states that BMA has “*opted in*” completely to Medicare’s “*bundling*” reimbursement program, which provides one basic fee per dialysis treatment, which is approximately \$240.00 per treatment. This fee includes all ancillary services which were previously billed separately.

The applicant projects revenues in Section X.2 and operating expenses in Section X.4 of the application. In Section X.2 - X.4, pages 59 - 66, the applicant projects revenues and expenses for BMA Lumberton as follows:

BMA LUMBERTON		
	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$6,465,386	\$6,432,942
Total Operating Costs	\$5,190,225	\$5,227,129
<b>Net Profit</b>	<b>\$1,275,161</b>	<b>\$1,205,813</b>

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X, pages 57 - 67, for the applicant’s assumptions.

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. In addition, the applicant states that there are no capital or working capital costs for this project. Therefore, the application is conforming to this criterion.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lumberton proposes to add two in-center dialysis stations to its existing facility for a total of 35 in-center dialysis stations upon project completion. Currently there are two dialysis providers in Robeson County, BMA and DaVita. In addition, there are six dialysis facilities, five of which are operated by BMA. In Section V.7, on page 44, the applicant states:

*“The DaVita Saint Pauls facility is approximately 12 road miles from the BMA Lumberton facility. In addition, there is another BMA facility closer to the DaVita facility. Consequently, this facility is not likely to be serving patients who might otherwise choose to receive dialysis treatment at the DaVita location.”*

In addition, the January 2014 SDR shows there is a surplus of eight dialysis stations in Robeson County; however, in this application, the applicant is applying for two additional stations at BMA Lumberton, based on the facility need methodology that is specific to this facility. The applicant adequately demonstrates the need for two additional stations at BMA Lumberton based on the number of in-center patients it proposes to serve. The January 2014 SDR reports that as of June 30, 2013, the BMA Lumberton facility was operating at 86.67% capacity, with 104 patients dialyzing on 30 certified stations [ $104 / 30 = 3.47$ ;  $3.47 / 4 = 0.8667$ ]. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility, pursuant to 10A NCAC 14C .2203(b). Based on the calculations above, the applicant is eligible to expand its facility based on the facility need methodology and may apply for additional stations. Upon completion of the proposed project, the facility will have 35 in-center dialysis stations serving up to 114 dialysis patients at the end of Operating Year 1, which is a utilization rate of 81% [ $114 / 35 = 3.25$ ;  $3.25 / 4 = 0.814$ ]. Therefore, the application is conforming to the performance standard promulgated in 10A NCAC 14C .2203.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Robeson 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 50, the applicant projects staffing for BMA Lumberton upon project completion, which is the same as the current staffing at the facility. See the following table:

<b>BMA LUMBERTON        FULL-TIME EQUIVALENT (FTE)        POSITIONS</b>	
RN	5.00
Tech	10.00
Clinical Mgr.	1.00
Admin (FMC Dir. Ops)	0.20
Home Training Nurse	1.00
Dietician	0.70
Social Worker	0.70
Chief Tech	0.10
Equip Tech	1.00
In-Service	0.25
Clerical	1.00
<b>Total FTEs</b>	<b>20.95</b>

The applicant projects a total of 20.95 FTE positions upon project completion. In Section V.4(c), page 42, the applicant identifies the current Medical Director for BMA Lumberton as Dr. Kenneth Melton. In Exhibit 21 the applicant provides a letter from Dr. Melton indicating his willingness to continue to serve as Medical Director of the facility. The applicant adequately documents the availability of resources, including health manpower and management personnel, for 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 40, the applicant lists the providers of the necessary ancillary and support services that will provide service to BMA Lumberton. Exhibit 25 contains a copy of a hospital affiliation agreement with Southeastern Regional Medical Center. Exhibit 26 contains documentation of an agreement with a transplantation center. In Exhibit 21 the applicant provides a referral letter from an area physician offering his support for the proposed project. See also BMA's response to 10A NCAC 14C .2204, Section II, pages 18 - 19. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will continue to be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

C

In Section VI.1, page 45 the applicant states:

*“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... The patient population of the BMA Lumberton facility is comprised of the following:”*

FACILITY	MEDICAID/	ELDERLY	MEDICARE	WOMEN	RACIAL
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	<b>LOW INCOME</b>	<b>(65+)</b>			<b>MINORITIES</b>
BMA Lumberton	49.2%	25.0%	65.3%	56.5%	67.7%

The applicant states:

*“The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 65.3% of the facility treatment reimbursement is from Medicare.”*

In Section, VI.1(b) and (c), page 46, the applicant provides the current and projected payor mix for BMA Lumberton. The applicant expects no change in the current payor mix once the two stations are added. The payor mix is illustrated in the following table.

