

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: August 8, 2012

PROJECT ANALYST: Jane Rhoe-Jones
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: M-8800-12 / Bio-Medical Applications of North Carolina, Inc.
d/b/a BMA Fayetteville / Add four dialysis stations for a total
of 39 stations / Cumberland County

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.

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Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Fayetteville, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add four dialysis stations for a total of 39 certified dialysis stations upon completion of this project and Project I.D # M-8776-12 [transfer three dialysis stations to FMC West Fayetteville]. The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of five dialysis stations in Cumberland County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for BMA Fayetteville in the January 2012 SDR is 3.5 patients per station. This utilization rate was calculated based on 133 in-center dialysis patients and 38 certified dialysis stations. (133 patients / 38 stations = 3.5 patients per station).

Application of the facility need methodology indicates an additional station is needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW --- BMA Fayetteville ---M-8800-12		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/11		106.3%
Certified Stations		38
Pending Stations		0
Total Existing and Pending Stations		38
In-Center Patients as of 6/30/11 (SDR2)		133
In-Center Patients as of 12/31/10 (SDR1)		133
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/10	0.0000
(ii)	Divide the result of step (i) by 12	0.0000
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January 2012 SDR (6/30/11) until the end of calendar year 2012 (6 months)	0.0000
(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	133.0000
(v)	Divide the result of step (iv) by 3.2 patients per station	41.5625
	and subtract the number of certified and pending stations as recorded in SDR2 [12] to determine the number of stations needed	4

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

Policy GEN-3: Basic Principles, page 40, of the 2012 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

In Section II.1, page 20, the applicant states:

“BMA is a high quality health care provider. ... In addition, BMA’s parent company, Fresenius Medical Care, encourages all BMA facilities to attain the FMC UltraCare certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for UltraCare certification.”

In Section II.3, page 26, the applicant states:

“BMA Fayetteville has a well-defined Quality Improvement program whose purpose is to establish an outcome focused review and evaluation of the quality, safety and effectiveness of patient care. The program’s work is conducted by the Continuous Quality Improvement Team and coordinated by the Clinical Manager and the Regional Quality Manager. The primary method of review is patient care audits and monitoring of critical patient indicators. Audits will be conducted monthly and results presented to the Quality Improvement Team for evaluation and recommendation. Other audits include Patient Satisfaction Surveys and chart audits. CQI membership includes the Medical Director, Director of Operations, Clinical Manager, Chief Technician, Social Worker and Dietitian. The committee will meet monthly. Individual teams may be assigned to individual projects to gather data as needed to conduct the “Check, Plan, Do, and Check, Act” process for addressing improvement opportunities.”

See Exhibit 13 for copies of the CQI process.

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

Promote Equitable Access

In Section II.3, pages 20-21, the applicant states:

“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, BMA is projecting that 75.6% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 10.6% are

expected to be covered by VA. Thus, 86.2% of the In-Center revenue is derived from government payors. ...

BMA is also keenly sensitive to the second element of “equitable access” – time and distance barriers. At this time, Cumberland County has four operational dialysis facilities. The January 2012 SDR reports that Cumberland County ESRD population is growing at an Average Annual Change Rate of 3.8%. As the dialysis patient population of Cumberland County continues to increase, the need for dialysis stations will continue to increase. ... BMA is planning to add four stations so that an adequate supply of necessary health resources remains in closer proximity to the residence location of patients residing in this area of Cumberland County.”

The applicant adequately demonstrates that the proposal will promote equitable access.

Maximize Healthcare Value

In Section II.3, page 21, the applicant states:

“BMA is not projecting a capital expenditure for this project. BMA is not seeking State or Federal monies to develop the CON application or the additional dialysis station [sic] at the facility; BMA is not seeking charitable contributions. Rather, BMA through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment close to the patient homes. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. For example, within this application, BMA projects that 80.2% of the treatments are covered by Medicare and Medicaid, and an additional 8.0% are covered by VA. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence BMA must work diligently to control costs of delivery for dialysis. BMA does.”

The applicant adequately demonstrates that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed services incorporate the basic principles in meeting the needs of the patients to be served. See criterion (3) and (13) for additional discussion. The application is consistent with the facility need determination in the January 2012 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.

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The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Fayetteville, proposes to add four dialysis stations for a total of 39 certified stations, upon completion of this project and Project I.D # M-8776-12 (transfer three stations to FMC West Fayetteville).

Population to be Served

In Section IV.1, page 35, the applicant identifies the population it served, as of December 31, 2011, as illustrated in the table below.

