

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 12, 2015
Findings Date: June 12, 2015

Project Analyst: Bernetta Thorne-Williams
Team Leader: Lisa Pittman

Project ID #: E-11009-15
Facility: BMA of Burke County
FID #: 150154
County: Burke
Applicant: Bio-Medical Applications of North Carolina
Project: Relocate existing facility and add six stations for a total of 31 stations upon project completion

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 Carolina, Inc. (BMA) d/b/a BMA of Burke County, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to relocate an existing facility and add six new dialysis stations for a total of 31 stations upon project completion. The facility will provide in-center hemodialysis and add home training support and services for home hemodialysis patients and continue to provide services for its peritoneal dialysis patients, in Morganton, Burke County.

Need Determination

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

According to the January 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is deficit of seven dialysis stations in Burke County, however, the identified deficit is not enough to trigger a need for a new dialysis facility within the county. However, the applicant has chosen to apply for additional stations based on the facility need methodology because the utilization rate reported for BMA of Burke County in the January 2015 SDR is 3.6 patients per station. This utilization rate was calculated based on 90 in-center dialysis patients and 25 certified dialysis stations. (90 patients / 25 stations = 3.6 patients per station).

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

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/14		90.00%
Certified Stations		25
Pending Stations		0
Total Existing and Pending Stations		25
In-Center Patients as of 6/30/14 (SDR2)		90
In-Center Patients as of 12/31/13 (SDR1)		82
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.1951
(ii)	Divide the result of step (i) by 12	0.0163
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.0976
(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	98.7805
(v)	Divide the result of step (iv) by 3.2 patients per station	30.8689
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	6

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

Policies

Additionally the following policies are applicable to this review, Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

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 II.1, pages 11-12, Section II.3, pages 20-21, Section V.7, page 44-45, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section II.1, pages 21-22, Section VI, pages 46-50 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section II.1, pages 22-23, Section V.7, page 44, and referenced exhibits. 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 need identified in the 2015 SMFP.

Policy GEN-4 states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its

certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

In Section II.1, page 24, the applicant states how the facility will assure improved energy efficiency and water conservation which includes the use of LED technology, motion sensors for lighting, motion activated sinks, and tankless water heaters.

The applicant adequately described the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The application is consistent with the facility need determination in the January 2015 SDR, Policy GEN-3 and Policy GEN-4. 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 of Burke County proposes to relocate an existing facility and add six dialysis stations for a total of 31 stations upon project completion. The applicant also proposes the addition of home training support and services for home hemodialysis patients and to increase the

training space its peritoneal dialysis patients. The current facility is located at 145 West Parker Road, in Morganton. The applicant identified a primary site, located at 814 West Union Street and secondary site, located at 105 Salem Farm Road, both proposed sites for the 13,155 square feet facility are located in Morganton. The applicant states on page 33, that both sites under consideration are located within three miles of the existing facility.

Population to be Served

In Section III.7, page 36, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

County	Operating Year 1			Operating Year 2			County Patients as a % of Total	
	In-Center	PD	HH	In-Center	PD	HH	Year 1	Year 2
Burke	106.3	10.5	2.0	109.8	11.0	4.1	98.3%	94.8%
Caldwell	1.0	1.0	0	1.0	1.0	0.0	1.7%	1.6%
Total	107.3	11.5	2.0	110.8	12.0	4.1	100%	100%

Need Analysis

In Section III.4, page 33, the applicant states the primary reason for the proposed relocation of the existing facility is to design a space to accommodate the growing needs of BMA of Burke County and its patients. The applicant states that BMA of Burke County also plans to add training and support space for home hemodialysis patients as well as expand its peritoneal dialysis training.

The applicant proposes to relocate the existing 25-stations ESRD facility and to add six new dialysis stations for a total of 31 certified dialysis stations upon project completion. The applicant’s projected utilization for its in-center patients will be 3.45 patients per station or 86.3% by the end of the first year of operation [107 patients / 31 stations = 3.45; 3.45 / 4 = .8625 or 86.3%].