<b>BMA LUMBERTON CURRENT (AND PROJECTED) PAYOR MIX</b>		
<b>PAYOR SOURCE</b>	<b>IN-CENTER</b>	<b>HOME</b>
Commercial Insurance	8.27%	32.87%
Medicare	78.03%	62.71%
Medicaid	9.10%	0.00%
Medicare/Medicaid	2.63%	0.00%
State Kidney Program	1.98%	4.42%
Total	100.0%	100.0%

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 Robeson County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Robeson County	31.0%	13.2%	23.9%
Statewide	17.0%	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 dialysis services offered by BMA Lumberton. In fact, only 5.8% of all newly diagnosed ESRD patients (incident ESRD patients) in North Carolina’s Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. However, a direct comparison

to the applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

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

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

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

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010: *“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”* Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

*“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”*

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

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

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

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

<b>Number and Percent of Dialysis Patients by Age, Race and Gender</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6.  
 Includes North Carolina, South Carolina and Georgia

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

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

C

In Section VI.6(a), page 49, the applicant states there have been no civil rights access complaints filed against BMA Lumberton or any BMA North Carolina facilities in the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 46, the applicant provides the projected payor mix for the proposed services at BMA Lumberton, as shown in the table below.

SOURCE OF PAYMENT	IN-CENTER	HOME
Commercial Insurance	8.27%	32.87%
Medicare	78.03%	62.71%
Medicaid	9.10%	0.00%
Medicare/Medicaid	2.63%	0.00%
State Kidney Program	1.98%	4.42%
Total	100.00%	100.00%

The applicant adequately demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 48, 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 Lumberton will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”*

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

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

C

In Section V.3, page 41, the applicant refers to Exhibit 19, which includes a letter to Robeson Technical Community College inviting the Director of Nursing Education Services to include BMA Lumberton in its clinical rotation schedule for student nurses. The application is conforming to this criterion.

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Lumberton proposes to add two dialysis stations to its existing facility for a total of 35 in-center dialysis stations upon project completion.

The January 2014 SDR shows there is a surplus of eight dialysis stations in Lumberton County; however, in this application, the applicant is applying for two additional stations based on the facility need methodology. The applicant adequately demonstrates the need for two additional stations at BMA Lumberton based on the number of in-center patients it proposes to serve. The January 2014 SDR reports that as of June 30, 2013, the BMA Lumberton facility was operating at 87% capacity, with 104 patients dialyzing on 30 certified stations [ $104 / 30 = 3.47$ ;  $3.47 / 4 = 0.8667$ ]. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility, pursuant to 10A NCAC 14C .2203(b).

In Section V.7, page 44, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states that the DaVita dialysis facility (Saint Pauls) is approximately 12 road miles from BMA Lumberton. The applicant states the other five dialysis facilities in Robeson County are operated by BMA. The applicant states its proposal to add two dialysis stations to its own facility will not adversely affect those patients who choose to dialyze at the DaVita or one of the other BMA facilities. In addition, the applicant states the two dialysis providers do not share nephrologists in Robeson County.

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

- The applicant adequately demonstrates the need, based on the facility need methodology, to add two dialysis stations for a total of 35 certified in-center dialysis stations upon completion of the proposed project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to BMA Lumberton dialysis patients;

- The applicant adequately demonstrates it will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 (pages 40 - 43), and VII (pages 50 - 52), and referenced exhibits is reasonable and credible and demonstrates the continued provision of quality care.
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations. In Section VI.1, page 45, the applicant states:

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

The applicant provides the following table to demonstrate that medically underserved populations will continue to have adequate access to BMA services, as illustrated below.

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
BMA Lumberton	49.2%	25.0%	65.3%	56.5%	67.7%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 65.3% of facility treatment reimbursement is from Medicare.

The applicant states in Section VI.1(a), page 45, that BMA has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, Medicaid and Medicare recipients, gender, or other considerations.

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 currently provides dialysis services at BMA Lumberton. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Lumberton 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.

### 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 Section II.1, page 10, the applicant states January 2014 SDR reports that the utilization rate for BMA Lumberton was 85.0%, with 34 patients dialyzing on 10 stations. However, the utilization rate was actually 87%, with 104 patients dialyzing on 30 stations, which is the data reported in the January 2014 SDR. Indeed, in Sections II and III, on pages 12, 16 and 33, the applicant states the utilization rate at BMA Lumberton, as reported in the January 2014 SDR was 87%, with 104 patients dialyzing on 30 stations.

The Agency is aware that BMA typically prepares many applications simultaneously and it is reasonable that an occasional typographical error caused by the inadvertent transfer of words from one application to another would occur, notwithstanding editing by the applicant

*(2) Mortality rates;*

-C- In Section II.1, page 10, the applicant states the mortality rates were 15.2%, 13.0% and 14.6% in 2011, 2012 and 2013, respectively.

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

-C- In Section II.3, page 10, the applicant states it currently has 14 patients dialyzing at home at the time the application was filed.

