

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 7, 2015

Findings Date: May 7, 2015

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: G-11005-15

Facility: BMA of Southwest Greensboro

FID #: 991046

County: Guilford

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

Project: Add no more than 2 dialysis stations for a total of no more than 33 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA of Southwest Greensboro (“the applicant”) proposes to add two dialysis stations for a total of 33 stations upon completion of this project. BMA of Southwest Greensboro is an existing facility located at 5020 Mackay Road, Jamestown, in Guilford County.

Need Determination

The 2015 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2015 Semiannual Dialysis Report (SDR), the county need methodology indicates there is a deficit of seven stations. Because the county station

deficit is less than 10, Guilford County’s December 31, 2015 station need is determined to be zero, as described in the County Need Methodology (1e), on page 364 of the 2015 SMFP. However, the applicant is eligible to apply for additional stations based on the facility need methodology, because the utilization rate reported for BMA of Southwest Greensboro in the January 2015 SDR is 3.32 patients per station. This utilization rate was calculated based on 103 in-center dialysis patients and 31 certified dialysis stations as of June 30, 2014 (103 patients / 31 stations = 3.32 patients per station).

Application of the facility need methodology indicates a potential need for two additional stations at BMA of Southwest Greensboro, as illustrated in the following table.

April 1 Review – January SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/14		83%
Certified Stations		31
Pending Stations		0
Total Existing and Pending Stations		31
In-Center Patients as of 6/30/14 (SDR2)		103
In-Center Patients as of 12/31/13 (SDR1)		99
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.0808
(ii)	Divide the result of step (i) by 12	0.0067
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.0404
(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	107.16
(v)	Divide the result of step (iv) by 3.2 patients per station	33.48
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed (31 stations)	2.48

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

Policies

There is one policy in the 2015 SMFP that is applicable to this review, *POLICY GEN-3: BASIC PRINCIPLES*. This policy, located on page 38 of the 2015 SMFP, states:

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

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section I, pages 4-8, Section II, pages 19-20, Section V, page 42, Section XI.6(g), page 68, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section II, pages 20-21, Section III, pages 33-35, Section V, pages 41-42, Section VI, pages 43-47, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section II, page 21, Section III, pages 34-35, Section V, pages 41-42, Section VIII, pages 52-54, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2015 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add two dialysis stations to the existing BMA of Southwest Greensboro facility for a total of 33 stations upon completion of this project.

Population to be Served

In Section IV.1, page 36, the applicant identifies the population of in-center and home dialysis patients served at BMA of Southwest Greensboro, as of December 31, 2014, as shown in the table below:

County of Residence	Home Patients	In-Center Patients
Guilford	0	94
Davidson	0	3
Randolph	0	2
Virginia	0	1
Other States	0	1
Total	0	101

BMA of Southwest Greensboro provides in-center dialysis treatment only as shown in the table above. The applicant states that BMA patients who are candidates for home dialysis services are referred to BMA Greensboro in Guilford County.

In Section III.7, page 33, the applicant provides the projected patient origin of the patients to be served at BMA of Southwest Greensboro for the first two years of operation following completion of the project, as shown in the following table.

Projected BMA of Southwest Greensboro Patient Origin

County	Operating Year One	Operating Year Two	County Patients as a Percent of Total	
	In-Center	In-Center	Year 1	Year 2
Guilford	100	102	94.34%	94.45%
Davidson	3	3	2.83%	2.78%
Randolph	2	2	1.89%	1.85%
Virginia	1	1	0.94%	0.93%
Total	106	108	100.00%	100.00%

Totals may not sum due to rounding.

The applicant adequately identifies the population BMA of Southwest Greensboro proposes to serve.

