

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 20, 2013

PROJECT ANALYST: Gloria C. Hale

TEAM LEADER: Craig R. Smith

PROJECT I.D. NUMBER: F-10181-13/ Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Albemarle/ Add two dialysis stations for a total of 24 dialysis stations upon project completion / Stanly 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.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Albemarle proposes to add two (2) in-center dialysis stations to the existing facility for a facility total of 24 in-center dialysis stations upon completion of this project.

The 2013 State Medical Facilities Plan (2013 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Stanly County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, BMA Albemarle is eligible to apply for two additional stations in its existing facility based on the facility need methodology, because the utilization rate reported in the July 2013 SDR is 3.36 patients per station, or 84.09%. This utilization rate was calculated based on 74 in-center dialysis patients and 22 certified dialysis stations as of December 31, 2012 (74 patients / 22 stations = 3.36 patients per station).

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

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/12		84.09%
Certified Stations		22
Pending Stations		0
Total Existing and Pending Stations		22
In-Center Patients as of 12/31/12 (SDR2, July 2013 SDR)		74
In-Center Patients as of 6/30/12 (SDR1, January 2013 SDR)		69
Difference (SDR2 - SDR1)		5
Step	Description	
(i)	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 6/30/12 (SDR1)	0.1449
(ii)	Divide the result of Step (i) by 12	0.0121
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July 2013 SDR (12/31/12) until the end of calendar year 2013 (12 months)	0.1452
(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	84.7448
(v)	Divide the result of Step (iv) by 3.2 patients per station	26.4828
	and subtract the number of certified and pending stations as recorded in SDR2 [22] 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 (4) 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 proposed to add only two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: BASIC PRINCIPLES in the 2013 SMFP is also 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 (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A 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, BMA Albemarle, is a subsidiary of Fresenius Medical Care Holdings, Inc. (FMC). The applicant describes how its proposal will promote safety and quality in Section I, pages 5-7, and Section II, pages 25-26, and 33-35. The applicant states in Section I, page 5:

*“FMC’s commitment to the quality and availability of dialysis services is evidenced in its organizational structure. The **Clinical Services Department**, within the Dialysis Division (Bio-Medical Applications, or BMA) serves as a central resource for the entire FMC network of health care providers. The department is devoted to assuring all FMC facilities are provide with the best procedures and equipment available and consistently meet the highest possible standards. Professional staff is available to assist facility managers and medical personnel with questions and concerns relative to clinical operations. Additionally, the department provides such services as an ongoing Clinical Review Program, guidelines for the comprehensive training of staff members, a Quality Assurance Program and a full range of services to support home care.*

*Another important resource for the provision of quality care is FMC’s **Technical Services Department**. The primary focus of this department is to oversee the technical and mechanical aspects of dialysis. The department is further supported be [by] a research and quality control team that consistently leads the industry in dealing with technically complex issues facing dialysis providers.*

...

The result of these services support the commitment and assurance that every patient receives care of the highest standards each time he or she is treated at an FMC facility.”

In addition, in Section II, pages 25-26, the applicant states BMA’s parent company, FMC, “encourages all BMA facilities to attain the FMC UltraCare® certification”, an ongoing quality care program focused on delivering optimum care to patients through “innovative programs, the latest technology, continuous quality improvement and a focus on superior customer service.” UltraCare training is provided to all employees.

Moreover, in Section II, page 35, the applicant discusses its continuous quality improvement program which includes goals for quality indicators that are more stringent than those of the Federal Centers for Medicare and Medicaid Services for assessing the quality of dialysis treatment outcomes. The following table is provided, on page 35, to illustrate BMA Albemarle’s averages on three quality indicators:

Core Indicator	Measurement	Result
Dialysis Adequacy	% of patients with Ekt/V > 1.2	100.0%
Nutrition	% of patients with Albumin > 3.5	87.0%
Vascular Access	% of patients with AV Fistula	50.0%
	% of patients with Catheter	18.0%

The applicant notes that the higher the number of patients with AV Fistula and the lower the number of patients with catheters, the better.