- (4) *The number of transplants performed or referred;*  
-C- In Section II.1, page 10, the applicant states BMA Lumberton referred six transplants in 2012 and seven in 2013. Three transplants were actually performed in 2012 and one in 2013.
- (5) *The number of patients currently on the transplant waiting list;*  
-C- In Section II.1, page 10, the applicant states BMA Lumberton has 14 patients currently on the transplant waiting list.
- (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 there were 380 hospital admissions in 2013, 82 of which were dialysis related and 298 of which were non-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 II.1, page 11, the applicant states that there were no patients at the facility in 2012 or 2013 with an infectious disease.

(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 Lumberton is an existing facility. The applicant, however, provides a copy of an existing hospital affiliation agreement in Exhibit 26.
- (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 Lumberton is an existing facility.

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

-NA- BMA Lumberton 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- See Exhibit 12 for a copy of the Emergency/Disaster Manual (which has policies and procedures for back-up electrical service in the event of a power outage) for BMA Lumberton.

(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 Lumberton 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 II.1, page 12, the applicant states, “BMA will provide all services approved by the Certificate of Need [sic] in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at BMA Lumberton.”

(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, pages 12 - 14, 16 – 18, and Section III.7, pages 32 - 35, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		PATIENTS AS % OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Robeson	110.2	19.4	113.0	19.9	97.0%	97.1%
Bladen	3.0	0	3.0	0	2.2%	2.2%
Columbus	1.0	0	1.0	0	0.7%	0.7%
Total	114.0	19.0	117.0	20.0	100.0%	100.0%

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

(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 Lumberton 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 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.”

#### **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 Lumberton does not propose to establish a new End Stage Renal Disease 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 Lumberton projects utilization of 80.71%, with 3.23 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 12 – 14, 16 - 18, and Section III.7, pages 32 - 35. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 12 – 14, 16 - 18, and Section III.7, pages 32 - 35. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

#### **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 II.1, page 18, the applicant states, “*Patients will be referred to Southeastern Regional Medical Center.*”
- (2) *maintenance dialysis;*  
-C- In Section II.1, page 18, the applicant states, “*The facility will provide in-center dialysis.*”
- (3) *accessible self-care training;*  
C- In Section II.1, page 18, the applicant states, “*Patients who are candidates for self care will be referred to the facility home training department.*”
- (4) *accessible follow-up program for support of patients dialyzing at home;*  
C- In Section II.1, page 18, the applicant states, “*Patients who are candidates for home dialysis will be referred to the facility home training department.*”
- (5) *x-ray services;*  
C- In Section II.1, page 18, the applicant states, “*Patients will be referred to Southeastern Regional Medical Center or Lumberton Radiology Center.*”
- (6) *laboratory services;*  
-C- In Section II.1, page 19, the applicant states, “*BMA provides on site laboratory services through contract with Spectra Labs.*” See Exhibit 18 for the laboratory services agreement with Spectra Laboratories.
- (7) *blood bank services;*  
-C- In Section II.1, page 19, the applicant states, “*Patients will be referred to Southeastern Regional Medical Center.*”
- (8) *emergency care;*  
-C- In Section II.1, page 19, the applicant states, “*Emergency care for patients is provided on site by BMA staff until emergency responders arrive. In the event of an adverse event while in the facility, BMA staff are appropriately trained; in addition a fully stocked ‘crash cart’ is maintained at the facility. If the patient event requires transportation to a hospital, emergency services are summoned via phone call to 911.*”
- (9) *acute dialysis in an acute care setting;*  
-C- In Section II.1, page 19, the applicant states, “*Patients admitted to hospital [sic] will be referred to Southeastern Regional Medical Center.*”
- (10) *vascular surgery for dialysis treatment patients;*  
-C- In Section II.1, page 19, the applicant states patients will be referred to Village Surgical Associates or Carolina Kidney Care Nephrology Procedure Center.

- (11) *transplantation services;*
- C- In Section II.1, page 19, the applicant refers to Exhibit 26, in which it provides a copy of an existing transplantation agreement with East Carolina University School of Medicine / Pitt County Memorial Hospital.
- (12) *vocational rehabilitation counseling and services; and*
- C- In Section II.1, page 19, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the Robeson County Division of Vocational Rehabilitation.*”
- (13) *transportation.*
- C- In Section II.1, page 19, the applicant states, “*Transportation services are provided by SEATS, Southeastern Area Transportation System.*”

**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.*
- C- In Section II., page 19, the applicant states that sufficient staffing for each shift is provided, and a chart illustrating staffing is included in Section VII.1, on page 50. In Section VII.2, page 51, BMA states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.
- (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 20, and Section VII.5, page 51, the applicant describes the training and continuing education required for all BMA clinical employees. The applicant states that new employees are required to successfully complete a ten-week training program, staff training is continually updated and documented in employee records. The applicant further states that training includes dialysis techniques, safety precautions, CPR, corporate policies and procedures. Exhibit 14 contains an outline of the training program and Exhibit 15 contains the outline of the continuing education information.