

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 15, 2016

Findings Date: January 15, 2016

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Project ID #: L-11093-15

Facility: BMA East Rocky Mount

FID #: 970528

County: Edgecombe

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

Project: Add six dialysis stations for a total of 30 dialysis stations upon completion of this project and Project ID #L-11011-15 (relocate six stations to FMC Tarboro)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA East Rocky Mount proposes to add six dialysis stations for a total of 30 certified dialysis stations upon completion of this project and Project I.D. #L-11011-15 (relocate six stations to FMC Tarboro).

Need Determination

The 2015 State Medical Facilities Plan (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 no need for an additional facility in Edgecombe County. However, 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 East Rocky Mount in the July 2015 SDR is 4.07 patients per station. This utilization rate was calculated based on 122 in-center dialysis patients and 30 certified dialysis stations as of December 31, 2014 (122 patients / 30 stations = 4.07 patients per station).

Application of the facility need methodology indicates that 11 additional stations are needed for this facility, as illustrated in the following table:

OCTOBER 1 REVIEW – JULY 2015 SDR

Required SDR Utilization		80%
BMA East Rocky Mount Utilization Rate as of 12/31/2014		101.67%
Certified Stations		30
Pending Stations		0
Total Existing and Pending Stations		30
In-Center Patients as of 6/30/2014 (SDR1, January 2015 SDR)		117
In-Center Patients as of 12/31/2014 (SDR2, July 2015 SDR)		122
Step	Description	
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/2014	.0855
(ii)	Divide the result of Step (i) by 12	.0071
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/2014 until December 31, 2015) for the July 2015 SDR	.0852
(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	132.3944
(v)	Divide the result of Step (iv) by 3.2 patients per station and subtract the number of certified and pending stations to determine the number of stations needed	11.3733

As shown in the table above, based on the facility need methodology for dialysis stations, which allows for rounding to the nearest whole number only in step (v), the potential number of stations needed at BMA East Rocky Mount is 11. 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 only six new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles, page 38, of the 2015 SMFP is applicable to this review. *Policy GEN-3* states:

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

Promote Safety and Quality

The applicant, a subsidiary of Fresenius Medical Care Holdings, Inc. (FMC), describes how its proposal will promote safety and quality in Section B.4, pages 12-13, and 16, and Section O.1, pages 61-64. 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 will promote equitable access in Section B.4, pages 14-15, Section C.3, pages 22-23, and Section L.1, pages 54-58. The applicant states in Section B.4, page 14, that the majority of its dialysis patients are covered by Medicare and/or Medicaid and projects that greater than 92% of its in-center dialysis treatments will be covered by government payors. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize health care value for resources expended in Section B.4, page 15, and Section N.1, page 60. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will 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

The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3: Basic Principles* and adequately demonstrates that the application is consistent with the facility need determination in the July 2015 SDR. Therefore, the application is conforming to this criterion.

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA East Rocky Mount, whose parent company is FMC, proposes to add six dialysis stations to its existing facility for a total of 30 certified dialysis stations upon completion of the proposed project and Project ID #L-11011-15 (relocate 6 stations to FMC Tarboro).

Population to be Served

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

In Section C.8, page 24, the applicant provides a table showing the historical patient origin for BMA East Rocky Mount, as follows:

**Historical Patient Origin
June 30, 2015**

County	Number of In-Center Dialysis Patients
Edgecombe	81
Halifax	5
Nash	40
Wilson	1
Totals	127

In Section C.1, 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 following table:

Projected Patient Origin by County

County	Operating Year 1 CY 2017	Operating Year 2 CY 2018	County Patients as Percent of Total	
	In-Center	In-Center	Year 1	Year 2
Edgecombe	78.4	78.9	71.0%	71.2%
Halifax	5.0	5.0	4.5%	4.5%
Nash	26.0	26.0	23.6%	23.4%
Wilson	1.0	1.0	0.9%	0.9%
Total	110.4	110.9	100.0%	100.0%

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to add six dialysis stations to BMA East Rocky Mount for a total of 30 stations upon completion of this project and Project ID #L-11011-15 (relocate six stations to FMC Tarboro) pursuant to the 2015 SMFP Facility Need Methodology.

