

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 31, 2013

PROJECT ANALYST: Gloria C. Hale  
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: G-10193-13/ Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Southwest Greensboro/ Relocate 2 dialysis stations from FMC East Greensboro to BMA Southwest Greensboro for a total of 31 dialysis stations upon completion /Guilford 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. d/b/a BMA Southwest Greensboro, whose parent company is Fresenius Medical Care Holdings, Inc. (FMC), proposes to relocate two in-center dialysis stations from FMC East Greensboro to BMA Southwest Greensboro for a facility total of 31 in-center dialysis stations upon completion of this project. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations. Therefore, neither of the two need methodologies in the 2013 State Medical Facilities Plan (SMFP) is applicable to this review. Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a new institutional health service for which there is a need determination in the 2013 SMFP. However, Policy ESRD-2 is applicable to this review.

Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS, on page 36 of the 2013 SMFP, is applicable to this review. The policy states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:*

- 1. Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate two dialysis stations from FMC East Greensboro, Greensboro, to BMA Southwest Greensboro, Jamestown. Both facilities are located in Guilford County. According to the July 2013 SDR, Guilford County has a surplus of 28 dialysis stations. Relocating two dialysis stations will result in no change in dialysis station inventory in Guilford County, thus the application is consistent with Policy ESRD-2 of the 2013 SMFP and is conforming to this criterion.

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

## C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Southwest Greensboro proposes to add two in-center dialysis stations to the existing facility by relocating them from FMC East Greensboro. Both facilities are located in Guilford County. This will result in a facility total of 31 stations upon completion of this project. In addition, four patients currently dialyzing at FMC East Greensboro have indicated their willingness to transfer to the BMA Southwest Greensboro facility to receive dialysis services. In Exhibit 22, the applicant provides letters from each of these patients indicating their willingness to transfer to BMA Southwest Greensboro. The patients' residences are in Guilford County and are well within 30 miles of the BMA Southwest Greensboro facility according to the patients' zip codes provided by the applicant.

### Population to be Served

In Section II, page 18, the applicant provides BMA Southwest Greensboro’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	IN-CENTER PATIENTS	YEAR 1	YEAR 2
Guilford	107.6	109.1	100.0%	100.0%
<b>Total</b>	107.6	109.1	<b>100.0%</b>	<b>100.0%</b>

However, according to data obtained by the Project Analyst from the Division of Health Service Regulation (DHSR), Medical Facilities Planning Branch, BMA Southwest Greensboro’s patient origin as of June 30, 2013 includes 94 patients from Guilford County, four from Randolph County, and one from Davidson County. The Project Analyst provides the revised projected patient origin for BMA Southwest Greensboro for the first two full operating years of the proposed project, as follows:

COUNTY	OPERATING YEAR 1 CY 2015	OPERATING YEAR 2 CY 2016	COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CENTER PATIENTS	IN-CENTER PATIENTS	YEAR 1	YEAR 2
Guilford	101.4	102.9	95.30%	95.37%
Randolph	4.0	4.0	3.76%	3.71%
Davidson	1.0	1.0	0.94%	0.93%
<b>Total</b>	106.4	107.9	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

The applicant proposes to relocate two dialysis stations from FMC East Greensboro, located in Greensboro, to BMA Southwest Greensboro, located in Jamestown. Both facilities are located in Guilford County. According to the July 2013 SDR, Guilford County has a surplus of 28 dialysis stations. This relocation would have no effect on the surplus of stations in Guilford County, however it would allow the applicant to relocate two underutilized dialysis stations at FMC East Greensboro to BMA Southwest Greensboro, the latter with a growing need for dialysis services. The applicant states, in Section II, page 13, that BMA Southwest Greensboro’s patient census increased from 94 on December 31, 2012 to 100 on June 30, 2013, a six month period. However, data submitted by the applicant to the DHSR, Medical Facilities Planning Branch indicates that BMA Southwest Greensboro had only 99 patients as of June 30, 2013. FMC East Greensboro’s census, for the same time period, increased from 96 to 99. In addition, Table B of the July 2013 SDR indicates that BMA Southwest Greensboro and FMC East Greensboro’s utilization rates for December 31, 2012 were 75.81% and 64.86%, respectively.

