

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 20, 2015

Findings Date: November 20, 2015

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: F-11096-15

Facility: BMA Kings Mountain

FID #: 960921

County: Gaston

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

Project: Add two dialysis stations for a total of 16 dialysis stations upon completion of this project

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Kings Mountain (“the applicant”) proposes to add two dialysis stations for a total of 16 certified dialysis stations at the BMA Kings Mountain facility upon completion of this project.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of one dialysis station in Gaston County, thus the applicant cannot apply to add any additional stations based on the county need methodology. 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%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for BMA Kings Mountain in the July 2015 SDR is 3.2857 patients per station, or 82.1% ($3.2857 / 4 \text{ patients per station} = 0.8214$). This utilization rate was calculated based on 46 in-center dialysis patients and 14 certified dialysis stations ($46 \text{ patients} / 14 \text{ stations} = 3.2857 \text{ patients per station}$).

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

BMA KINGS MOUNTAIN OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/14		82.1%
Certified Stations		14
Pending Stations		
Total Existing and Pending Stations		14
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR2)		46
In-Center Patients as of 6/30/14 (Jan 2015 SDR) (SDR1)		42
Step	Description	
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.1905
(ii)	Divide the result of Step (i) by 12	0.0159
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	0.1905
(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	54.7619
(v)	Divide the result of Step (iv) by 3.2 patients per station	17.1131
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	3.1131

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

Policies

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

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 12-13 and 15-16 and Section O, pages 62-67. 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 B, pages 14-16, Section C, pages 22-23, Section I, pages 44-47, Section L, pages 55-59 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 B, pages 15-16, Section N, page 61, 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 facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2015 SDR and Policy Gen-3. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add two dialysis stations for a total of 16 dialysis stations at the existing BMA Kings Mountain facility upon completion of the project.

Population to be Served

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

In Section C, page 24, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by BMA Kings Mountain. The applicant does not currently serve home hemodialysis (HH) or peritoneal dialysis (PD) patients at this facility.

BMA KINGS MOUNTAIN Patient Origin June 30, 2015			
County	IC	HH	PD
Gaston County	21	NA	NA
Cleveland County	29	NA	NA
South Carolina	3	NA	NA
TOTAL	53	NA	NA

In Section C, page 19, 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.

**Projected BMA Kings Mountain Patient Origin
 By County of Residence**

County	Operating Year 1	Operating Year 2	County Patients as a Percent of Total	
	In-Center	In-Center	OY 1	OY2
Gaston	22.9	23.7	41.3%	42.1%
Cleveland	29.0	29.0	53.2%	52.5%
South Carolina	3.0	3.0	5.5%	5.4%
Total	54.9	55.7	100.0%	100.0%

Note: BMA Kings Mountain does not provide HH or PD

The applicant provides the assumptions and methodology for the above projections on pages 20-22.

Exhibit C-1 includes a letter signed by 26 patients currently dialyzing at BMA Kings Mountain, documenting their support for the proposed project.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to add two dialysis stations to the existing BMA Kings Mountain facility for a total of 16 certified dialysis stations upon project completion. In Section C, pages 21 – 22, the applicant states the need for the proposed project is based on the following factors:

- ESRD patients require dialysis treatment on a regular and consistent basis in order to maintain life.
- Failure to add the proposed stations will lead to higher utilization rates at the existing facility.
- BMA Kings Mountain census has been increasing at a rate greater than the Five-Year Average Annual Change Rate for Gaston County of 3.5%. The applicant calculates a growth rate of 19.048% for this facility.

Projected Utilization

The applicant projects to serves 54 in-center dialysis patients on 16 dialysis stations at the end of the first operating year. This is 3.4 patients per station or an 84% utilization rate.

In Section C, pages 20-21, the applicant provides the assumptions and methodology it uses to demonstrate the need that this population has for the services proposed at BMA Kings Mountain. The applicant’s assumptions and methodology are summarized below:

- The applicant assumes that the BMA Kings Mountain patient population residing in Gaston County will increase at a rate comparable with the county five year average annual change rate (AACR) as published in the July 2015 SDR, which is 3.5%.

- The applicant states that 29 out of 54 patients reside in Cleveland County, which is contiguous to Gaston County; although there are four dialysis facilities in Cleveland County.
- The applicant assumes that the Cleveland County patients will continue by choice, to dialyze at BMA Kings Mountain. At this time the applicant is not projecting an increase in the Cleveland County patient population.
- The applicant assumes that the South Carolina patients will continue by choice, to dialyze at BMA Kings Mountain. At this time the applicant is not projecting an increase in the South Carolina patient population.
- The applicant assumes this project will be complete and stations certified by December 31, 2016.
- The applicant states the operating years are calendar years.