Projected Utilization

As of December 31, 2014, as reported in the July 2015 SDR, the utilization rate at BMA East Rocky Mount was 101.67% or 4.07 patients per station per week based on 122 in-center patients utilizing 30 certified dialysis stations.

In Section C.1, page 20, the applicant provides the following assumptions used to project utilization:

The applicant projects that the growth rate for Edgecombe County patients dialyzing at BMA East Rocky Mount continue to increase at a rate commensurate with the Edgecombe County Five Year Average Annual Change Rate (AACR) of 0.7% as reported in the July 2015 SDR. In addition, the applicant projects that 14 of its 40 current patients from Nash County will transfer their care to FMC South Rocky Mount, a new facility projected to be certified by December 31, 2015 (Project I.D. #L-10177-13). The applicant also projects that four of its current patients from Edgecombe County will transfer their care to FMC Tarboro, a new facility projected to be certified by December 31, 2016 (Project I.D. #L-11011-15). The applicant states it does not project any increases in the number of patients dialyzing at BMA East Rocky Mount from other counties.

In Section C.1, page 21, the applicant provides the following methodology used to project utilization:

BMA East Rocky Mount	In-Center
Beginning facility census of Edgecombe County patients only, June 30, 2015	81
Project Edgecombe County patient population forward six months to December 31, 2015 using one-half the Edgecombe County Five Year AACR of 0.35%	$(81 \times .035) + 81 = 81.3$
Project Edgecombe County patient population forward one year to December 31, 2016, the date of projected project completion	$(81.3 \times .007) + 81.3 = 81.9$
Subtract the four Edgecombe County patients transferring to FMC Tarboro	$81.9 - 4 = 77.9$
Add the patients from Halifax (5), Nash (26 remaining after 14 transfer to FMC South Rocky Mount), and Wilson (1) for beginning census.	$77.9 + 5 + 26 + 1 = 113.3$ [109.9]
Project the Edgecombe County population forward one year to December 31, 2017 using Edgecombe County 0.7% Five Year AACR	$(77.9 \times 0.007) + 77.9 = 78.4$
Add the 32 patients from the other counties for the projected census for the end of Operating Year One	$78.4 + 5 + 26 + 1 = 110.4$
Project the Edgecombe County population forward one year to December 31, 2018 using Edgecombe County 0.7% Five Year AACR	$(78.4 \times .007) + 78.4 = 78.9$
Add the 32 patients from the other counties for the projected census for the end of Operating Year Two	$78.9 + 5 + 26 + 1 = 110.9$

The applicant states, in Section C.1, page 21, that it has rounded down to 110 patients to be dialyzing at the BMA East Rocky Mount facility at the end Operating Year One. Therefore, the applicant projects that 110 patients will be dialyzing on 30 stations for a projected utilization rate of 3.67 patients per station per week ($110 \text{ in-center patients} / 30 \text{ stations} = 3.67$) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for six additional dialysis stations at BMA East Rocky Mount.

Access

In Section C.3, page 22, the applicant states that it is the policy of BMA to provide “*services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.*” The applicant projects, in Section C.3, page 22, that 91.3% of its in-center patients will be covered by either Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for six additional stations at BMA East Rocky Mount 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 the submission of this application, summarized as follows:

1. Maintain the Status Quo – the applicant dismissed this alternative based on the fact that the facility is projected to have greater than 80% utilization at the end of the first operating year. The applicant states, *“Failure to develop additional capacity at the facility will result in higher utilization rates at the facility and potentially restrict patient admissions.”*
2. Apply for Fewer Stations - the applicant states that this alternative also does not address increasing patient utilization at the facility and that *“Fewer stations would result in higher utilization rates.”*

Thus, after considering the above alternatives, the applicant concluded that its proposal to add six dialysis stations to BMA East Rocky Mount is the most effective alternative to meet the need.

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

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. 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 East Rocky Mount shall materially comply with all representations made in the certificate of need application.**

2. **The certificate of need for Project I.D. #L-11093-15 shall not be issued until the certificate of need is issued for Project I.D. #L-11011-15.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA East Rocky Mount shall develop no more than six additional stations for a total of no more than 30 certified stations upon completion of this project, which shall include any home hemodialysis or isolation stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA East Rocky Mount 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 six dialysis stations for a total of 30 dialysis stations at BMA East Rocky Mount upon completion of this proposed project and Project I.D. #L-11011-15 (relocate six stations to FMC Tarboro).