In Section II, pages 13-15, the applicant provides the assumptions and methodology used to project patient utilization and the need for two additional dialysis stations at BMA Southwest Greensboro, summarized as follows:

- Based on the data reported in Table A, page 4 of the July 2013 SDR, BMA Southwest Greensboro had 94 in-center patients and 31 certified dialysis stations as of December 31, 2012. However the report also showed a decrease of two certified dialysis stations pending certification. The applicant states, on page 13, that two certified dialysis stations have been relocated to BMA Asheboro. The utilization rate for BMA Southwest Greensboro for December 31, 2012, as reported in the July 2013 SDR, was 75.81%.
- The applicant states, in Section II, pages 13-14, that for June 30, 2013, there were 100 patients dialyzing at BMA Southwest Greensboro. However, according to data submitted by the applicant to the DHSR, Medical Facilities Planning Branch, only 99 patients were dialyzing at BMA Southwest Greensboro for June 30, 2013.
- The applicant applied a 1.4% Five-Year Average Annual Change Rate for Guilford County, as indicated on page 2 of Table B of the July 2013 SDR, to all 100 patients to project the number of patients by December 31, 2013.  $\{[100 \text{ patients} \times (.014/12 \text{ months} \times 6 \text{ months})] = 0.72; 100 + 0.72 = 100.7\}$  However, according to data obtained by the Project Analyst from the DHSR Medical Facilities Planning Branch, there were 99 patients at BMA Southwest Greensboro and 94 of them were from Guilford County. Therefore, the 1.4% Five-Year Average Annual Change Rate for Guilford County should be applied to only 94 patients, calculated by the Project Analyst as follows:  $\{[94 \text{ patients} \times (.014/12 \text{ months} \times 6 \text{ months})] = 0.68; 94 + 0.68 = 94.7\}$  The Project Analyst kept the five patients from other counties (four from Randolph County and one from Davidson County) static to calculate the number of patients projected for December 31, 2013  $[94.7 + 5 = 99.7]$ .
- To calculate the number of patients projected for December 31, 2014, the applicant applied the 1.4% Five-Year Average Annual Change Rate (AACR) for Guilford County to the number of projected patients on December 31, 2013. The Project Analyst applied the 1.4% Five-Year AACR for Guilford County to the Guilford County patients only and then added the five patients from Randolph and Davidson Counties, as follows:  $\{[(94.7 \times .014) + 94.7] + 5 = 101.03\}$ .
- Based on letters of support received by the applicant indicating four patients' willingness to transfer to BMA Southwest Greensboro from FMC

East Greensboro upon project completion, as stated on page 14, the applicant adds four transferring patients to get the final projected number of patients by December 31, 2014. The Project Analyst's calculations were:  $[101.03 + 4 = 105.03]$ .

- Next, the number of patients is projected forward by 12 months, to December 31, 2015, the projected end of Operating Year One. This was calculated by the Project Analyst by applying the Five Year AACR for Guilford County to all of the Guilford County patients, including the four transferred, and adding the five patients from Randolph and Davidson Counties as follows:  $\{[(100.03 \times .014) + 100.03] + 5 = 106.43\}$ .
- The applicant then projects the number of patients forward by another 12 months, to December 31, 2016, the projected end of Operating Year Two. The Project Analyst's calculations resulted in the following:  $[(101.43 \times .014) + 101.43] + 5 = 107.85]$ .

BMA Southwest Greensboro's projected utilization at the end of Operating Year One, December 31, 2015, is summarized as follows:

106 patients dialyzing on 31 stations = 3.42 patients per station per week ( $106/31 = 3.42$ ) 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 Southwest Greensboro 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, through relocation of two stations from FMC East Greensboro, for a facility total of 31 in-center dialysis stations following project completion. In Section III.9, pages 39-40, the applicant states that it considered several alternatives to the project, and discusses two of its “*most significant alternatives considered.*” The first of these was not to relocate the two stations, however this would create “*limited opportunity for additional patients.*” By relocating two underutilized stations, better utilization of approved services and better access to care would be realized. The second alternative was to relocate the two underutilized stations to a different facility. However, the applicant states, “...*only BMA Southwest Greensboro has demonstrated need for these stations.*” The applicant adequately explains why it chose the selected alternative over the other two stated alternatives. Furthermore, the application is conforming to all other applicable statutory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a) and (20) for additional discussion. 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 Southwest Greensboro. 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 Southwest Greensboro 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 Southwest Greensboro shall develop and operate no more than two additional dialysis stations for a total of 31 certified stations which shall include any home hemodialysis training or isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Southwest Greensboro shall install plumbing and electrical wiring through the walls for two additional dialysis stations for a total of 31 dialysis stations which shall include any isolation stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Southwest Greensboro shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
  - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Southwest Greensboro 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.