In Section C, page 21, the applicant provides the calculations used to arrive at the projected in-center patient census for Operating Year 1, ending December 31, 2017 and Operating Year 2, ending December 31, 2018, as shown below.

BMA KINGS MOUNTAIN	CALCULATIONS
BMA begins with the Gaston County patients dialyzing at BMA Kings Mountain on June 30, 2015.	21
BMA projects this patient population forward for six months December 31, 2015, using the [sic] one half the Gaston County Five Year Average Annual Change Rate of 3.5%.	$[21 \times (.035 / 12 \times 6)] + 21 = 21.4$
BMA projects Gaston County population forward for one year to December 31, 2016.	$(21.4 \times .035) + 21.4 = 22.1$
BMA adds the 29 Cleveland County patients and three South Carolina patients. This is the projected starting census for this project.	$22.1 + 29 + 3 = 54.1$
BMA projects the Gaston County patient population forward for one year to December 31, 2017.	$(22.1 \times .035) + 22.1 = 22.9$
BMA adds the 29 Cleveland County patients and three South Carolina patients. This is the projected ending census Operating Year 1.	$22.9 + 29 + 3 = 54.9$
BMA projects the Gaston County patient population forward for one year to December 31, 2018.	$(22.9 \times .035) + 22.9 = 23.7$
BMA adds the 29 Cleveland County patients and three South Carolina patients. This is the projected ending census Operating Year 2.	$23.7 + 29 + 3 = 55.7$

As shown in the previous table, at the end of Operating Year One, the applicant is projecting an in-center patient census at BMA Kings Mountain of 54.9 patients, which the applicant rounds down to 54, for a utilization rate of 84% or 3.4 patients per station ($54 \text{ patients} / 16 \text{ stations} = 3.375 / 4 = .84375$). At the end of Operating Year Two, the applicant is projecting an in-center patient census of 55.7, rounded down to 55, for a utilization rate of 86.0% or 3.4 patients per

station. The projected utilization of 3.4 patients per station per week for Operating Year 1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

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

Access

In Section C, pages 22 - 23, the applicant states:

“... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”

The applicant states that the patient population of the BMA Kings Mountain facility is expected to be comprised of the following:

FACILITY	MEDICAID/LOW INCOME	ELDERLY(65+)	MEDICARE	WOMEN	RACIAL MINORITIES
BMA Kings Mountain	9.4%	37.7%	92.5%	35.8%	56.6%
Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 92.5% of the facility treatment reimbursement is from Medicare.					

The applicant states that the above projections are based on the current BMA Kings Mountain patient population.

On page 23, the applicant states that Medicare and Medicaid represented 82.54% and 4.63%, respectively, of dialysis treatments in BMA facilities in North Carolina in fiscal year 2014. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by BMA Kings Mountain and that the facility will conform to all federal, state and local codes and standards for handicapped access.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons,

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

In Section E-1, page 28, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would result in higher utilization rates and potentially restrict patient admissions at BMA Kings Mountain.
2. Apply to add three stations – Although BMA Kings Mountain would qualify for the addition of three stations per the facility need methodology; the facility does not have physical space to add more than two stations.
3. Apply for one station – one station would not accommodate the projected utilization rate of 80% at BMA Kings Mountain at the end of OY 1. Fewer stations would result in higher utilization rates.

After considering the above alternatives, the applicant believes the most cost effective alternative is to add two stations to ensure adequate access for the patients of BMA Kings Mountain.

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

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Kings Mountain 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 Kings Mountain shall develop and operate no more than two additional dialysis stations at BMA Kings Mountain for a total of no more than 16 certified dialysis stations which shall include any isolation or home hemodialysis training stations upon completion of this project.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Kings Mountain shall install plumbing and electrical wiring through the walls for no more than two**

additional dialysis stations, which shall include any isolation or home hemodialysis training stations.

- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Kings Mountain 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

The applicant proposes to add two dialysis stations for a total of 16 dialysis stations at the existing BMA Kings Mountain facility upon completion of the project.

Capital and Working Capital Costs

In the table in Section F, page 30, the applicant states the capital cost of the project is \$9,000, for equipment and furniture. The applicant states dialysis machines will be leased, and the facility is an existing facility, thus, no construction costs will be incurred.