Capital and Working Capital Costs

In Section F.1, page 29, the applicant states that there will be no capital costs for the project. In Section F.9, page 33, the applicant states that the dialysis machines will be leased.

In Section F.10 and F.11, page 33, the applicant projects no initial start-up costs or initial operating expenses because this is an existing facility.

Availability of Funds

In Exhibit F-1, the applicant provides a letter dated September 15, 2015 from the Vice President and Treasurer of the parent company, Fresenius Medical Care (FMC) Holdings, Inc., authorizing the project and confirming that the project will not require any capital expenditure.

Financial Feasibility

In Section R, page 82, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

Allowable Charges

Payor	In-Center Charge
Self Pay/Indigent/ Charity	\$219.06
Commercial Insurance	\$486.59
Medicare	\$249.45
Medicaid	\$219.74
Medicare/Commercial	\$283.67
VA	\$330.26

In Section R, page 84, the applicant states that it used an average number of in-center patients, rounded down to the nearest whole number, to calculate its revenues for the first and second operating years of the project. Therefore, the number of in-center patients used in operating year one was 110 and the number of in-center patients used in operating year two was also 110. In Section R, pages 77-78, and 81, the applicant projects operating expenses and revenues, respectively, summarized as follows:

BMA East Rocky Mount

	Operating Year 1	Operating Year 2
Total Net Revenue	\$4,311,626	\$4,311,626
Total Operating Costs	\$4,229,310	\$4,274,125
Net Profit	\$82,316	\$37,501

The applicant projects that revenue will exceed operating expenses in each of the first two operating years of the project. The assumptions used in preparation of the pro forma financial statements are reasonable, including projected utilization, cost and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the proposal is based on reasonable projections of cost and charges. Therefore, the application is conforming to this criterion.

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

C

BMA, Inc. d/b/a BMA East Rocky Mount, whose parent company is FMC, proposes to add six dialysis stations to its existing facility for a total of 30 certified dialysis stations upon completion of this proposed project and Project I.D. #L-11011-15 (relocate six stations to FMC Tarboro).

On page 361, the 2015 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham*

Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Edgecombe County. Facilities may serve residents of counties not included in their service area.

According to the July 2015 SDR, there are two operational dialysis facilities in Edgecombe County, one operated and controlled by FMC, and one by DaVita Healthcare Partners, Inc. (DaVita). In addition, one dialysis facility has been proposed that will be owned by FMC, but has not yet been issued a certificate of need. These dialysis facilities are listed as follows:

**Edgecombe County Dialysis Facilities
December 31, 2014**

Name of Facility	Owner	Location	Number of Stations, Existing and Approved	Utilization
BMA East Rocky Mount	FMC	Rocky Mount	24	101.67%
Dialysis Care of Edgecombe County	DaVita	Tarboro	26	83.65%
FMC Tarboro*	FMC	Tarboro	10	0.00%

*FMC Tarboro, CON Project I.D. #L-11011-15, was conditionally approved by the Agency on August 28, 2015. The Agency’s decision is under appeal. Six of the 30 stations at BMA East Rocky Mount would be relocated to FMC Tarboro. Four stations would be relocated from Pitt County.

As shown in the table above, BMA East Rocky Mount was operating at over 101% of capacity as of December 31, 2014 and Dialysis Care of Edgecombe County was operating at over 83%.

According to Table B in the July 2015 SDR, there is a surplus of 12 dialysis stations in Edgecombe County. However, the applicant is applying for additional stations based on the facility need methodology. In Section C.1, page 21, the applicant demonstrates that BMA East Rocky Mount will serve a total of 110 in-center patients on 30 dialysis stations at the end of the first operating year, which is 3.67 patients per station per week, or a utilization rate of 91.7% ($101/30 = 3.67$; $3.67/4 = 91.7\%$). Therefore, the facility is expected to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates the proposed project will not result in the unnecessary duplication of existing or approved dialysis services or facilities in Edgecombe County. Consequently, the application is conforming to this criterion.