C

In Sections VIII.1(a), page 57, the applicant states, “*The project does not involve any capital costs on behalf of BMA.*” In Sections IX.1 and IX.2, page 61, the applicant states that there are no start-up or initial operating expenses since the facility is an existing facility.

In Section VIII.5, page 58, the applicant refers to Exhibit 24 for a letter of commitment for the project signed by the Vice President of Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc. This letter states, in part:

*“BMA proposes to relocate two dialysis stations from FMC East Greensboro to its BMA Southwest Greensboro facility for a facility total of 31 dialysis stations upon completion of this project [sic] The project does not require any capital costs on behalf of BMA. As Vice President, I am authorized and do hereby authorize the addition of six [sic] new dialysis stations.”*

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 financial security of the applicant.

Based on information provided by the applicant in Section X.1, page 62, the applicant lists the following charges per treatment for each payment source:

**BMA Southwest Greensboro  
Projected Allowable  
In-Center Charges per Treatment**

<b>SOURCE OF PAYMENT</b>	<b>IN-CENTER CHARGE</b>
Medicare	\$234.00
Medicaid	\$137.29
Commercial Insurance	\$1,375.00
VA	\$146.79
Private Pay	\$1,375.00

The applicant states, on page 62, that it is using the Medicare basic rate shown above, which is also the minimum Medicare rate. The applicant notes, on page 62, “*...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 63, “*...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 63-69, the applicant reports projected revenues and expenses as follows:

	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
Total Net Revenue	\$4,959,760	\$5,064,684
Total Operating Costs	\$4,445,476	\$4,575,534
Net Profit	\$514,285	\$489,150

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 62-69 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 Southwest Greensboro proposes to add two in-center dialysis stations to the existing facility in Greensboro, Guilford County. The two additional stations will be relocated from FMC East Greensboro which is also located in Guilford County. Four patients currently receiving services at FMC East Greensboro have indicated a willingness to transfer to BMA Southwest Greensboro. According to the July 2013 SDR, BMA Southwest Greensboro is currently serving 94 patients, six days a week with 2 shifts per day, and has 31 stations. However, from data obtained from the DHSR, Medical Facilities Planning Branch, BMA Southwest Greensboro is currently serving 99 in-center patients and has 29 dialysis stations. Two stations were transferred from BMA Southwest Greensboro to BMA Asheboro and certified on July 21, 2013 according to a letter from DHSR, provided by the applicant in Exhibit 1. 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. BMA Southwest Greensboro’s current utilization equates to 3.41 patients per station, which is 85.25% of capacity ( $99/29 = 3.41$ ;  $3.41/4 = 85.25\%$ ). The target



utilization rate is 80%. According to the July 2013 SDR, Guilford County has a surplus of 28 stations. There are six other dialysis facilities in Guilford County: BMA Greensboro, BMA South Greensboro, FMC of East Greensboro, High Point Kidney Center (WFU), Northwest Greensboro Kidney Center, and Triad Dialysis Center (WFU). According to the July 2013 SDR, all of these facilities but one, Triad Dialysis Center (WFU), located in High Point, are operating below the target utilization rate of 80%. The July 2013 SDR provides certification and utilization data on the dialysis facilities in Guilford County as follows:

Facility	City	Certified Stations	CON Issued/ Not Certified	Patients Per Station	% Utilization
BMA Greensboro	Greensboro	56	0	2.82	70.54%
BMA South Greensboro	Greensboro	59	0	2.90	72.46%
BMA Southwest Greensboro	Jamestown	31	-2	3.03	75.81%
FMC East Greensboro	Greensboro	37	0	2.59	64.86%
High Point Kidney Center (WFU)	High Point	42	0	3.07	76.79%
Northwest Greensboro Kidney Center	Greensboro	25	0	3.04	76.00%
Triad Dialysis Center (WFU)	High Point	22	0	3.45	86.36%