Furthermore, BMA Albemarle participates in FMC’s continuous quality improvement program whereby the facility is monitored by a Regional Quality Team for quality improvement, regulatory compliance, systems education and technical proficiency. Activities of the Regional Quality Team include discussion of clinical variance reports and mortality reviews. Follow-up on issues raised at Quality Improvement Committee meetings, in addition to unannounced audits, are performed to improve quality of care.

Promote Equitable Access

The applicant describes how its proposal will promote equitable access in Section II, pages 26-27, and in Section VI, pages 52-55. The applicant states in Section II, pages 26-27, that the majority of its dialysis patients are covered by Medicare and Medicaid and that 91.9% of its in-center revenue is from government payers. In Section VI, page 52, the applicant states:

“BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

In addition, the applicant states on page 54 that there are some patients who do not have sufficient financial resources to pay for the services rendered and that *“BMA allocates these un-collectables to a ‘Bad Debt’ account.”* The amount of bad debt was \$369,336 for FY 2012. Although it is BMA’s admission policy to require patients to have some type of insurance to receive dialysis services, the applicant states on page 53, *“...in the interest of providing services where needed, the Regional Vice President does have the authority to override the policy. The Social Worker and Business office staff will assist the patient by identifying sources of funding and completing the required information necessary to obtain assistance.”*

Moreover, the applicant states in Section II, page 27, that it is sensitive to time and distance barriers and that it will *“apply to develop new dialysis facilities when needed”* to address the growing dialysis population in Stanly County. By applying for two additional dialysis stations at BMA Albemarle, it is addressing a growing need for dialysis services in the county.

The applicant adequately demonstrates how its proposal will promote access to medically underserved groups.

Maximize Healthcare Value

The applicant describes how its proposal will maximize health care value for resources expended in Section II, page 27, and Section III.9, pages 42-43. The applicant states on page 27 that its parent company, FMC, will expend the resources necessary to add the additional two dialysis stations to BMA Albemarle to serve a growing need and to bring dialysis services closer to patients' homes. Since the majority of BMA Albemarle's patients are covered by government payers, BMA "*must work diligently to control costs of delivery for dialysis. BMA does.*" In addition, in Section III.9, pages 42-43, the applicant states that the BMA Albemarle facility is growing 14.5% annually which is at a greater rate than Stanly County's Five Year Annual Change Rate for dialysis services. Therefore, the addition of two dialysis stations at BMA Albemarle addresses a need.

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion.

The applicant adequately demonstrates how its proposal will promote safety and quality, promote equitable access, and maximize health care value for resources expended. Therefore, the application is consistent with Policy GEN-3, and 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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Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Albemarle proposes to add two in-center dialysis stations to the existing facility, pursuant to a Facility Need Determination, for a facility total of 24 stations upon completion of this project.

Population to be Served

In Section III.7, page 41, the applicant provides BMA Albemarle’s projected patient origin during the first two operating years as illustrated below:

COUNTY	OPERATING YEAR 1 CY 2015			OPERATING YEAR 2 CY 2016			COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CENTER PATIENTS	HOME PERITONEAL PATIENTS	HOME HEMO- DIALYSIS	IN-CENTER PATIENTS	HOME PERITONEAL PATIENTS	HOME HEMO- DIALYSIS	YEAR 1 (CY 2015)	YEAR 2 (CY 2016)
Stanly	67.1	1.0	1.0	67.5	2.0	2.0	84.8%	84.8%
Montgomery	9.0	0	0	9.1	0	0	11.4%	11.4%
Rowan	1.0	0	0	1.0	0	0	1.3%	1.3%
Cabarrus	1.0	0	0	1.0	0	0	1.3%	1.3%
Davidson	1.0	0	0	1.0	0	0	1.3%	1.3%
Total*	79.2	1	1	79.6	2	2	84.8% [100%]	84.8% [100%]

*Totals may not foot due to rounding. Corrections to calculations made by Project Analyst are in brackets.