Analysis of Need

BMA proposes to add two dialysis stations to the BMA of Southwest Greensboro facility, for a total of 33 dialysis stations. In Section III.7, pages 31-33, the applicant provides the assumptions and methodology it uses to determine the need for the additional dialysis stations at BMA of Southwest Greensboro. The assumptions and methodology are summarized below:

- The applicant assumes that the patient census at BMA of Southwest Greensboro residing within Guilford County will increase commensurate with the 2.1% Guilford County Five Year Average Annual Change Rate as reported in the January 2015 SDR.
- The applicant assumes that those BMA of Southwest Greensboro patients residing in Davidson and Randolph counties in North Carolina and the patient from Virginia will continue to dialyze at the facility as a function of patient choice; however, the applicant does not project an increase in these patient numbers. The applicant states that those patients will be added to the facility census at appropriate points in time in the methodology.
- The applicant assumes the one patient residing in “Other States” was a transient patient visiting the area and will not project this patient to continue dialysis at the facility. The patient will not be added to the facility census.
- The project is scheduled to be completed December 31, 2016. Operating Year One is January 1, 2017 – December 31, 2017. Operating Year Two is January 1, 2018 – December 31, 2018.

Projected Utilization

In Section III, page 33, the applicant provides the calculations used to arrive at the projected patient census for Operating Year One, as of December 31, 2017 and Operating Year Two, as of December 31, 2018, as shown below.

<i>BMA of Southwest Greensboro</i>	<i>In-Center Dialysis</i>
BMA begins with the in-center Guilford County dialysis patients at BMA of Southwest Greensboro as of December 31, 2014.	94
BMA projects growth of the Guilford County patients by the Guilford County Five Year Average Annual Change Rate (2.1%) for one year to December 31, 2015.	$(94 \times .021) + 94 = 95.97$
BMA projects this census forward for one year to December 31, 2016, projected certification date of this project.	$(95.97 \times .021) + 95.97 = 97.98$
BMA adds the 6 patients from Davidson County, Randolph County and Virginia for the projected beginning patient census on June 30, 2016	$97.98 + 6 = 103.98$
BMA projects growth of the Guilford County patients by the Guilford County Five Year Average Annual Change Rate for one year to June 30, 2017.	$(97.98 \times .021) + 97.98 = 100.04$
BMA adds the 6 patients residing outside Guilford County. This is the projected ending patient census for Operating Year One.	$100.04 + 6 = 106.04$
BMA again projects the growth of the Guilford County patient census by the Guilford County Five Year Average Annual Change Rate for one year to June 30, 2018.	$(100.04 \times .021) + 100.04 = 102.14$
BMA adds the 6 patients residing outside Guilford County. This is the projected ending patient census for Operating Year Two.	$102.14 + 6 = 108.14$

As shown in the previous table, at the end of Operating Year One, BMA of Southwest Greensboro is projecting an in-center patient census of 106 patients for a utilization rate of 80.3% or 3.21 patients per station ($106 \text{ patients} / 33 \text{ stations} = 3.21 / 4 = 0.803$). At the end of Operating Year Two, the applicant is projecting an in-center patient census of 108, for a utilization rate of 81.8% or 3.27 patients per station ($108 \text{ patients} / 33 \text{ stations} = 3.27 / 4 = 0.818$). The projected utilization of 3.21 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

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

Access

In Section VI.1, page 43, the applicant states:

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

On page 43, the applicant states that the patient population of the BMA of Southwest Greensboro facility is expected to be comprised of the following, based upon the facility’s historical payor mix:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
BMA of Southwest Greensboro	49.5%	33.7%	60.4%	38.6%	69.3%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 60.4% of the facility treatment reimbursement is from Medicare.

On page 44, the applicant projects that approximately 83.08% of its in-center patients will be covered by some form of Medicare or Medicaid, including Medicare/Commercial insurance. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

In Section III.9, pages 34-35, the applicant discusses the alternatives considered prior to submitting this application, which include:

- 1) Relocation of stations from another BMA facility in Guilford County to the BMA of Southwest Greensboro facility. However, the applicant states that the BMA facilities in Guilford County have an overall utilization rate of 77.79%. The applicant states that while only two of the five facilities exceed 80% as of December 31, 2014, the overall utilization did increase from June 30, 2014 and all BMA facilities are at or above 75% utilization. Consequently, the applicant states, *"It would not be appropriate to consider a relocation of certified stations to the BMA Southwest Greensboro facility."*
- 2) Submitting an application for fewer stations. The applicant states that it did not consider this alternative as viable because the facility is growing at 8.1% annually, which is far greater than the Guilford County Five Year Average Annual Change Rate. However, BMA of Southwest Greensboro's growth rate from June 30, 2013 to June 30, 2014 was 4% annually, not 8.1%, but still almost double the Guilford County growth rate of 2.1%, as published in the 2015 SDR.
- 3) Maintain the Status Quo - the applicant states that failure to develop the additional stations will eventually remove choice from the patient.