The addition of two stations at BMA Southwest Greensboro will not duplicate services being provided by any other dialysis center in Guilford County. Projections for the in-center patient population at BMA Southwest Greensboro are provided in Section II, page 14, however they have been adjusted by the Project Analyst. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein. At the end of operating year two, with 31 dialysis stations and 107 patients projected, the applicant's projected utilization will be 3.45 patients per station operating at 86.25% of capacity ( $107 \text{ patients} / 31 \text{ stations} = 3.45$ ;  $3.45 / 4 = 86.25\%$ ). This utilization projection is based on applying the Five Year Average Annual Change Rate (AACR) of 1.4% for Guilford County to only the patients from Guilford County while keeping the number of existing patients from two other counties static. 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 Guilford 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 54, the applicant provides current and projected staffing for BMA Southwest Greensboro 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	4.00	0.75	4.75
Technician	9.00	1.00	10.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract	0.00	Contract
Administrator (FMC Director Operations)	0.15	0.00	0.15
Dietician	1.00	0.00	1.00
Social Worker	1.00	0.00	1.00
Medical Records	1.00	0.00	1.00
Chief Technician	0.20	0.00	0.20
Equipment Technician	0.80	0.00	0.80
In-Service	0.20	0.00	0.20
Clerical	1.00	0.00	1.00
<b>Total</b>	<b>19.35</b>	<b>1.75</b>	<b>21.10</b>

In Exhibit 21 of the application, the applicant provides a letter from, Dr. Michael Mattingly, Carolina Kidney Associates, P.A., stating that he will continue to serve as the Medical Director of BMA Southwest Greensboro. The applicant provides a copy of Dr. Michael Mattingly's resume in Exhibit 23. He is board certified in Internal Medicine with a subspecialty board in Nephrology. 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.

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In Section V.1, page 43, the applicant provides a table listing all ancillary and support services, indicating whether these services are provided on the premises or off site, and if off site, by whom. Moses Cone Hospital will provide most ancillary and support services to BMA Southwest Greensboro dialysis patients, including acute care dialysis in an acute

care setting, diagnostic evaluation services, x-ray services, blood bank, and psychological counseling. The applicant states, in reference to emergency care, “*All BMA staff [sic] trained to respond and fully stocked crash cart available...*” and ambulance transport is available to a local hospital. Self care training is available through referral to BMA Greensboro and transplantation is available through Carolinas Medical Center in Charlotte. All laboratory services are provided on the premises by SPECTRA. BMA Southwest Greensboro provides isolation-hepatitis, nutritional counseling, and social work services on the premises. Other services will be provided by stated providers.

The applicant provides a copy of a hospital affiliation agreement with Carolinas Medical Center in Exhibit 16 which describes the hospital’s relationship with the dialysis facility and the services it will provide in regard to transplantation services. The applicant’s transplant agreement with Carolinas Medical Center is provided in Exhibit 17. In addition, several letters of support are provided from area nephrologists. Moreover, the applicant states its many years of experience in serving dialysis patients has led to relationships with physicians, local hospitals, and other health professionals in Guilford County as well as surrounding counties.

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 49, 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 Southwest Greensboro, as shown in the table below:

BMA SOUTHWEST	PERCENT OF
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<b>GREENSBORO PAYOR SOURCE</b>	<b>TOTAL</b>
Medicare	82.8%
Medicaid	2.5%
Commercial Insurance	11.6%
VA	2.4%
Private Pay	0%
Other: Self/Indigent	0.7%
<b>Total</b>	<b>100.0%</b>

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

<b>COUNTY</b>	<b>TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010</b>	<b>TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010</b>	<b>% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)</b>
Guilford	15.3%	5.9%	19.5%
Statewide	16.5%	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 ...”*<sup>1</sup>

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<sup>1</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

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:

<b>Number and Percent of Dialysis Patients by Age, Race and Gender 2012</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
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%
<b>Gender</b>		
Female	6,692	44.9%
Male	8,226	55.1%
<b>Race</b>		
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.<sup>2</sup>

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.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

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<sup>2</sup> [www.esrdnetwork6.org/publications/reports.html](http://www.esrdnetwork6.org/publications/reports.html)

In Section VI.1(c), page 50, the applicant provides the projected payor mix for the proposed services at BMA Southwest Greensboro. The applicant projects no change from the current payor mix for dialysis visits, illustrated in the table below:

<b>BMA SOUTHWEST GREENSBORO PAYOR SOURCE</b>	<b>PERCENT OF TOTAL</b>
Medicare	82.8%
Medicaid	2.5%
Commercial Insurance	11.6%
VA	2.4%
Private Pay	0.0%
Other: Self/Indigent	0.7%
<b>Total</b>	<b>100.0%</b>

In Section VI.1(d), page 51, 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.”** [Emphasis in original.]