In Section F, page 33, BMA Kings Mountain is an existing dialysis facility; therefore the applicant does not project any working capital needs.

Availability of Funds

In Section F, page 31, the applicant states:

“BMA is utilizing accumulated reserves to finance this project. Please refer to Exhibit F-1 for letter of commitment from Mark Fawcett, Vice President and Treasurer, Fresenius Medical Care Holdings, Inc. This letter will verify the availability of the FMC funds necessary for the project.”

Exhibit F-1 contains a September 15, 2015 letter from the Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., which confirms the availability of the funds needed for the capital cost of the project, as well as a commitment to use those funds for the development of the project.

In Exhibit F-2, the applicant provides a copy of the most recent audited FMC Holdings, Inc., consolidated balance sheets for 2013 and 2014. As of December 31, 2014, Fresenius Medical Care Holdings, Inc. and Subsidiaries had \$195,280,000 in cash and cash equivalents with \$18,507,042,000 in total assets and \$9,460,268,000 in net assets (total assets less total liabilities).

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

Financial Feasibility

In Section R, Form C, pages 77-85, the applicant provides its allowable charge per treatment for each payment source for in-center dialysis patients, along with its revenue assumptions.

The applicant provides the following assumptions for patient treatments:

- Treatments = Patients (rounded down) x 3 treatments per week x 52 weeks (156 treatments per patient)
- Missed Treatments for In-center patients = 5%
- CY2015 is considered an interim year with the June 30, 2015 in-patient census of 53 considered to be average census for the year.

The applicant projects revenues and expenses in Section R, Form B, page 81, as summarized below in the table.

BMA Kings Mountain Revenue and Expenses		
	OPERATING YEAR 1 CY 2017	OPERATING YEAR 2 CY 2018
Gross Patient Revenue	\$31,915,964	\$32,506,188
Deductions from Gross Patient Revenue	\$29,696,328	\$30,245,504
Net Patient Revenue	\$ 2,219,636	\$ 2,260,684
Operating Expenses	\$ 2,056,290	\$ 2,099,113
Net Profit	\$ 163,346	\$ 161,571

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The applicant's projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

In Section H, page 41, the applicant provides projected staffing and salaries. Form A in Section R, page 77, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

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

C

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

The applicant proposes to add two dialysis stations to the existing BMA Kings Mountain facility in Gaston County. The July 2015 SDR indicates there are four dialysis facilities in Gaston County, as shown in the table below:

Gaston County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
BMA Kings Mountain	14	46	3.28	82.14%
FMC Belmont*	16	54	3.37	84.38%
FMC Gastonia	39	130	3.33	83.33%
FMC South Gaston	20	72	3.60	90.00%

Data reported in the July 2015 SDR, as of 12/31/14.

*Certificate issued 6/5/15 (F-11010-15) to add two stations for a total of 18 stations upon project completion.

As illustrated above, the applicant's parent company, Fresenius Medical Care Holdings, Inc. (Fresenius), operates all of the dialysis facilities listed in the table above. All four of the BMA dialysis facilities are operating above 80% utilization. In Section G, pages 39-40, the applicant states:

"This application does not create a new dialysis facility in Gaston County. Approval of this application will result in two additional stations in the Service Area. ...Based solely on the growth of the census within the operational facilities, BMA suggests that adding two stations at BMA Kings Mountain is not duplicating existing capacity. ..."

In Section C, page 19, the applicant demonstrates that BMA Kings Mountain will serve a total of 54.9 patients at the end of Operating Year One, which the applicant rounds down to 54, for a utilization rate of 84% or 3.4 patients per station (54 patients / 16 stations = 3.375 / 4 = .84375). The projected utilization of 3.4 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant states that the projected utilization rates are based on patients currently dialyzing at BMA Kings Mountain.

The applicant adequately demonstrates the need to add two additional stations at BMA Kings Mountain based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Gaston County. Consequently, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section H, page 41, the applicant provides the following table to illustrate projected staffing in Full Time Equivalents (FTEs) for BMA Kings Mountain. The facility is operational, so the staffing table illustrates current and projected staff following completion of this project. The applicant states the Medical Director is a contracted position and not reflected in the staffing chart.

POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	1.50	0.50	2.00
Technician (Patient Care)	5.0	1.00	6.00
Clinical Manager	1.00	-	1.00
Admin. (Dir. Ops)	0.15	-	0.15
Dietician	0.67	-	0.67
Social Worker	0.67	-	0.67
Chief Technician	0.15	-	0.15
Equipment Technician	0.50	-	0.50
In-Service	0.15	-	0.15
Clerical	1.00	-	1.00
Total	10.79	1.50	12.29

On page 43, in Section H, the applicant illustrates the projected direct care staff for BMA Kings Mountain in Operating Year 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	2.00	2,080	4,160	3,120	1.33
Patient Care Tech	6.00	2,080	12,480	3,120	4.00
Total	8.00	2,080	16,640	3,120	5.33

As the above table shows, Form A budgets 8.0 FTE hours of direct care staffing per hour of facility operation. Budgeted staffing appears adequate for Operating Year 2's projected 3,120 annual hours of operation and projected 86% utilization on 16 stations.

In Section I, page 45, the applicant identifies Dr. Jonathan Planer as the Medical Director of the facility. In Exhibit I-6, the applicant provides a September 1, 2015 letter signed by Dr. Planer of Metrolina Nephrology Associates, supporting the project and confirming his commitment to serve as Medical Director. Exhibit I-7 contains Dr. Planer's curriculum vitae. In Section H, page 42, the applicant states, "BMA anticipates no difficulties in filling staff positions." In Section I,

page 46, the applicant lists 11 nephrologists who have agreed to provide medical coverage at the facility.

The applicant adequately documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In Section I-1, page 44, the applicant lists the providers of the necessary ancillary and support services to be provided at the proposed facility. The applicant discusses coordination with the existing health care system on page 47. Exhibits I-3, I-4 and I-5 contain documents from Spectra Labs, CaroMont Regional Medical Center and Carolinas Medical Center (CMC), respectively, as evidence of laboratory, patient transfer and transplant services that will be available to dialysis patients. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I, clarifying information received on November 5, 2015 and corresponding exhibits is reasonable and supports a finding of conformity 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 L, pages 55-56, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 100 dialysis facilities in 42 North Carolina counties, which includes its affiliations with Renal Research Institute facilities (RRI). The applicant further states that each of its facilities serves low income persons, racial and ethnic minorities, women, handicapped, the elderly, and other “*traditionally underserved*” persons.

In addition, the applicant states that BMA of North Carolina has historically provided “... *care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.*” In Section L, page 56, the applicant states that Medicare and Medicaid represented 82.54% and 4.63%, respectively, of North Carolina dialysis treatments in North Carolina BMA facilities in FY 2014.

In Section L, page 59, the applicant reports that as of December 31, 2014, 78.2% of the patients who were receiving treatments at BMA Kings Mountain had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical payor sources for BMA Kings Mountain:

PAYOR TYPE	PERCENT PATIENTS
Private Pay	3.6%
Commercial Insurance	9.1%
Medicare	54.5%
Medicaid	7.3%
VA	9.1%
Other Medicare Commercial	16.4%
Total	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 Gaston and Cleveland counties and statewide.

County	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) *
Gaston	19.8%	8.6%	19.0%
Cleveland	23.4%	10.6%	18.6%
Statewide	16.5%	6.7%	19.7%
*More current data, particularly with regard to the estimated uninsured percentages, was not available.			

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those persons who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).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. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

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

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

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

Source: Southeastern Kidney Council Network6 Inc. 2014 Annual Report.²

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

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

C

In Section L, page 58, 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.”

In Section L, page 58, the applicant states, *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”*

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

The application is conforming to this criterion.

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

C

In Section C, page 22, the applicant projects the patient population of BMA Kings Mountain will be comprised of the following, based on its historical experience at the facility.

	Medicaid/Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Kings Mountain	9.4%	37.7%	92.5%	35.8%	56.6%
Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say that 60% of the facility treatment reimbursement is from Medicare.					

In Section L, page 57, 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.”

In Section L, page 56, the applicant reports that it expects 78.2% of the in-center patients who receive treatments at BMA Kings Mountain to have all or part of their services paid for by Medicare or Medicaid, as indicated below in the table.

PAYOR TYPE	PERCENT PATIENTS
Self Pay/Indigent/Charity	3.6%
Medicare	54.5%
Medicaid	7.3%
Commercial Insurance	9.1%
Medicare Commercial	16.4%
VA	9.1%
Total	100.0%

On page 56, the applicant states:

“BMA payor mix has historically been calculated based upon treatment volumes. In this application, revenues will be projected using a payor mix based upon treatment volumes. The above table has requested the percent of patients by category. BMA notes that that it is projecting to serve few Medicaid and VA patients at the end of Operating Year 2. Assigning a projected payor mix classification to categories with small numbers, and resultant efforts to project “whole” patients does not allow for

an accurate projection of the payor mix, by percentage of patients expected by the facility. For purposes of this table, the Applicant has rounded to the nearest whole number.”