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

C

In Section H.1, page 41, the applicant states that BMA East Rocky Mount currently employs 24.73 full time equivalent (FTE) positions and that it does not propose to add additional FTEs upon completion of the project, as illustrated in the table below:

BMA East Rocky Mount Full-Time Equivalent (FTE) Positions			
Position	Current	Additional	Total
Medical Director*			
Registered Nurse	5.00	0.00	5.00
Patient Care Technician	14.00	0.00	14.00
Dietary Consultant	1.00	0.00	1.00
Social Services	1.40	0.00	1.40
Clinical Manager	1.00	0.00	1.00
Director of Operations	0.13	0.00	0.13
In-Service	0.20	0.00	0.20
Clerical	1.00	0.00	1.00
Chief Technician	0.15	0.00	0.15
Equipment Technician	0.85	0.00	0.85
Total FTEs	24.73	0.00	24.73

*This is a contractual position.

In Exhibit I.6, the applicant provides a letter from Dr. Charles Jere, dated September 2, 2015, indicating his support of the project and his willingness to continue to serve as Medical Director of the facility. In Section H.3, page 42, the applicant states it does not anticipate any difficulties in filling staff positions as it provides a range of benefits and competitive salaries to attract qualified staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 44, the applicant lists the providers of the necessary ancillary and support services. See Exhibits I.2, I.3, I.4, and I.5 for documentation of service agreements. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 45-46, stating that it will work with local nephrology physicians and with other physicians, local hospitals and other healthcare professionals in the community that it has developed relationships with over the years. 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 healthcare system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

NA

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.1, pages 54-55, the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... 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.

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

In Section L.7, page 58, the applicant provides the historical in-center payor mix for BMA East Rocky Mount, as follows:

**Historical Payor Source
CY 2014**

Payor Source	Percentage
Private Pay/Indigent/ Charity	0.00%
Medicare	80.91%
Medicaid	6.36%
Commercial Insurance	5.45%
Medicare/Commercial	5.45%
Medicare/Medicaid	0.00%
VA	1.82%
Total	100.00%

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 Edgecombe 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)*
Edgecombe County	30.6%	13.5%	21.3%
Statewide	16.5%	6.7%	19.7%

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

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

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 Network 6 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.3, page 57, 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. ...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.6, page 57, 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/utis/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 L.1, page 55, the applicant provides the projected payor mix for the proposed services at BMA East Rocky Mount as shown in the table below:

Payor Source	Percentage
Self Pay/Indigent/Charity	0.0%
Medicare	79.1%
Medicaid	4.5%
Commercial Insurance	8.2%
Medicare/Commercial	6.4%
Medicare/Medicaid	0.9%
VA	0.9%
Total	100.0%

As shown in the table above, the applicant projects that 90.9% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. In Section L.1, page 55, the applicant provides the assumptions used to project payor mix. The applicant's payor mix percentages vary slightly from the historical payor mix percentages provided. The applicant states, on page 55, that a slight change is expected due to patients' conversions from commercial insurance coverage to Medicare coverage once commercial insurance no longer pays, and due to the transfer of some patients to the FMC South Rocky Mount facility once it becomes operational. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 57, 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 East Rocky Mount 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.”

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

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

C

In Section M.1, page 59, 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.*” Exhibit M-1 includes a letter from the applicant to Edgecombe Community College, dated September 15, 2015, which encourages the school to include BMA East Rocky Mount as a clinical training site for its nursing students. The information provided in Section M.1 and Exhibit M-1 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

BMA, Inc. d/b/a BMA East Rocky Mount, whose parent company is FMC, proposes to add six dialysis stations to its existing facility for a total of 30 certified dialysis stations upon completion of this proposed project and Project I.D. #L-11011-15 (relocate six stations to FMC Tarboro).

On page 361, the 2015 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service

area is Edgecombe County. Facilities may serve residents of counties not included in their service area.