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 52, 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 Southwest Greensboro 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, referrals will also be received from UNCH.”*

In addition, the applicant states, on page 52, that it has established working relationships with local physicians, home health agencies, and area hospitals from which to receive referrals within Guilford County.

The applicant adequately demonstrates that BMA Southwest Greensboro 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, pages 44-45, the applicant states that Guilford Community College has been invited to include BMA Southwest Greensboro as a site for the college’s Health Occupations students to do clinical rotations. A copy of the letter of invitation, signed by the Administrative Assistant for Operations, Certificate of Need Office for Fresenius is included in Exhibit 19. In addition, the applicant states that all health related education and training programs are welcomed to the facility to receive instruction and observe operations. 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 in Guilford County for a total of 31 certified stations upon completion of the proposed project. The July 2013 SDR shows that there is a surplus of 28 dialysis stations in Guilford County. Two stations would be relocated to BMA Southwest Greensboro in Jamestown, Guilford County

from FMC East Greensboro in Greensboro, Guilford County. Therefore there will be no change in the number of dialysis stations in the county. BMA Southwest Greensboro is one of seven in-center dialysis facilities in Guilford County. Table A, page 4 of the July 2013 SDR lists the other dialysis centers, their locations, and their respective utilization rates, as follows:

Facility	Location	Utilization Rate
BMA of Greensboro	Greensboro	70.5%
BMA of South Greensboro	Greensboro	72.5%
FMC of East Greensboro	Greensboro	64.9%
High Point Kidney Center (WFU)	High Point	76.8%
Northwest Greensboro Kidney Center	Greensboro	76.0%
Triad Dialysis Center (WFU)	High Point	86.4%

In Section V.7, pages 47-48, 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:

*“Approval of this application will not alter the competitive nature of dialysis facilities and providers serving Guilford County. Approval of this application will not change the number of dialysis stations in the county. Approval of this application will enhance patient access to care.*

...

*BMA has not asserted that it would capture 100% of new dialysis patients in Guilford County. Rather, BMA projections of future patient populations to be served focus on the existing patient population served by BMA.”*

In addition, the applicant states that the project adds value through the involvement of nephrology physicians at Carolina Kidney Associates and is cost effective as necessitated by fixed reimbursement rates from Medicare and Medicaid, considering 85.3% of BMA’s projected in-center patients will be covered by these government insurers. The applicant further states that BMA has continued to contain operating costs while providing outstanding care and that it *“thoroughly plans for the success of a facility prior to the application”* and that staff work toward the *“clinical and financial success of the facility”* after project completion.

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 Southwest Greensboro dialysis facility will have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The applicant adequately demonstrates the need to relocate two dialysis stations for a total of 31 certified dialysis stations following project completion. The applicant also demonstrates that the proposed project will provide additional access to Guilford 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 Southwest Greensboro 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 75.81%. See Exhibit 2 (copy of the July 2013 SDR, Table A, page 4).
- . 2202(a)(2) *Mortality rates;*
  - C- In Section IV.2, page 41, the applicant reports the 2010, 2011 and 2012 facility mortality rates, which were 12.7%, 7.4%, and 6.8%, 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 II, page 11, that BMA Southwest Greensboro is not certified to provide home training services, however patients may obtain home training for dialysis through referral to BMA Greensboro.
- .2202(a)(4) *The number of transplants performed or referred;*
  - C- In Section II, page 11, the applicant states that BMA Southwest Greensboro referred 12 patients for transplant evaluation in 2012. Two patients received transplants in 2012.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
  - C- In Section II, page 11, the applicant states that the BMA Southwest Greensboro has seven 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 states, in Section II, page 12, that BMA Southwest Guilford [sic] had a total of 129 hospital admissions in 2012; 99.2% were non-dialysis related and 0.08% were 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 II, page 12, the applicant states that there are currently two patients with infectious disease, but none converted to infectious status during 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 Southwest Greensboro 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 Southwest Greensboro 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 Southwest Greensboro 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 Southwest Greensboro 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 Section VII.2, page 55, and Sections XI.6(e) and XI.6(g), page 72.