County of Residence	# of Patients Dialyzing In-Center 12-31-11	# Home Patients 12-31-11
Cumberland	121	58
Hoke	4	4
Harnett	1	2
Sampson	1	1
Scotland	0	1
Mecklenburg	0	1
Total	127	67

In Section III.7, page 32, 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.

County	Year 1 2013		Year 2 2014		County Patients as a Percent of Total	
	In-center Patients	Home Patients	In-center Patients	Home Patients	Year 1	Year 2
Cumberland	125.2	62.5	129.9	64.9	92.60%	92.85%
Hoke	4	4	4	4	3.95%	3.81%
Harnett	1	2	1	2	1.48%	1.43%
Sampson	1	1	1	1	0.99%	0.95%
Scotland	0	1	0	1	0.49%	0.48%
Mecklenburg	0	1	0	1	0.49%	0.48%
Total	131.2	71.5	135.9	73.9	100.0%	100.0%

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III, pages 15-16, the applicant states:

“BMA is currently a 39 [sic 38] station dialysis facility. BMA has a pending CON, Project ID# M-8776-12 to transfer three dialysis stations from BMA Fayetteville to FMC West Fayetteville. In this application, BMA proposes to add four dialysis

stations for a net of 39 dialysis stations at BMA Fayetteville; two stations will be dedicated to Home Hemodialysis training and support, while 37 stations will continue to be used for the provision of in-center dialysis.

... BMA must project to serve 124.8, rounded to 125 [sic: rounded to 124 as the Agency rounds down] dialysis patients at the end of Operating Year 1. As noted in the calculations produced in response to 10A NCAC 14C .2200 (b) (7), BMA has projected to serve 131.2 dialysis patients. This equates to a utilization rate of 3.36 patients per station. The projected utilization rates exceed the minimum required by this rule.”

“Assumptions:

BMA assumes that the patient population of BMA Fayetteville will continue to increase commensurate with the Cumberland County Five Year Average Annual Change Rate [.038] as published in the January 2012 SDR. BMA does not project growth of patients from other counties who are dialyzing at the BMA Fayetteville facility; rather, BMA assumes that these patients are dialyzing at BMA Fayetteville by patient choice and will continue to dialyze at the facility by patient choice. ...

In addition to the foregoing, BMA also projects that the five patients currently dialyzing at BMA Fayetteville will transfer to the FMC West Fayetteville facility as of September 30, 2012, upon completion of the transfer project, CON Project ID# M-8776-12. Within this application, BMA will continue to project these transfers. In addition to these transfers, BMA notes that some portion of the BMA Fayetteville patients reside in counties other than Cumberland. BMA does not project any change to these patient populations and assumes that these patients are dialyzing at BMA Fayetteville as a function of patient choice. BMA will add these patients to the facility census at appropriate points in time. The following table illustrates the methodology leading to projections for the future census of the BMA Fayetteville facility:

	<i>In-Center</i>	<i>Home</i>
<i>BMA begins with Cumberland County patients at BMA Fayetteville as of December 31, 2011.</i>	<i>121</i>	<i>58</i>
<i>This patient population is projected</i>		

<i>forward for nine months using the Cumberland County Five Year Average Annual Change Rate to produce a calculated census of Cumberland County patients for September 30, 2012.</i>	$121 \times (0.038 / 12 \times 9) + 121 = 125.6$	$[58 \times (0.038 / 12 \times 9)] + 58 = 60.2$
<i>BMA has projected that 5 in-center patients would transfer to FMC West Fayetteville at September 30, 2012. The patients are subtracted here. This is the expected certification date of this project.</i>	$125.6 - 5 = 120.6$	60.2 (No change to Home)
<i>At this point, BMA adds patients from other Counties; this is the beginning census for this project.</i>	$120.6 + 6 = 126.6$	$60.2 + 9 = 69.2$
<i>BMA projects the calculated census of Cumberland County patients forward for one year to September 30, 2013.</i>	$(120.6 \times .038) + 120.6 = 125.2$	$(60.2 \times .038) + 60.2 = 62.5$
<i>BMA adds the patients from other counties to determine the calculated ending census for Operating Year 1. This is September 30, 2013.</i>	$125.2 + 6 = 131.2$	$62.5 + 9 = 71.5$
<i>BMA again projects the calculated census of Cumberland County patients forward for one year to September 30, 2014.</i>	$(125.2 \times .038) + 125.2 = 129.9$	$(62.5 \times .038) + 62.5 = 64.9$
<i>BMA adds the patients from other counties to determine the calculated ending census for Operating Year 2. This is September 30, 2014.</i>	$129.9 + 6 = 135.9$	$64.9 + 9 = 73.9$

The applicant projects to serve 131 in-center patients or 3.7 patients per station (131/39=3.4) by the end of Year 1 and 136 in-center patients or 3.9 patients per station (136/39=3.5) by the end of Year 2 for the proposed 39 station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

In summary, the applicant adequately identifies the population to be served and demonstrates the need the population has for four additional stations following completion of Project I.D # M-8776-12 and this project. 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.