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III, pages 39-41, the applicant provides the assumptions and methodology used to project patient utilization and the need for two additional dialysis stations, summarized as follows:

- Based on the data reported in Table A, page 15 of the July 2013 SDR, BMA Albemarle had 74 in-center patients as of December 31, 2012. There are 22 certified dialysis stations at the facility and a utilization rate of 84.09%.
- Based on information provided by the applicant in Section III.2, and illustrated in a table provided by the analyst (see Criterion 1), the facility is eligible for four additional stations based on facility need methodology.
- Table B of the July 2013 SDR, page 20, indicates there were 69 total patients from Stanly County, however 5 were home patients. Therefore, there were only 64 in-center patients as of December 31, 2012. As Table A of the July 2013 SDR reports, BMA Albemarle had 74 in-center patients. Therefore, it is clear that some patients receiving treatment at BMA Albemarle are from counties other than Stanly County.
- The applicant assumes that the number of patients utilizing the facility will increase by 3.1% based on a five year average of the BMA Albemarle facility census, as depicted on page 39 and illustrated as follows:

SDR Data	July 2009	July 2010	July 2011	July 2012	July 2013	BMA Albemarle Five Year Average Annual Change Rate
BMA Albemarle Total Patient Census	67	59	70	69	74	
Raw Number Change		- 8	11	1	5	
Annual Change		- 0.1194	0.1864	- 0.0143	0.0725	0.0313

- The applicant uses a growth rate of 3.13% based on BMA Albemarle’s Five Year Average Annual Change Rate as calculated in the table above. (Note: the Stanly County Five Year Average Annual Change Rate, listed in Table B, page 20, of the 2013 SDR, is -0.015. The number of Stanly County patients has declined, however the facility utilization has increased.)
- The applicant projects BMA Albemarle’s future patients, by county of origin, on page 40, by “*applying a pro-rata share of the county population served by the facility today.*” This is illustrated as follows:

County	June 30, 2013	% of Patients by County of Residence
Stanly	67	84.8%
Montgomery	9	11.4%
Rowan	1	1.3%
Cabarrus	1	1.3%
Davidson	1	1.3%
Total	79	100%

- The applicant projects that it will serve home dialysis patients through training at a rate of two Stanly County patients per year. These patients will be current in-center patients who will convert to home dialysis, one converting to peritoneal dialysis and one converting to home hemodialysis, each operating year.
- BMA Albemarle is projected to have 79 in-center patients by the end of operating year 1 (January 1, 2015 - December 31, 2015) and 79 in-center patients by the end of operating year two (January 1, 2016 – December 31, 2016). The applicant illustrates this in Section III, page 40, applying its own facility Five Year Average Annual Change Rate as follows:
- BMA Albemarle census as of December 31, 2012 = 74 in-center patients
- January 1, 2013 – December 31, 2013 - $(74 \times .031) + 74 = 76.3$ in-center patients

- January 1, 2014 – December 31, 2014 – $(76.3 \times .031) + 76.3 = 78.7$ in-center patients for the projected completion date of the project
- January 1, 2015 – December 31, 2015 – $(78.7 \times .031) + 78.7 = 81.2$ in center patients, minus 2 home dialysis patients equals 79 in-center patients for the end of Operating Year One ($81.2 - 2 = 79.2$)
- January 1, 2016 – December 31, 2016 – $(81.2 \times .031) + 81.2 = 83.6$ in center patients, minus 4 home dialysis patients equals 79 in-center patients for the end of Operating Year Two ($83.6 - 4 = 79.6$)

The applicant states, on page 41, “*In financial projections and utilization projections for this application, BMA has rounded down to the nearest whole number.*”

The applicant’s projected utilization at the end of Operating Year One is 3.29 patients per station per week, (79 patients dialyzing on 24 stations = 3.29 patients per station), which exceeds the minimum of 3.2 patients per station per week as required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need for two additional dialysis stations at the BMA Albemarle facility. Consequently, 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