In Section III.7, pages 34-36, the applicant provides its methodology and assumptions for projecting to serve 111 in-center patients by the end of the second year of operation. The applicant states:

“Assumptions

1. *The project is scheduled for completion December 31, 2016.
 Operating Year 1 is the period January 1 through December 31, 2017;
 Operating Year 2 is the period January 1 through December 31, 2018.*

2. *BMA assumes ... BMA Burke County will increase at a rate commensurate with the Burke County Five Year Average Annual Change Rate, 5.2%, as published in the January 2015 SDR.*
3. *[F]or the period ended December 1, 2014 ... BMA [provided dialysis treatment] for one patient residing in "Other States". BMA assumes ... this patient was ... transient ... BMA will not carry that patient forward in projections of future patient population of the facility.*
4. *BMA assumes ... the home hemodialysis patient population of Burke County patients will increase. ... BMA Burke County does not have any dialysis patients residing within Burke County who are home hemodialysis patients. [A]cross North Carolina ... home hemodialysis patient population is increasing at a higher rate than peritoneal dialysis population.*
5. *BMA will project two Burke County dialysis patients to change from in-center dialysis to home hemodialysis during the course of each year, after certification ... Home hemodialysis is reimbursed at the same rate as in-center dialysis. To the extent that this projection of two patients per year to change modality may not materialize, the patient would then continue dialysis as an in-center dialysis patient. Thus the projections of revenues would not be impacted. Any impact then would be an increase in projected utilization of the dialysis stations.*

The applicant provides its methodology in table format for in-center patient utilization in Section III.7, page 35, its methodology for its home hemodialysis and peritoneal dialysis on pages 35-36, as summarized in the tables below:

Methodology for In-Center Patients

<i>BMA begins with the Burke County patient population dialyzing ... December 31, 2014.</i>	93 <i>in-Center patients</i>
<i>BMA projects this census forward for 1 year to December 31, 2015 using the Burke County Five Year Average Annual Change Rate.</i>	$(93 \times .052) + 93 = 97.8$
<i>BMA projects this ... patient population forward for 1 year to December 31, 2016.</i>	$(97.8 \times .052) + 97.8 = 102.9$
<i>BMA adds the patient residing in Caldwell County. This is the projected certification date and beginning census: December 31, 2016</i>	$102.9 + 1 = 103.9$
<i>BMA projects the Burke County patient population forward for 1 year.</i>	$(102.9 \times .052) + 102.9 = 108.3$
<i>BMA subtracts two patients projected to change to home hemodialysis.</i>	$108.3 - 2 = 106.3$
<i>BMA adds the patient residing in Caldwell County. This is the projected ending census for Operating Year 1, December 31, 2017.</i>	$106.3 + 1 = 107.3$
<i>BMA projects the ... patient population forward for 12 months</i>	$(106.3 \times .052) + 106.3 = 111.8$
<i>BMA subtracts two patients projected to change to home hemodialysis.</i>	$111.8 - 2 = 109.8$
<i>BMA adds the patient residing in Caldwell County. This is the projected ending census for Operating December 31, 2018</i>	$109.8 + 1 = 110.8$

Methodology for Home Hemodialysis and Peritoneal Dialysis Patients

Home Hemodialysis		Peritoneal Dialysis	
Assumed two patients per year will change from in-center dialysis to home hemodialysis ... BMA will not demonstrate a home hemodialysis patient population until December 31, 2016, the end of the first operating year.	0	BMA's beginning census as of December 31, 2014	9
Operating Year 1, BMA projected two patients to change to home hemodialysis by year end, December 31, 2016.	2	Census is projected forward to December 31, 2015 using the Burke County Five Year Average Annual Change Rate	$(9 \times .052) + 9 = 9.5$
Patient population is projected forward using Burke County's Five Year Average Annual Change Rate for 1 year.	$(2 \times .052) + 2 = 2.1$	Patient population is projected forward 1 year to December 31, 2016	$(9.5 \times .052) + 9.5 = 10.0$
BMA adds two patients projected to change to home hemodialysis ... This is the projected ending census for Operating Year 2, December 31, 2017.	$2.1 + 2 = 4.1$	The 1 patient residing in Caldwell County is added. This is the projected certification and beginning census: December 31, 2016	$10.0 + 1 = 11.1$
		Patient population is projected forward 1 year.	$(10.0 \times .052) + 10.0 = 10.51$
		The 1 patient residing in Caldwell County is added. This is the projected ending census: December 31, 2016	$10.5 + 1 = 11.5$
		Patient population is projected forward 1 year.	$(10.5 \times .052) + 10.5 = 11.0$
		The 1 patient residing in Caldwell County is added. This is the projected ending census: December 31, 2017	$11.0 + 1 = 12.0$