.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 III, page 38, BMA Southwest Greensboro provides projected patient origin based on historical experience using Guilford County’s Five Year Average Annual Change Rate (AACR) for all of its patients. However, based on June 30, 2013 data obtained from DHSR, Medical Facilities Planning Branch, the Project Analyst determined that in addition to Guilford County, four of the facility’s patients were from Randolph County and one was from Davidson County. Therefore, the Project Analyst recalculated the projected patient origin for the first two full years of operation following completion of the project by applying the Guilford County’s Five Year AACR to the Guilford County patients only while leaving the Randolph and Davidson county patient numbers static, as follows:

<b>BMA Southwest Greensboro</b>		
	Operating Year 1 2015	Operating Year 2 2016
County	In-center Patients	In-center Patients
Guilford	101.4	102.9
Randolph	4.0	4.0
Davidson	1.0	1.0

.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 Southwest Greensboro 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 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.”

## **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 Southwest Greensboro 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- The applicant provides its utilization projections in Section III.7, page 38, however an error was made, therefore the Project Analyst re-calculated the projections with the following results: the applicant projects to serve 106 in-center patients by the end of Operating Year 1, which is 3.42 patients per station ( $106/31 = 3.42$ ) or 85.5% of capacity ( $3.42/4 = .855$ ). See Criterion (3) for discussion, incorporated hereby as if set forth fully herein.

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

-C- In Section III.7, pages 37-38, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. Adjustments were made to the assumptions and methodology by the Project Analyst based on patient census and patient origin data from DHSR, Medical Facilities Planning Branch. See Criterion (3) for discussion, incorporated hereby as if set forth fully herein.

## **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 43. Diagnostic evaluation services are provided by Moses Cone Hospital or a hospital of the patient's choice.
- .2204(2) *Maintenance dialysis;*
  - C- See Section V.1, page 43. BMA Southwest Greensboro provides maintenance dialysis.
- .2204(3) *Accessible self-care training;*
  - C- See Section V.1, page 43. Hemodialysis self-care training is provided by BMA Greensboro.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
  - C- See Section V.2(d), page 44. Training and follow-up for support of patients dialyzing at home is provided by BMA Greensboro.
- .2204(5) *X-ray services;*
  - C- See Section V.1, page 43. X-ray services are provided by Moses Cone Hospital.
- .2204(6) *Laboratory services;*
  - C- See Section V.1, page 43. All laboratory services are provided by SPECTRA on the premises.
- .2204(7) *Blood bank services;*
  - C- See Section V.1, page 43. Blood bank services are provided by Moses Cone Hospital.
- .2204(8) *Emergency care;*
  - C- See Section V.1, page 43. Emergency care is provided by all BMA Southwest Greensboro staff fully trained to respond to medical emergencies and ambulance transport is available to the local hospital.
- .2204(9) *Acute dialysis in an acute care setting;*
  - C- See Section V.1, page 43. Acute dialysis in an acute care setting is provided by Moses Cone Hospital.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
  - C- See Section V.1, page 43. Vascular surgery for dialysis treatment patients is provided by Vascular Vein Specialists of Greensboro.
- .2204(11) *Transplantation services;*
  - C- See Section V.1, page 43. Transplantation services are provided by Carolinas Medical Center.
- .2204(12) *Vocational rehabilitation counseling and services; and*
  - C- See Section V.1, page 43. Vocational rehabilitation counseling and services are provided by Guilford Rehabilitation Service.
- .2204(13) *Transportation*
  - C- See Section V.1, page 43. Transportation is provided by Specialized Community Area Transit and Piedmont Authority Regional 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, pages 54-55, the applicant provides the proposed staffing. In Section VII.2, page 55, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. 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 herein.

*.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 Sections VII.3 and VII.5, page 55, for the qualifications and certifications required for BMA Southwest Greensboro's direct patient care staff. Exhibits 14 and 15 contain outlines for the facility's training program and continuing education programs.