The applicant proposes to add two in-center dialysis stations to its existing facility, for a facility total of 24 in-center dialysis stations following project completion. In Section III.9, pages 42-43, the applicant states that it considered the alternative of applying for fewer additional stations at the facility, however the facility has recently experienced a rate of growth of 14.5% as indicated in the need methodology calculations. The applicant further states that patient choice would be adversely affected if the stations were not added, and that the facility is expected to exceed 80% utilization. The applicant adequately explains why it chose the selected alternative over the status quo. Furthermore, the application is

conforming to all other applicable statutory review criteria. Therefore, the applicant adequately demonstrates that the selected proposal is its least costly or most effective alternative to meet the identified facility need for two additional dialysis stations at BMA Albemarle. Consequently, the application is conforming to this criterion and is approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Albemarle shall materially comply with all representations made in its certificate of need application.**
 2. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Albemarle shall develop and operate no more than two additional dialysis stations for a total of 24 certified stations which shall include any home hemodialysis training or isolation stations.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Albemarle shall install plumbing and electrical wiring through the walls for two additional dialysis stations for a total of 24 dialysis stations which shall include any isolation stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Albemarle shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Sections VIII.1(b), page 61, the applicant states that the capital cost is projected to be \$4,555. In Sections IX, page 65, the applicant states that there are no start-up or initial operating expenses since BMA Albemarle is an existing facility.

In Section VIII.2, page 62, the applicant indicates that this project will be funded from accumulated reserves. Exhibit 24 includes a letter dated September 16, 2013 from the Vice President of Fresenius Medical Care Holdings, Inc. verifying the availability of funds for the project, which states in part:

“As Vice President, I am authorized and do hereby authorize the addition of two dialysis stations, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$4,555 as may be needed for this project.”

In Exhibit 10, the applicant provides a copy of the most recent audited financial reports for FMC. As of December 31, 2012, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$341,071,000 with \$17,841,509,000 in total assets and \$9,469,431,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the proposed project.

Based on information provided by the applicant in Section X.1, page 66, the applicant lists the following charges per treatment for each payment source:

**BMA Albemarle Projected Allowable
 In-Center Charges per Treatment**

SOURCE OF PAYMENT	IN-CENTER CHARGE	HOME PERITONEAL DIALYSIS CHARGE	HOME HEMODIALYSIS CHARGE
Medicare	\$234.00	\$234.00	\$234.00
Medicaid	\$137.29	\$137.29	\$137.29
Commercial Insurance	\$1,375.00	\$1,375.00	\$1,375.00
VA	\$146.79	\$147.85	\$147.85
Private Pay	\$1,375.00	\$1,375.00	\$1,375.00

The applicant states, on page 66, that it is using the Medicare basic rate shown above, which is also the minimum Medicare rate. The applicant notes, on page 66, “...there is some speculation that Medicare will cut dialysis reimbursement by as much as 9%.” Further, “Out of an abundance of caution, BMA has evaluated the revenues for this proposal with Medicare Reimbursement at \$213 (\$234 less 9%).” Moreover, the applicant states, on page 66, “...this reduction in reimbursement is a possibility, and that the project remains financially viable with the lower Medicare reimbursement rates.” The applicant utilizes projected lower Medicare reimbursement rates to calculate its projected revenues. In Sections X.2 through the applicant’s “Supplemental Information: Analysis of Possible Medicare Reduction”, pages 67-74, the applicant reports projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$3,349,166	\$3,560,355
Total Operating Costs	\$3,080,092	\$3,220,179
Net Profit	\$269,075	\$340,176

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X, pages 66-70 of the application, for the applicant’s assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on 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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Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Albemarle proposes to add two in-center dialysis stations to the existing facility. BMA Albemarle is currently serving 74 patients, six days a week with 2 shifts per day, with 22 stations. Dialysis facilities that operate four shifts per week (2 patients dialyzing per day at each station on alternate days) have a capacity of four patients per station. This equates to 3.36 patients per station, which is 84.09% of capacity ($74/22 = 3.3636$; $3.3636/4 = 84.09\%$). The target utilization rate is 80%. The applicant does not propose to establish a new facility. Projections for the in-center patient population are provided in Section II, pages 15-16 of the application. At the end of operating year two, with 24 dialysis stations and 79 patients projected, the applicant's projected utilization will be 3.29 patients per station operating at 82% of capacity ($79 \text{ patients} / 24 \text{ stations} = 3.29$). This utilization projection is based on applying the Five Year Average Annual Change Rate (AACR) of 3.1% in dialysis patients utilizing BMA Albemarle. BMA Albemarle is the only dialysis facility in Stanly County. The applicant adequately demonstrates the need to add two dialysis stations to the existing facility based on the number of in-center patients it proposes to serve. Therefore, the applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved dialysis facilities in Stanly County, and 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.