- (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.

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In Section III.9, page 34, the applicant states the alternatives considered by BMA Fayetteville, including not pursuing the facility expansion and developing fewer than four new stations. The applicant adequately demonstrated the need for four additional stations based on the continued growth of Cumberland County and the facility's projected utilization. See Criterion (3) for discussion. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C .2200 for discussion. The applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Fayetteville 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 Fayetteville shall develop no more than four additional stations for a total of no more than 39 stations, which shall include any home hemodialysis training or isolation stations, upon completion of Project ID # M-8796-12 (transfer three stations to FMC West Fayetteville) and this project.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Fayetteville shall install plumbing and electrical wiring through the walls for four additional dialysis stations for a total of 39 dialysis stations which shall include any isolation stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Fayetteville shall submit a letter of support from the Medical Director of BMA Fayetteville which also states the physician's willingness to continue to serve as medical director, prior to issuance of the certificate of need.**
 - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Fayetteville shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to insurance 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.

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In Section VIII.1, page 51, the applicant projects no capital cost for the proposed project. In Section IX, page 54, the applicant further states that there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 24 includes a letter dated March 15, 2012 from the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

“BMA is submitting a Certificate of Need Application to add four dialysis stations to its existing dialysis facility at Fayetteville Kidney Center for a total of 39 stations upon completion of this project, and CON Project ID # M-8776-12, transfer of three stations to FMC West Fayetteville. BMA will not incur any capital cost as a result of this project.”

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2009 and 2010. As of December 31, 2010, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$163,292,000 with \$12,017,618,000 in total assets and \$6,561,629,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds, if required, for the proposed project.

The Medicare/Medicaid rates in Section X.1 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application. The applicant projects revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	Project Year 1	Project Year 2
Net Revenue	\$7,563,638	\$7,852,265
Operating Expenses	\$7,424,985	\$7,711,474
Profit	\$138,653	\$140,791

Source: Application pages 56 and 62.

The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is conforming to this criterion.

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

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The applicant proposes to add four dialysis stations to the existing facility for a total of 39 stations upon completion of Project ID # M-8776-10 and the proposed project. The applicant adequately demonstrates the need for four additional stations based on the number of in-center patients it proposes to serve. As of December 31, 2011, the 38 station facility was operating at 87.5% capacity ($133/38 = 3.5$; $3.5/4 = 87.5\%$). The applicant projects to serve 131 in-

center patients or 3.4 patients per station ($131/39 = 3.35$) by the end of Year 1 and 136 in-center patients or 3.5 patients per station ($136/39 = 3.48$) by the end of Year 2 for the proposed 39 station facility. Assuming 131 in-center patients, the facility will operate at 83.9 % of capacity at the end of Year 1 ($131/39 = 3.35$; $3.35/4 = 83.9\%$). Also assuming 136 in-center patients, the facility will operate at 87.1% of capacity at the end of Year 2 ($136/39 = 3.48$; $3.48/4 = 87.1\%$).

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. 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.

CA

In Section VII, page 48, the applicant provides the current number of full-time equivalent positions and projects that an additional 3.5 FTEs will be added to BMA Fayetteville following completion of the proposed project, as illustrated in the table below.

Position	Current # of FTEs	Projected # of New FTEs	Total # of FTEs
RN	6.50	1.50	8.00
Tech	16.00	2.00	18.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract Position – Not an FTE		
Administrator	0.35	0.00	0.35
Dietitian	1.00	0.00	1.00
Social Worker	1.00	0.00	1.00
Home Training Nurse	3.00	0.00	3.00
Chief Tech	0.50	0.00	0.50
Equipment Tech	2.00	0.00	2.00
In-Service	0.50	0.00	0.50
Clerical	2.00	0.00	2.00
Total	33.85	3.50	37.35

The applicant states in Section V4 (c) that Dr. Maureen Achuko has expressed willingness to serve as Medical Director and that Dr. Achuko’s letter of support is found in Exhibit 21. However, the letter of support in Exhibit 21 is not from Dr. Achuko, but from Dr. Richmond K. Nuamah. The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with this criterion as conditioned in Criterion (4), Condition 4 of these findings.