The applicant projects to serve 107 in-center patients or 3.4 patients per station by the end of Year 1 ($107/31 = 3.45$) and 111 in-center patients or 3.5 patients per station by the end of Year 2 for the proposed 31-station facility. This exceeds the minimum 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

The applicant projects to have two home hemodialysis patients by the end of OY 1(2016) and four patients by the end of OY 2 (2017). Additionally, the applicant projects that its peritoneal dialysis patient population (which includes one patient from Caldwell County) will be 11.5 and 12.0 patients for OY 1 and OY 2, respectively.

Access to Services

In Section VI, page 46, the applicant states that BMA currently operates 100 facilities in 42 North Carolina Counties, each of which serve low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. On page 47, the applicant projects that 93.01% of BMA of Burke County patients will have Medicare, Medicaid or VA as their payor source.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has to relocate the facility and to add six 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.

C

The applicant proposes to relocate an existing facility and add six new dialysis stations for a total of 31 stations upon project completion. In Section III.4, page 33, the applicant reports the relocation of the existing facility will have no impact on the patients currently being served by BMA of Burk County as the proposed primary site is within three miles of the existing facility. The applicant further states on page 33, that the proposed relocation of the facility is due to physical plant limitations at the existing facility. Thus, the applicant concludes that it is more reasonable to relocate the existing facility and develop the space within the new building to better meet the growing needs of BMA of Burke County.

The applicant states the medically underserved population will continue to have access to the

services provided by BMA of Burke County, as stated in Section VI.1, page 46 of the application. Therefore, the applicant demonstrates that the needs of the population presently served at BMA of Burke County will continue to be adequately met following the relocation of the existing facility. Additional discussion relating to promoting equitable access in Criterion (13) is incorporated herein by reference.

- (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 37-38, the applicant describes the alternatives considered, which include:

1. Relocate to another area within the county - BMA concluded the relocation of the facility to another city in Burke County would not be in the best interest of its patients, as Morganton is in the center of Burke County.
2. Relocate the facility and not expand - BMA concluded that to relocate the facility without adding the additional stations, per the facility need methodology, was not in the best interest of the patients being served at the facility as BMA's current utilization exceeds 80%.
3. A partial relocation and development of a second facility - BMA concluded that this was not a cost effective alternative.
4. Relocation of the existing facility and the addition of six new dialysis stations- BMA concluded that the project, as proposed, was its best alternative.

The applicant adequately demonstrated that the proposed alternative is the most effective or least costly alternative.

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

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative. The applicant adequately demonstrated the need to relocate the existing facility and to add six new stations based on the continued growth of the ESRD patient population of Burke County and the facility's projected utilization. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein.

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 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 relocate the existing facility and add six new dialysis stations for a total of no more than 31 dialysis stations at BMA of Burke County, which shall include any isolation and home hemodialysis training stations, upon project completion.**
 - 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 31 dialysis stations which shall include any isolation and home hemodialysis training 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

In Section VIII.1, page 54, the applicant projects that the total capital cost will be \$2,830,729, including \$2,071,472 in construction costs, \$210,000 for water treatment equipment, \$179,516 for additional equipment, \$162,894 for architect and engineering fees, \$108,205 for other (generator), and \$98,642 for contingency costs. In Section VIII.2, page 55, the applicant states Fresenius Medical Care, Inc., parent company of BMA, will finance the project with accumulated reserves. In Section IX, page 58, the applicant projects no start-up or initial operating expenses associated with the proposed project. In Exhibit 24 the applicant provides a letter dated March 16, 2015 from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

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

BMA is submitting a Certificate of Need Application to Relocate the entire dialysis facility and add six dialysis stations for a facility total of 31 stations ... The project calls for the following capital expenditure:

<i>Capital Expenditure</i>	<i>\$2,830,729</i>
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As Vice President, I am authorized and do hereby authorize the relocation of the facility and the addition of six dialysis stations, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$2,830,729 as may be needed for this project.”