Form C – Revenue Assumptions, pages 83-84, show the payor mix as a percent of treatments, as shown below.

**BMA Kings Mountain
Projected Payor Mix Project Year 2
Percent of Treatments**

Payor Source	In-Center
Self Pay/Indigent/Charity	3.25%
Medicare	54.04%
Medicaid	7.70%
Commercial Insurance	9.35%
Medicare/Commercial	15.62%
VA	10.04%
TOTAL	100.00%

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

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

C

In Section L, page 58, 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 Kings Mountain has an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.

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

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section M, page 60, the applicant states:

“All health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. This experience enhances the clinical experience of the students enrolled in these programs enabling them to learn about the disease, prognosis and treatment for the patient with end stage renal disease.”

Exhibit M-1 contains a copy of the agreement with Gaston College for student nurse clinical rotations at BMA Kings Mountain. The information provided in Section M and referenced exhibits is reasonable and supports a finding of conformity to this criterion.

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

C

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

The applicant proposes to add two dialysis stations for a total of 16 dialysis stations at the existing BMA Kings Mountain facility upon completion of the project. Table A in the July 2015 SDR indicates there are four existing dialysis facilities in Gaston County, as follows:

Gaston County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
BMA Kings Mountain	14	46	3.28	82.14%
FMC Belmont*	16	54	3.37	84.38%
FMC Gastonia	39	130	3.33	83.33%
FMC South Gaston	20	72	3.60	90.00%
Data reported in the July 2015 SDR, as of 12/31/14.				

*Certificate issued 6/5/15 (F-11010-15) to add two stations for a total of 18 stations upon project completion.

As illustrated above, the applicant's parent company, Fresenius Medical Care Holdings, Inc. (Fresenius), operates all of the dialysis facilities listed in the table above. All four of the BMA dialysis facilities are operating above 80% utilization. In Section G, pages 39-40, the applicant states:

"This application does not create a new dialysis facility in Gaston County. Approval of this application will result in two additional stations in the Service Area. ...Based solely on the growth of the census within the operational facilities, BMA suggests that adding two stations at BMA Kings Mountain is not duplicating existing capacity. ..."

In Section N, page 61, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

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

...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 87% of the In-center patients will be relying upon government payors (Medicare / Medicaid/VA). The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."

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

The information provided by the applicant in the sections above and referenced exhibits is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

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

Therefore, the application is conforming to this criterion.

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

C

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

In Section O, pages 62-67, the applicant discusses the methods it uses to ensure and maintain quality. In Section O-3, page 66, the applicant states:

“BMA has incurred two Immediate Jeopardy citations within the recent 18 month period.

- a. BMA Lumberton dialysis facility on May 6, 2015;*
- b. BMA East Charlotte dialysis facility on August 11, 2015.”*

The applicant further states:

*“BMA Lumberton is back in full compliance with all CMS Guidelines.
BMA East Charlotte is back in full compliance with all CMS Guidelines.”*

Based on a review of the certificate of need application and publicly available data, 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 application is conforming to all applicable criteria, as discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

- C- In Section P, page 69, and Exhibit G-1 (copy of the July 2015 SDR, Tables A and B), the applicant provides the utilization rates for BMA Kings Mountain. The December 31, 2014 utilization rate was reported as 82.14% with 46 in-center patients dialyzing on 14 stations.

.2202(a)(2) Mortality rates;

- C- In Section P, page 69, the applicant provides the BMA Kings Mountain mortality rates, as follows:

BMA Kings Mountain	Beginning In-center Patients	Ending In-center Patients	Average	Deaths	% Gross Mortality
2012	36	36	36	6	16.7%
2013	36	46	41	7	17.1%
2014	46	54	50	4	8.0%

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

- C- In Section P, page 69, the applicant states that BMA Kings Mountain is not certified to offer home dialysis training and support. Home patients are referred to BMA Gastonia.

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

- C- In Section P, page 70, the applicant reports that BMA Kings Mountain referred nine patients for transplant evaluation in 2014.

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

- C- In Section P, page 70, the applicant states that BMA Kings Mountain has three patients on the transplant waiting list.