- (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 V.1, page 37, the applicant lists the providers of the necessary ancillary and support services. The information regarding coordination of services in Section V of the application and referenced in exhibits is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

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

NA

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

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;

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The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2009, respectively. The data in the table was obtained on June 15, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Cumberland	18%	6.7%	20.3%
Statewide	17%	7.4%	19.7%

Data for BMA Fayetteville is not available on the DMA web site.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by BMA Fayetteville.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina.

However, as of June 15, 2012, no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

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

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

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

In Section VI.1(a), page 43, the applicant states, “BMA has a long history of providing dialysis services to the underserved populations of North Carolina.” Further, on page 43, 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 patient population of the BMA Fayetteville is as follows:

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>BMA Fayetteville</i>	<i>32.5%</i>	<i>29.4%</i>	<i>78.4%</i>	<i>47.4%</i>	<i>70.1%</i>

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 78.4% [sic] of facility treatment reimbursement is from Medicare.

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

In Section VI.1(b), page 44, the applicant indicates that 80.3 percent of patients at BMA Fayetteville have some or all of their services paid for by Medicare or Medicaid. The table below illustrates the historical payor mix for the facility.

Historical Payor Source	
Payor Source	In-Center
Medicare	76.1%
Commercial Insurance	10.3%
VA	8.0%
Medicaid	4.2%
Other: Self/Indigent	1.4%
Total	100.0%

The applicant demonstrates that it 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;

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

“BMA of North Carolina facilities, and BMA Fayetteville 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 VI.6(a), page 46, the applicant states, *“There have been no Civil Rights complaints lodged against BMA Fayetteville or any BMA North Carolina facilities in the past five years.”* The application is conforming to this criterion.

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

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In Section VI.1(c), page 44, the applicant states it does not anticipate a “*significant change*” in the payor mix resulting from this proposal, as illustrated in the table below.

Projected Payor Source		
Payor Source	In-Center	Home
Medicare	76.1%	72.1%
Commercial Insurance	10.3%	23.2%
VA	8.0%	3.0%
Medicaid	4.2%	1.7%
Other: Self/Indigent	1.4%	0.0%
Total	100.0%	100.0%

As shown in the table above, the applicant projects that 80.3% of all in-center patients and 100% of its home training patients would have some or all of their services paid for by Medicare or Medicaid.

The applicant demonstrates that it will provide adequate access to elderly and medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5(a), page 46, 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 Fayetteville 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, Nephrologists or hospitals.”

The applicant adequately demonstrates that it will provide a range of means by which a person can access 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

See Exhibit 19 for a copy of a letter from the Area Manager (Northern Cape Fear Area), Fresenius Medical Care to the Director of Nursing for Methodist University, Fayetteville, North Carolina (not Fayetteville Technical Community College as stated on page 39 of the application) which offers BMA Fayetteville as a clinical training site. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion.

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

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

C

See Sections II, III, V, VI and VII. In particular, see Section V.7, pages 41-42, in which BMA Fayetteville discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Cumberland County. This determination is based on the information in the application, and the following:

- ◆ The applicant adequately demonstrates the need to add four dialysis stations for a total of 39 certified dialysis stations, following completion of Project I.D. # M-8776-12 and this project, the applicant also demonstrated that the proposed project is a cost-effective alternative;
- ◆ The applicant has and will continue to provide quality services; and
- ◆ The applicant has and will continue to provide adequate access to medically underserved populations.

In Section VI.1, page 43, the applicant provides the following table to demonstrate that the medically underserved population will have access to its serves, as illustrated below.

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>BMA Fayetteville</i>	32.5%	29.4%	78.4%	47.4%	70.1%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 78.4% of facility treatment reimbursement is from Medicare.