In Exhibit 4, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2013 and 2012. As of December 31, 2013, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$275,719,000 with \$16,597,314,000 in total assets and \$8,521,824,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of funds for the capital needs of the project.

The Medicare/Medicaid rates in Section X.1, page 59 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services as shown in the following table:

Allowable Charges per Treatment			
	In-Center	Home Hemo	Home PD
Private	\$1,425.00	\$1,425.00	\$1,425.00
Commercial Insurance	\$1,425.00	\$1,425.00	\$1,425.00
Medicare	\$239.02	\$239.02	\$239.02
Medicaid	\$140.23	\$120.18	\$140.23
Medicare/Medicaid	\$239.02	\$239.02	\$239.02
Medicare/Commercial	\$239.02	\$239.02	\$239.02
State Kidney Program	\$100.00	\$100.00	\$100.00
VA	\$231.12	\$196.90	\$231.12
Other: Self/Indigent	\$1,425.00	\$1,425.00	\$1,425.00

The applicant states on page 59, that the commercial charges does not reflect actual reimbursement as it is industry standard to have various contractual relationships with various payors which could result in less reimbursement.

The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application on pages 60 and 69. The applicant projected revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	PY1 2017	PY2 2018
Net Revenue	\$6,028,925	\$6,369,779
Operating Expenses	\$5,085,731	\$5,322,534
Profit	\$943,194	\$1,047,245

The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable and adequately supported. See Section X, pages 61-70, for the applicant’s assumptions.

In Section VII.1, page 50 and Section X, pages 69 and 70, the applicant provides projected staffing and salaries. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the proposed project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. 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

The applicant proposes to relocate an existing facility and add six new dialysis stations for a total of 31 stations upon project completion. The facility will provide in-center hemodialysis, continue to provide services for its peritoneal dialysis patients and add training support services for home hemodialysis patients, in Morganton, Burke County.

According to the January 2015 SDR, BMA of Burke County is the only dialysis facility in Burke County. BMA of Burke County operated with a utilization rate of 90% as of June 30, 2014.

Consequently, the applicant adequately demonstrates the proposal would not result in the unnecessary duplication of existing health service capabilities or facilities. Therefore, 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 51, the applicant provides projected staffing for BMA of Burke County, which includes an increase of 3.45 Full-Time Equivalent (FTE) Positions, upon completion of this project, as illustrated in the following table:

BMA of Burke County		
POSITION	CURRENT FTES	PROJECTED FTES
Registered Nurse	3.50	4.50
Patient Care Technician	11.65	13.15
Clinical Manager	1.00	1.00
Admin	0.15	0.15
Dietitian	0.75	0.85
Social Worker	0.65	0.80
Home Training Nurse	1.75	2.00
Chief Tech	0.25	0.25
Equipment Tech	0.75	1.00
In-Service	0.20	0.25
Clerical	1.35	1.50
TOTAL	22.0	25.45

On page 52, the applicant discusses BMA’s recruitment policy and states that they do not anticipate difficulty in recruiting and retaining qualified staff because of their aggressive recruiting practice and their competitive salary structure. The applicant further states on page 52, that BMA of Burke County will continue to comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 53. In Section V.4, page 43, the applicant identifies the Medical Director for BMA of Burke County as Dr. Michele Higerd. In Exhibit 21, the applicant provides a letter from Dr. Higerd indicating her support for the project and her willingness to continue to serve as the Medical Director. Additionally, in Section VII.10, page 53, the applicant states BMA of Burke County will operate two shifts, six days a week from 7:00 a.m. to 5:00 p.m.

The information provided in Sections V and VII is reasonable, credible and adequately supported. Therefore, this 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 41, the applicant lists the proposed providers of the necessary ancillary and support services. The applicant states the method for providing these services in response to 10A NCAC 14C .2204, beginning in Section II, page 17 of the application. Diagnostic and evaluation services, x-ray services, blood bank services, and acute dialysis in an acute care setting services will be provided by Carolinas HealthCare System – Blue Ridge Morganton. Transplantation services will be provided by UNC Hospital. See Exhibit 15 (Spectra Lab Agreement), Exhibit 19 (Health Professional Educational Facility Agreement), Exhibit 25 (Hospital Affiliation Agreement) and Exhibit 26 (Transplantation Agreement).