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In Section VII.1, page 57, the applicant provides current and projected staffing for the BMA Albemarle facility following the addition of two stations, as illustrated in the following table:

POSITION	CURRENT FTEs	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
Registered Nurse	2.50	0.50	3.00
Technician	7.50	2.00	9.50
Clinical Manager	1.00	0	1.00
Administrator (FMC Director of Operations)	0.15	0	0.15
Dietician	0.50	0	0.50
Social Worker	0.40	0	0.40
Home Training Nurse	0.50	0	0.50
Chief Technician	0.10	0	0.10
Equipment Technician	0.50	0	0.50
In-Service	0.15	0	0.15
Clerical	1.00	0	1.00
Totals	14.30	2.50	16.80

In Exhibit 21 of the application, the applicant provides a letter from Dr. Thomas Smarz, Metrolina Nephrology Associates, PA, stating that he will continue to serve as the Medical Director of BMA Albemarle. The information provided in Section VII is reasonable and credible. The applicant adequately demonstrates the availability of adequate health manpower and management personnel, including a medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section V.1, page 46, the applicant provides a table listing all ancillary and support services, indicating whether they are provided on the premises or off site, and if off site, by whom. Carolinas Medical Center-NorthEast will provide acute dialysis services when needed, diagnostic evaluation services, and blood bank services to BMA Albemarle patients. Stanly Regional Medical Center will also provide diagnostic evaluation services and blood bank services, in addition to x-ray services. Dialysis/ maintenance, all laboratory services, nutritional counseling, and social work services will be provided onsite. Other services will be provided by stated providers.

The applicant states that it has existing professional relationships with local physicians and that it does not expect referral patterns to change. In addition, the applicant states, in Section V.6(a), page 50:

“As an active longstanding facility in Stanly County, BMA Albemarle enjoys the support of the medical community and community leadership. The applicant keeps the

medical community apprised of developments through the relationship with Nephrology physicians who refer patients to the facility.”

In addition, the applicant provides a patient petition of support in Exhibit 22.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. 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;

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In Section VI.1(a), page 52, the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA, currently operates 100 facilities in 42 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has seven facilities under development or pending CON approval. 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 addition, in Section VI.1(b), page 53, the applicant provides the current in-center dialysis payor mix at BMA Albemarle, as shown in the table below:

BMA ALBEMARLE PAYOR SOURCE	PERCENT OF TOTAL
Medicare	86.2%
Medicaid	5.0%
Medicare/Medicaid	0%
Commercial Insurance	8.1%
VA	0.7%
Medicare/Commercial	0%
Private Pay	0%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and Calendar Year 2008 – 2009, respectively. More current data, particularly with regard to the estimated uninsured percentages, was not available.

COUNTY	TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010	TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010	% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)
Stanly	17.0%	7.6%	18.3%
Statewide	17.0%	6.7%	19.7%

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 with respect to dialysis services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

The United States Renal Data System, in its *2013 USRDS Annual Data Report* (page 216) provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*¹

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

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

The report states, on page 118, that the overall Medicare expenditures for chronic kidney disease for 2011 were \$45.5 billion, including Medicare Part D.

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

Number and Percent of Dialysis

¹ www.usrds.org/adr.aspx

Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6.
 Table includes North Carolina statistics only.²

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;

C

In Section VI.6 (a), page 56, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 53, the applicant provides the projected payor mix for the proposed services at BMA Albemarle. The applicant projects no change

² www.esrdnetwork6.org/publications/reports.html

from the current payor mix for dialysis visits, however it states “*the payor mix should be considered dynamic and not fixed.*” Its proposed payor mix is illustrated in the table below:

BMA ALBEMARLE PAYOR SOURCE	PERCENT OF TOTAL
Medicare	86.2%
Medicaid	5.0%
Commercial Insurance	8.1%
VA	0.7%
Private Pay	0%
Total	100.0%

In Section VI.1(d), page 54, 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 is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

The applicant demonstrates it will provide adequate access to medically underserved populations, including the elderly. 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 55, the applicant states that patients have access to dialysis services through Nephrologists who apply for and receive medical staff privileges to admit patients to the facility. Further, the applicant states, “*BMA Albemarle will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.*

...