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

The applicant currently provides dialysis services at BMA Fayetteville. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Fayetteville has operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

- (a) An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:
 - (1) Utilization rates;
 - C- In Section II(1), page 11, and Section III.7, page 33, the applicant provides the utilization rate as reported in the January 2012 SDR of 87.50% with 3.5 patients per station.
 - (2) Mortality rates;

- C- In Section II.1, page 11 and Section IV.2, page 35, the applicant provides the mortality rates.
- (3) The number of patients that are home trained and the number of patients on home dialysis;
- C- In Section II(3), page 11 and Section IV.3, page 35, the applicant provides the number of patients that are home trained and the number of patients on home dialysis. See correspondence folder for information as clarified on June 12, 2012.
- (4) The number of transplants performed or referred;
- C- In Section II(4), page 11 and Section IV.4, page 35, the applicant provides the number of transplants performed and referred.
- (5) The number of patients currently on the transplant waiting list;
- C- In Section II(5), page 11 and Section IV.5, page 35, the applicant provides the number of patients on the BMA Fayetteville transplant waiting list.
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- C- In Section II(6), page 11 and Section IV.6, page 36, the applicant states the 2011 dialysis related and non-dialysis related hospital admissions. See correspondence folder for information as clarified on June 12, 2012.
- (7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.
- C- In Section II(7), page 12 and Section IV.7, page 36, the applicant states that there were no patients at the facility in 2010 and 2011 with an infectious disease.

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

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

-NA- BMA Fayetteville is an existing facility.

(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- BMA Fayetteville is an existing facility.

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

-NA- BMA Fayetteville is an existing facility.

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

-C- See Exhibit 12 for a copy of BMA Fayetteville which has policies and procedures for back-up electrical service in the event of a power outage.

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

-NA- BMA Fayetteville is an existing facility.

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

-C- In Section II.1, page 13, the applicant states, "*BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and*

regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at BMA Fayetteville.”

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

-C- See Section III.7, pages 31-33, and Criterion (3).

(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 Fayetteville is an existing facility.

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

-C- In Section II.1, pages 14-15, the applicant states, *“BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- BMA Fayetteville does not propose to establish a new End Stage Renal Disease facility.

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

-C- See Section II.1, pages 13-17 and Section III.7, pages 31-33, for the assumptions used by the applicant in determining its utilization for the BMA Fayetteville would

be 3.4 patients per station per week as of the end of the first operating year of the additional stations ($131/39 = 3.36$).

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 13-17 and Section III.7, pages 31 -33.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

(1) diagnostic and evaluation services;

-C- In Section II(1), page 17, the applicant states, “*Patients will be referred to Cape Fear Valley Hospital for diagnostic and evaluation services.*” See Exhibit 16 for a copy of the hospital agreement with Cape Fear Valley Health System.

(2) maintenance dialysis;

-C- See Section II(2), page 17.

(3) accessible self-care training;

C- See Section II(3), page 17.

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

C- See Section II(4), page 17.

(5) x-ray services;

C- See Section II(5), page 18. See Exhibit 16 for a copy of the hospital agreement with Cape Fear Valley Hospital.

(6) laboratory services;

-C- See Section II(6), page 18. See Exhibit 18 for the laboratory services agreement with Spectra Laboratories.

(7) blood bank services;

-C- See Section II(7), page 18.

(8) emergency care;

- C- See Section II(8), page 18. Exhibit 14 contains a copy of FMCNA Dialysis Services Training Manual. According to the manual's table of contents, Emergency Solutions can be found on page 2.
- (9) acute dialysis in an acute care setting;
- C- See Section II(9) page 18. Acute dialysis in an acute care setting will be provided at WakeMed Cary or WakeMed Raleigh. See Exhibit 16 for a copy of the hospital agreement with Cape Fear Valley Hospital
- (10) vascular surgery for dialysis treatment patients;
- C- In Section II(10), page 18.
- (11) transplantation services;
- C- In Section II(11), page 18. Several transplantation agreements are contained in Exhibit 17.
- (12) vocational rehabilitation counseling and services; and
- C- See Section II(12), page 18.
- (13) transportation.
- C- See Section II(13), page 18.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

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

- C- In Section VII.1, page 48, the applicant provides the current and projected number of FTEs for BMA Fayetteville following completion of the proposed project. The applicant adequately demonstrates that its proposed number of FTEs will meet the staffing requirements as stated in 42 C.F.R., Section 405.2100.
- (b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.
- C- In Section II, pages 19, 26-27, the applicant states that BMA Fayetteville will provide ongoing program training for nurses and technicians in dialysis techniques. See Section VII, page 49, of the application, for information concerning the training and continuing education programs currently in place at BMA Fayetteville. Exhibit 14 contains copies of FMCNA Dialysis Services Training Manual which outlines its training program. Also see Exhibit 15 for

examples of information presented as part of staff's mandatory in-service training.