The information regarding coordination of services in Section V of the application and referenced exhibits is reasonable, credible, and adequately supported, thus the application is conforming 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 Section XI, pages 71-73, the applicant discusses the primary and secondary sites being considered for the proposed relocation. The applicant states that BMA of Burke County plans to lease space for the proposed relocated facility. The applicant states there are two sites being considered. The primary site consists of 4.17 acres and is located at 814 West Union Street, in Morganton. The secondary consists of 2.5 acres and is located at 105 Salem Farm Road, in Morganton. Both sites are currently zoned for dialysis facility use. See Exhibits 30 and 31 for documentation on the availability of both sites for leasing. Also, see Exhibits 30 and 31 for documentation on the availability of water, sewer, and electric

services for the proposed sites. A map of the proposed sites can be found in Exhibit 29. The applicant further states on page 72, that both sites are located on major highways that are easily accessible by patients and transportation agencies.

In Section XI.6, page 74, the applicant states that each dialysis station will be 173 square feet with energy saving features. The isolation station is projected to be 134 square feet and the home hemodialysis training rooms are projected to be 148 square feet. The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 77:

BMA of Burke County	
Facility Area	Estimated Total Sq. Ft.
Ancillary Areas:	
Administration/Offices/Receptions/Elevator & Lobby	1430
Public Lobby	628
Mechanical Equipment	207
Housekeeping	58
General Storage	1758
Exam/Treatment	118
Staff Lounge	250
RO	583
Other: Toilets/Circulation	2549
Sub-Total Support	7581
Treatment Areas:	
Dialysis Stations	4849
Patient Home Training Area	591
Isolation Room(s)	134
Sub-Total Treatment	5574
Total Square Feet	13,155

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative and that the construction project would not unduly increase the costs of or charges for providing the proposed dialysis services. Therefore, 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;

In Section VI.1(b), page 47, the applicant reports that 83.9% of the patients who received in-center treatments and 67% of those who received in home training at BMA of Burke County had some or all of their services paid for by Medicare or Medicaid in the past year (2014). The table below illustrate the historical payment source for the facility:

BMA OF BURKE COUNTY HISTORICAL PAY MIX		
	IN-CENTER	HOME
SOURCE OF PAYMENT	PERCENTAGE	PERCENTAGE
Commercial Insurance	3.19%	10.5%
Medicare	66.61%	54.0%
Medicaid	3.33%	13.0%
Medicare/ Commercial	13.99%	0.0%
State Kidney Program	0.0%	22.6%
VA	9.08%	0.0%
Other: Self/Indigent	3.80%	0.0%
Total	100.0%	100.0%

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 Durham County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Burke County	18%	7.7%	17.7%
Statewide	17%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/21/2013, page 99*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age,

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

race or gender do not include information on the number of elderly, handicapped, minorities or women utilizing health services.

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

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

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

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

The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

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

² www.usrds.org/adr.aspx

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

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

The applicant demonstrates that medically underserved populations currently have adequate access to services available at BMA of Burke County. 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.1(f), page 48, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The 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/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

In Section VI.6(a), page 50, the applicant states there have been no Civil Rights complaints filed against any BMA of North Carolina facilities in the past 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 47, the applicant provides the projected payor source for its services, as illustrated in the table below.

“Projections of future in-center reimbursement are presented the same as historical facility in-center performance.”

BMA OF BURKE COUNTY PROJECTED PAY MIX		
	IN-CENTER	HOME
SOURCE OF PAYMENT	PERCENTAGE	PERCENTAGE
Commercial Insurance	3.19%	10.5%
Medicare	66.61%	54.0%
Medicaid	3.33%	13.0%
Medicare/ Commercial	13.99%	0.0%
State Kidney Program	0.0%	22.6%
VA	9.08%	0.0%
Other: Self/Indigent	3.80%	0.0%
Total	100.0%	100.0%

As shown in the table above, the applicant does not project a change in its payor mix from its historical payor mix. The applicant projects 83.9% of the patients who receive in-center treatments and 67% of those who receive in home training at BMA of Burke County will have some or all of their services paid by Medicare or Medicaid.