The Nephrologists expect to continue receiving referrals from the local physician community, home health agencies, and acute care facilities.”

In addition, the applicant states, on page 55, that it has established working relationships with local physicians, home health agencies, and area hospitals from which to receive referrals within Stanly County.

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

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

C

In Section V.3(a), page 48, the applicant states that the parent company of BMA Albemarle, FMC, has done outreach to Stanly Community College to encourage its nursing students to do clinical rotations at BMA Albemarle. The applicant further states that all health related training programs are welcome to learn about the facility and receive instruction on ESRD, its prognosis and treatment. Exhibit 19 contains letters from the FMC Director of Operations to Stanly Community College. The information provided in Section V.3 and Exhibit 19 is reasonable and credible for an existing facility 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

The applicant proposes to add two dialysis stations to its existing dialysis facility for a total of 24 certified stations upon completion of the proposed project. The July 2013 SDR shows that there is no need for additional dialysis stations in Stanly County, however, the applicant qualifies for two additional dialysis stations based on the facility need methodology in the 2013 SMFP. Bio-Medical Applications of North Carolina, LLC d/b/a BMA Albemarle is the only provider of in-center dialysis services in Stanly County. The utilization rate currently exceeds 84%.

In Section V.7, page 51, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost effectiveness, quality and access. The applicant states that it “*had added value*” due to its relationship with Metrolina Nephrology Associates which has 28 nephrologists to provide care to patients dialyzing at BMA Albemarle. In addition, the facility is compelled to operate efficiently since it relies heavily on Medicare and Medicaid

payors to cover treatment expenses at fixed rates. Moreover, the applicant states that its combined efforts to contain operating costs and to provide outstanding care to patients contribute to the overall success of the facility and that its proposal to add two dialysis stations will “*enhance the quality of the ESRD patients’ lives.*”

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

- The applicant adequately demonstrates the need, based on ‘Facility Need,’ to add two dialysis stations for a total of 24 certified dialysis stations following project completion. The applicant also demonstrates that the proposed project will provide additional access to Stanly County residents and is a cost-effective alternative;
- The applicant adequately demonstrates it will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R. Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V and VII is reasonable and credible and demonstrates the provision of quality services.
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations as discussed in Section VI.1.

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

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, BMA Albemarle operated in compliance with the Medicare Conditions of Participation within the 18 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 regulatory review criteria. The specific criteria are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

. 2202(a)(1) Utilization rates;

-C- The utilization rate as of December 31, 2012 as shown in the July 2013 SDR is 84.09%. See Exhibit 2 (copy of the July 2013 SDR, Table A, page 8).

. 2202(a)(2) Mortality rates;

-C- In Section IV.2, page 44, the applicant reports the 2010, 2011 and 2012 facility mortality rates, which were 27.9%, 8.6%, and 14.3%, respectively.

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

-NA- The applicant states, in Section IV.3, page 44, that it does not currently have any patients that are home trained.

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

-C- In Section IV.4, page 44, the applicant states that BMA Albemarle referred eight patients for transplant evaluation in 2012. However, only one patient received a transplant in 2012.

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

-C- In Section IV.5, page 44, the applicant states that BMA Albemarle has eight patients on the transplant waiting list.

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

- C- The applicant reports, in Section IV.6, page 45, that there were a total of 135 hospital admissions in 2012; 10.4% were dialysis-related and 89.6% were non-dialysis related.

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

- C- In Section IV.7, page 45, the applicant reports that in 2012 there were no patients with an infectious disease and no patients who converted to infectious status in 2012.

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

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

- NA- BMA Albemarle is an existing facility.

.2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*

(E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- BMA Albemarle is an existing facility.

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

-NA- BMA Albemarle is an existing facility.

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

-C- Exhibit 12 contains a copy of FMC's written policies and procedures for back up for electrical service in the event of a power outage.