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

- C- In Section P, page 70, the applicant reports hospital admission rates as: Dialysis related are 8 or 11.8%; Non-dialysis related are 60 or 88.2%.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

- C- In Section P, page 70, the applicant reports that BMA Kings Mountain has no patients dialyzing in isolation due to infectious disease. The applicant also states that there were no conversions to infectious status during the last calendar year.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).*

- NA- This application is to add stations and does not propose a new facility.

- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
 - (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

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

- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section P, page 71, the applicant states: “BMA of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements.” See also Section B, pages 12 - 18; Section H pages 41 and 42; Section K, pages 50 - 52; and Exhibits K-2 and K-3.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section C, page 19, the applicant provides projected patient origin by county for BMA Kings Mountain, based on the patients who currently dialyze there. The applicant's assumptions and methodology for its projections are provided on pages 21 - 22 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- This application is to add stations and does not propose a new facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

-C- In Section P, page 72, the applicant states, "BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- This application is to add stations and does not propose a new facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C, pages 19 - 22, the applicant documents the need for the project and demonstrates that it will serve a total of 54 in-center patients on 16 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 84%. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

- C- In Section C, pages 19 - 23, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) Diagnostic and evaluation services;

- C- In Section I, page 44 and Section P, page 72, the applicant states that diagnostic and evaluation services will be referred to CaroMont Regional Medical Center (per clarifying information received on November 5, 2015). CaroMont is formerly known as Gaston Memorial Hospital.

.2204(2) Maintenance dialysis;

- C- In Section I, page 44 and Section P, page 72 the applicant states in-center maintenance dialysis is provided at BMA Kings Mountain.

.2204(3) Accessible self-care training;

- C- In Section I, page 44 and Section P, page 73, the applicant states candidates for self-care are referred to BMA Gastonia. On page 73, the applicant states, “*Upon completion of the training, the patient will perform self-care dialysis at the facility.*”

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

- C- In Section I, page 44 and Section P, page 73, the applicant states that patients who are candidates for home training will be referred to the BMA Gastonia home training department.

.2204(5) X-ray services;

- C- In Section I, page 44, Section P, page 73 and supplemental information received on November 5, 2015, the applicant states that patients in need of x-ray services will be referred to CaroMont Regional Medical Center.

.2204(6) Laboratory services;

- C- In Section I, page 44 and Section P, page 73, the applicant states laboratory services will be provided on-site by the applicant through a contract with Spectra Labs. Exhibit I-3 contains a copy of a letter from the Vice President at Spectra

Laboratories and an agreement documenting their intention to provide the above services to the proposed facility.

.2204(7) Blood bank services;

- C- In Section I, page 44 and Section P, page 73, the applicant states that patients in need of blood bank services will be referred to CaroMont Regional Medical Center.

.2204(8) Emergency care;

- C- In Section I, page 44 and Section P, page 73, the applicant states that facility staff will provide emergency care on site until emergency responders arrive, and that a fully stocked ‘crash cart’ will be available for use at the proposed facility. Patients in need of emergency care at a hospital are transported via emergency services.

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

- C- In Section I, page 44 and Section P, page 73, the applicant states that patients in need of acute dialysis services will be referred to CaroMont Regional Medical Center.

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

- C- In Section I, page 44 and Section P, page 73, the applicant states that patients in need of vascular surgery will be referred to CaroMont Heart and Vascular, Gastonia Surgical Associates or the Metrolina Vascular Access Center.

.2204(11) Transplantation services;

- C- In Section I, page 44 and Section P, page 73, the applicant states that transplantation services will be referred to Carolinas Medical Center. Exhibit I-5 contains a copy of an agreement between BMA and Carolinas Medical Center, documenting the provision of transplantation services to the proposed facility.

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

- C- In Section I, page 44 and Section P, page 74, the applicant states vocational rehabilitation counseling and services will be provided by the North Carolina Division of Vocational Rehabilitation Services.

.2204(13) Transportation

- C- In Section I, page 44 and Section P, page 74, the applicant states that transportation services will be provided by Access of Gaston County.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).*
- C- In Section H, page 41, the applicant provides a proposed staffing chart. In Section H, page 42, the applicant states the proposed facility will comply with all staffing requirements set forth in the Code of Federal Regulations. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.
- .2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- In Section P, page 74, the applicant discusses the required training for staff and states that training at BMA facilities is continually updated by the In-Service Instructor and Director of Nursing. In Section H, page 42, the applicant further discusses its ongoing training program. See also Exhibit H-1, which contains the FMC Training Program Outline and Exhibit H-2, which contains an outline of FMC's continuing education programs, annual training requirements and a training module content summary.