In Section VI.2, pages 48-49, the applicant states the facility design provides easy access for handicapped persons and complies with the Americans with Disabilities Act (ADA) requirements.

The applicant demonstrates it will provide adequate access to the elderly and medically underserved populations. 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(a), page 49, the applicant states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA of Burke County 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 demonstrated that it will provide a range of means by which a person can access the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3, page 43, the applicant states that 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. See Exhibit 19 for a copy of a letter sent to Western Piedmont Community College offering BMA of Burke County as a clinical training site. The applicant adequately demonstrated that the facility will continue to accommodate the clinical needs of health professional training programs in the proposed service area. The application is in conformity to this criterion.

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

C

The applicant proposes to relocate an existing facility and add six new dialysis stations for a total of 31 stations upon project completion. The facility will add home training support and services for home hemodialysis patients and continue to provide services for its peritoneal

dialysis patients. According to the January 2015 SDR, BMA of Burke County is the only dialysis facility in Burke County. The January 2015 SDR reported a 90% utilization rate for BMA of Burke County, as of June 30, 2014.

In Section V.7, pages 44-45, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states, as the only dialysis facility in Burke County, the proposed project will not have an impact on competition in the service area. However, the applicant states that the relocation and expansion of the facility will allow BMA to maximize efficiency.

See Sections II, III, V, VI and VII of the application for additional discussion by the applicant about the impact of relocating the existing facility and adding six ESRD stations on cost effectiveness, quality and access to end stage renal services in the service area.

The applicant adequately demonstrates that its proposal would enhance competition by promoting cost effectiveness, quality and access to the proposed services based on the information in the application and the following analysis:

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

Therefore, the application is conforming to this criterion.

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

C

In Section I.13 and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant 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.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.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 provides the utilization rate, as reported in the January 2015 SDR, as 90% with 90 patients dialyzing on 25 dialysis stations at BMA of Burke County.

(2) *Mortality rates;*

-C- In Section II.1, page 10, the applicant provides the mortality rates as 9.8%, 16.6% and 13.7% for 2012, 2013 and 2014, respectively for BMA of Burke County.

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

-C- In Section II.1, page 10, the applicant states, “BMA of Burke County had 10 home trained patients as of December 2014.”

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

-C- In Section II.1, page 10, the applicant states, BMA of Burke County referred 11 transplants patients in 2013 and 16 in 2014. Three transplants were performed in 2013 and two were performed in 2014.

- (5) *The number of patients currently on the transplant waiting list;*
- C- In Section II.1, page 10, the applicant states that BMA of Burke County currently has eight patients 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 10, the applicant states that there were 124 hospital admissions in 2014 for BMA of Burke County patients, five of which were dialysis related and 119 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 there were no patients at BMA of Burke County in 2013 or 2014 with an infectious disease. However, there are currently three patient with an infectious disease (Hepatitis B) dialyzing at BMA of Burke County.
- (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.*
- C- The applicant proposes to relocate the entire existing facility and to add six new stations. See Exhibit 25 for a copy of the acute care agreement with Grace Hospital.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

- C- The applicant proposes to relocate the entire existing facility and to add six new stations. See Exhibit 26 for a copy of the transplant agreement with the University of North Carolina Hospitals.
 - (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- The applicant states that documentation of power and water availability is included within site specific exhibits (Primary Site, Exhibit 30; Secondary Site, Exhibit 31).
 - (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 copies of 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.*
- C- The applicant proposes to relocate the entire existing facility and to add six new stations. See Section XI, pages 71-72 and Exhibit 16 for information concerning the availability of the primary and secondary sites proposed in this application.
 - (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 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 of Burke County.”
 - (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section II.1, pages 12-14 and Section III.7, pages 34-36 for the methodology and assumptions the applicant uses to project patient origin, as illustrated in the table below:

County	Operating Year 1			Operating Year 2			County Patients as a % of Total	
	In-Center	PD	HH	In-Center	PD	HH	Year 1	Year 2
Burke	106.3	10.5	2.0	109.8	11.0	4.1	98.3%	94.8%
Caldwell	1	1	0	1	1	0	1.7%	1.6%
Total	107.3	11.5	2.0	110.8	12.0	4.1	100%	100%

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-C- In Section II, page 14, the applicant states that 100% of its patients live within 30 miles of the proposed replacement 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.”