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

-NA- BMA Albemarle is an existing facility.

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

-C- The applicant provides documentation that it provides its services in conformity with all applicable laws and regulations in Sections VII.2, page 58, XI.6(e), page 76, and XI.6(g), page 77.

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

- C- In Section II, page 15, BMA Albemarle provides projected patient origin based on its facility’s average five year growth rate. The projected patient origin for the first two years of operation following completion of the project is provided as follows:

County	Operating Year One			Operating Year Two		
	IN-CENTER PATIENTS	HOME PERITONEAL PATIENTS	HOME HEMO-DIALYSIS	IN-CENTER PATIENTS	HOME PERITONEAL PATIENTS	HOME HEMO-DIALYSIS
Stanly	67.1	1.0	1.0	67.5	2.0	2.0
Montgomery	9.0	0	0	9.1	0	0
Rowan	1.0	0	0	1.0	0	0
Cabarrus	1.0	0	0	1.0	0	0
Davidson	1.0	0	0	1.0	0	0
Total*	79.2	1	1	79.6	2	2

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

- NA- BMA Albemarle is an existing facility.

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

- C- In Section II.1(a)(9), page 16, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- BMA Albemarle is an existing facility.

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

-C- In Section III.9, page 41, the applicant projects to serve 79 in-center patients by the end of Operating Year 1, which is 3.29 patients per station ($79/24 = 3.29$) or 82.3% of capacity ($3.29/4 = .823$).

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

-C- In Section II, pages 13-15 and Section III.7, pages 39-41, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) Diagnostic and evaluation services;

- C- See Section V.1, page 46. Diagnostic evaluation services are provided by Carolinas Medical Center, Northeast Medical Center, and Stanly Regional Medical Center.
- .2204(2) *Maintenance dialysis;*
- C- See Section V.1, page 46. BMA Albemarle provides maintenance dialysis.
- .2204(3) *Accessible self-care training;*
- C- See Section V.1, page 46. Self-care training in hemodialysis, intermittent peritoneal dialysis, CAPD, and CCPD is provided by BMA Albemarle.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- See Section V.2(d), page 47. The applicant states it trains and provides follow up through its home training program.
- .2204(5) *X-ray services;*
- C- See Section V.1, page 46. X-ray services are provided by Stanly Regional Medical Center.
- .2204(6) *Laboratory services;*
- C- See Section V.1, page 46. All laboratory services are provided on the premises by BMA Albemarle.
- .2204(7) *Blood bank services;*
- C- See Section V.1, page 46. Blood bank services are provided by Stanly Regional Medical Center and Northeast Medical Center.
- .2204(8) *Emergency care;*
- C- See Section V.1, page 46. Emergency care is provided by fully trained BMA Albemarle staff and ambulance transport is available.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- See Section V.1, page 46. Acute dialysis in an acute care setting is provided by Carolinas Medical Center and Northeast Medical Center.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
- C- See Section V.1, page 46. Vascular surgery for dialysis treatment patients is provided by Dillworth Surgical Associates and Piedmont Surgical.
- .2204(11) *Transplantation services;*
- C- See Section V.1, page 46. Transplantation services are provided by Carolinas Medical Center.
- .2204(12) *Vocational rehabilitation counseling and services; and*
- C- See Section V.1, page 46. Vocational rehabilitation counseling and services are provided by the Stanly County Vocational Rehabilitation Services and Stanly County Department of Social Services.
- .2204(13) *Transportation*
- C- See Section V.1, page 46. Transportation is provided by SCUSA Transportation.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.

-C- In Section VII.1, page 57, the applicant provides the proposed staffing. In Section VII.2, page 58, the applicant states the proposed facility does and will comply with all staffing requirements set forth in 42 C.F.R. Section 494. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully therein.

.2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

-C- See Section VII.3, page 58 for discussion of training and certifications held or required for the BMA Albemarle direct patient care staff. In addition, the applicant states that BMA Albemarle continually updates its training and Corporate staff monitors policies and procedures to keep up to date with federal and state regulations. Moreover, see Exhibit 14 for FMC's Training Program Outline and Exhibit 15 for FMC's Continuing Education Outline.