According to the July 2015 SDR, there is a surplus of 12 dialysis stations in Edgecombe County. The applicant is applying for additional stations based on the facility need methodology. According to the July 2015 SDR there are two operational dialysis facilities and one proposed dialysis facility in Edgecombe County. One of the two operational dialysis facilities is ultimately operated and controlled by FMC and the other by DaVita. The proposed dialysis facility is ultimately operated and controlled by FMC. These dialysis facilities are listed as follows:

Edgecombe County Dialysis Facilities – July 2015 SDR

Name of Facility	Owner	Location	Number of Stations, Existing and Approved	Utilization
BMA East Rocky Mount	FMC	Rocky Mount	24	101.67%
Dialysis Care of Edgecombe County	DaVita	Tarboro	26	83.65%
FMC Tarboro*	FMC	Tarboro	10	0.00%

*FMC Tarboro, CON Project I.D. #L-11011-15, was conditionally approved by the Agency on August 28, 2015. The Agency’s decision is under appeal. Six of the 30 stations at BMA East Rocky Mount would be relocated to FMC Tarboro. Four stations would be relocated from Pitt County.

As of December 31, 2014, both of the operational dialysis facilities in Edgecombe County were operating above 80% capacity.

In Section N.1, page 60, the applicant discusses how any enhanced competition in the service area would have a positive impact on 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 Edgecombe County.

...

BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA East Rocky Mount facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Edgecombe County five year average annual change rate of 0.7% as published within the July 2015 SDR.”

In addition, the applicant states, on page 60, that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and proposes that over 94% of its patients at BMA

East Rocky Mount will rely on Medicare or Medicaid to pay for their dialysis services. Moreover, the applicant states, on page 60, that its proposal will “*enhance the quality of the ESRD patients’ lives...*”

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

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis 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 Criterion (3) and (4), respectively, are 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), is incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3) and (13) is 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 provides a listing of 103 FMC and FMC-affiliated ESRD facilities owned and operated in the state. In Section O.3, pages 64-66, the applicant provides information on quality of care provided at its facilities, including citations received during the 18 months immediately preceding the submittal of the application through the date of the decision, and their resolution. One FMC facility had two citations and another had one citation. As stated on page 66, both facilities are 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. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-C- In Section G.1, page 39, the applicant states the utilization rate was 101.67% ($122/30 = 4.07$ patients per station) as reported in the July 2015 SDR.

(2) *Mortality rates;*

-C- In Section C.9, page 25, the applicant states the mortality rates were 18.3%, 22.9% and 10.8% for 2012, 2013 and 2014, respectively.

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

-NA- In Section C.1, page 19, the applicant states that BMA East Rocky Mount does not have a home training program.

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

-C- In Section C.10, page 25, the applicant states that 14 transplants were performed or referred during 2014.

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

- C- In Section C.10, page 25, the applicant states that BMA East Rocky Mount has 12 patients on the transplant waiting list as of September 1, 2015.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section C.11, page 25, the applicant states that there were 235 hospital admissions in 2014; 60 dialysis related and 175 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 C.10, page 25, the applicant states that there was one patient with an infectious disease as of September 1, 2015 and 19 patients converted to infectious status at the facility during 2015.

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

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

-NA- BMA East Rocky Mount is an existing facility.

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) composition of the assessment/evaluation team at the transplant center,*
- (C) method for periodic re-evaluation,*
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- BMA East Rocky Mount is an existing facility.

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

-NA- BMA East Rocky Mount is an existing facility.

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

-C- See Exhibit K-3 for a copy of the Emergency Management & Disaster Planning Section of BMA's Policy and Procedure Manual Volume II which includes a policy and procedure for back-up electrical service in the event of a power outage.

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

-NA- BMA East Rocky Mount is an existing facility.

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

-C- In Section K.1, page 51, the applicant states, "BMA of North Carolina 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." In addition, in Section C.3, page 23, the applicant states, "The facility will conform to the North Carolina Building Code, the National Fire Protection Association 101 Life Safety Code, the Americans with Disabilities Act, ANSI Standards for Handicapped Access, and any other requirement of federal, state, and local bodies."

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

-C- In Section C.1, page 19, the applicant provides the projected patient origin for BMA East Rocky Mount. The applicant's assumptions and methodology are provided in Section C.1, pages 20-21, and in Section J.1, page 48. The

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

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

-NA- BMA East Rocky Mount is an existing facility.