.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 of Burke County 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- In Section II, page 16, the applicant projects to serve 107 in-center patients or 3.45 patients per station by the end of Operating Year 1. See Section II.1, pages 12-14 and Section III.7, pages 34-36 for the methodology and assumptions used by the applicant in projecting its utilization.

.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 17, the applicant states, *“Patients... will be referred to Carolinas Healthcare System-Blue Ridge Morganton (formerly Grace Hospital).”*
- (2) *maintenance dialysis;*
- C- In Section II.1, page 17, the applicant states, *“The facility will provide in-center dialysis and training for patients to dialyze at home.”*
- (3) *accessible self-care training;*
- C- In Section II.1, page 17, the applicant states, *“Patients who are candidates for self-care are referred to the facility [sic] home training department...the patient is assessed...and training is provided as may be appropriate.”*
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- In Section II.1, page 17, the applicant states, *“Patients who are candidates for home dialysis are referred to the facility [sic] home training department.”*
- (5) *x-ray services;*
- C- In Section II.1, page 17, the applicant states that patients in need of x-ray services will be referred to Carolinas HealthCare System-Blue Ridge Morganton (formerly Grace Hospital). See Exhibit 25 for a copy of the hospital affiliation agreement with Grace Hospital.
- (6) *laboratory services;*
- C- In Section II.1, page 17, the applicant states that laboratory services will be provided by Spectra Labs. See Exhibit 15 for documentation of the agreement with Spectra Labs.
- (7) *blood bank services;*
- C- In Section II.1, page 17, the applicant states, *“Patients in need of blood transfusion will be referred to Carolinas HealthCare System-Blue Ridge*

Morganton.” See Exhibit 25 for a copy of the hospital affiliation agreement with Grace Hospital.

(8) *emergency care;*

-C- In Section II.1, page 17, 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 17, the applicant states that patients in need of acute care dialysis in an acute care setting will be referred to Carolinas HealthCare System-Blue Ridge. See Exhibit 25 for a copy of the hospital affiliation agreement with Grace Hospital.

(10) *vascular surgery for dialysis treatment patients;*

-C- In Section II.1, page 18, the applicant states, “*Patients will be referred to Dr. Randall Best at Horizon Surgical in Lenoir, NC.*”

(11) *transplantation services;*

-C- In Section II.1, page 18, the applicant states that BMA of Burke County has a transplant agreement with UNC Hospital. See Exhibit 26 for a copy of a transplant agreement with UNC Healthcare Comprehensive Transplant Center.

(12) *vocational rehabilitation counseling and services; and*

-C- In Section II.1, page 18, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the Burke County Vocational Rehabilitation Office.*”

(13) *transportation.*

-C- In Section II.1, page 18, the applicant states that transportation services will be provided by Greenway Transportation, Specialized Transport or Medical Transport.

.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 VII.2, page 52, the applicant states that BMA of Burke County will provide sufficient staffing on each dialysis shift as required in 42 C.F.R., Section 405.2100. Table VII.1 identifies all staff for the facility. BMA of Burke County plans to operate two patient shifts, six days a week, from 7:00 a.m. until 5:00 p.m.

(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 19, the applicant states that BMA of Burke County will provide ongoing training for nurses and technicians in dialysis techniques, including training in facility and corporate policies and procedures; safety precautions, regulations, CPR, and in-service training on changes/developments in procedures, product line, equipment, Center for Disease Control and Prevention guidelines and OSHA compliance. See Section VII.5, page 52 of the application for information concerning the training and continuing education programs currently in place. Exhibit 9 contains copies of FMC's Dialysis Services Training Manual which outlines its training program and Exhibit 10 contains a Continuing education outline and annual training requirements.