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

-C- In Section P, page 71, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- BMA East Rocky Mount does not propose to establish a new facility. BMA East Rocky Mount 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 C.2, pages 21-22, and Section P, page 71, the applicant projects 110 in-center patients dialyzing on 30 stations at the end of the first operating year for a utilization rate of 3.67 patients per station per week, thereby documenting the need for the additional stations. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 20-22, and Section C.6, page 24. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

(1) *diagnostic and evaluation services;*

- C- In Section P, page 71, the applicant states that diagnostic and evaluation services will be provided by UNC Nash Healthcare Systems.

(2) *maintenance dialysis;*

- C- In Section I.1, page 44, and Section P, page 71, the applicant states that BMA East Rocky Mount will provide in-center dialysis.

(3) *accessible self-care training;*

- C- In Section I.1, page 44, and Section P, page 72, the applicant states that self-care training will be referred to FMC South Rocky Mount or BMA Rocky Mount.

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

- C- In Sections I.1 and I.2, pages 44-45, and Section P, page 72, the applicant states that an accessible follow-up program is available through referral to FMC South Rocky Mount or to BMA Rocky Mount.

(5) *x-ray services;*

- C- In Section I.1, page 44, the applicant states that x-ray services will be provided by UNC Nash Healthcare Systems. In addition, in Section P, page 72, the applicant states that patients will be referred to “*any of the local diagnostic centers offering x-ray services if requested by the patient.*”

(6) *laboratory services;*

- C- In Section I.1, page 44, and Section P, page 72, the applicant states that it provides on-site laboratory services from Spectra Labs through a contract. See Exhibit I-3 for the laboratory services agreement with Spectra Laboratories.

(7) *blood bank services;*

-C- In Section I.1, page 44, and Section P, page 72, the applicant states that blood bank services will be available upon patient referral to UNC Nash Healthcare Systems.

(8) *emergency care;*

-C- In Section P, page 72, the applicant states that BMA staff are trained to provide emergency care, however if needed, emergency transport is requested by calling 911. In addition, in Section I.1, page 44, the applicant states that UNC Nash Healthcare Systems or Vidant of Edgecombe will provide emergency care.

(9) *acute dialysis in an acute care setting;*

-C- In Section I.1, page 44, and Section P, page 72, the applicant states that patients needing acute dialysis requiring admission to a hospital will be referred to UNC Nash Healthcare Systems.

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

-C- In Section I.1, page 44, and Section P, page 72, the applicant states patients needing vascular surgery will be referred to Eastern Nephrology Access Center, Raleigh Access Center, Triangle Vascular Access, or Nash Day Hospital.

(11) *transplantation services;*

-C- In Section I.1, page 44, and Section P, page 72, the applicant states that patients needing a transplant will be referred to Vidant Healthcare in Greenville. See Exhibit I-4 for a copy of the Affiliation Agreement between BMA East Rocky Mount and other BMA facilities, and Pitt County Memorial Hospital, Incorporated, to provide inpatient treatment for its patients, including kidney transplantation services.

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

-C- In Section I.1, page 44, and Section P, page 73, the applicant states that patient referrals for vocation rehabilitation counseling and services will be provided to the Edgecombe County/Rocky Mount, North Carolina Division of Vocational Rehabilitation Services.

(13) *transportation.*

-C- In Section I.1, page 44, and Section P, page 73, the applicant states that various transportation services will be provided to patients, including Tar River Transit, K&L Transport, Bostic Transport, Eastern Medical Transportation, or Nash and/or Edgecombe Rescue departments.

(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 P, page 73, the applicant states, “BMA will provide sufficient staffing on each dialysis shift.” In Section H.2, page 42, the applicant states that BMA East Rocky Mount “will comply with all staffing requirements as stated in 42 C.R.R. Section 494.” The applicant provides its facility staffing in Section H.1, page 41, and provides a table showing the projected direct care staff hours in Section H.7, page 43. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

- C- In Section H.4, page 42, the applicant describes the training required for all BMA employees. In Section P, page 73, the applicant states that all employees receive training in any changes in policies and procedures as directed by corporate staff. Exhibit H-2 contains an employee training checklist and a list of annual training requirements for BMA employees.