After considering the above alternatives, the applicant states that the alternative represented in this application, add two stations to the BMA of Southwest Greensboro facility, is the most effective alternative.

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Southwest Greensboro shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Southwest Greensboro shall develop and operate no more than two**

additional dialysis stations for a total of 33 stations upon completion of this project.

- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Southwest Greensboro shall install plumbing and electrical wiring through the walls for no more than 2 additional dialysis stations for a total of no more than 33 dialysis stations, which shall include any home hemodialysis training or isolation stations.**
 - 4. Prior to issuance of the certificate of need, Bio-Medical Applications of North Carolina, Inc. shall provide the Agency with the number of BMA of Southwest Greensboro patients with infectious disease in the last calendar year (2014) and the number of patients who converted to infectious status during the last calendar year (2014) as required in 10A NCAC 14C .2202(a)(7).**
 - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Southwest Greensboro shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII, pages 51-52, the applicant states that BMA will incur capital costs for water treatment and other equipment and furniture totaling \$12,600 with the proposed project.

In Section IX, page 55, the applicant states that as an existing facility, no start up or initial operating expenses are associated with the proposed project.

Exhibit 24 contains a March 16, 2015 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states,

“BMA is submitting a Certificate of Need Application to add two dialysis stations dialysis to its BMA Southwest Greensboro facility in Gaston [sic] County. The facility will have a total of 33 dialysis stations. The project calls for the following capital expenditure:

Capital Expense \$12,600

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 \$12,600 as may be needed for this project.”

In Section VIII.7, page 53, the applicant refers to Exhibit 4 for a copy of the most recent audited Fresenius Medical Care Holdings, Inc. Consolidated Balance Sheets for 2012 and 2013 along with a copy of the Auditor’s letter. As of December 31, 2013, FMC Holdings, Inc. and Subsidiaries had \$275,719,000 in cash and cash equivalents with \$16,597,314,000 in total assets and \$8,521,824,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the proposed project’s capital needs.

In Section X.1, page 56, the applicant provides its allowable charges per treatment for each payment source, as illustrated below:

Payment Source	In-Center
Private Pay	\$ 1,425.00
Commercial Insurance	\$ 1,425.00
Medicare	\$ 239.02
Medicaid	\$ 140.23
Medicare/Medicaid	\$ 239.02
Medicare/Commercial	\$ 239.02
State Kidney Program	\$ 100.00
VA	\$ 231.12
Other: Self/Indigent	\$ 1,425.00

The applicant provides the following explanations for charges and reimbursement on pages 56-58,

“The commercial charges above do not reflect actual reimbursement rates, and should not be taken as absolute. It is industry standard for providers to have contractual relationships with various payors, resulting in less reimbursement than the stated charge.

The majority of dialysis treatments are reimbursed through Medicare or Medicaid. As noted in this application, it is expected that greater than 83% of the treatments will be at Medicare (includes Medicare Advantage) reimbursement rates. These rates are fixed by the payor.

BMA also notes that Medicare began the “Bundling” reimbursement program in 2010. The Bundling program provides one basic fee for the dialysis treatment; this fee includes all ancillary services which were previously billed separately. As

a consequence of this, the basic rate for Medicare reimbursement has been approximately \$240 per treatment. Medicare will provide additional reimbursement for some co-morbid conditions. BMA has reflected a Medicare rate of \$239 in the above table.”

The applicant projects revenues in Section X.2-4, pages 57-63, and operating expenses in Section X.4, page 62, as summarized in the table below:

BMA of Southwest Greensboro	Operating Year One 7/1/16-6/30/17	Operating Year Two 7/1/17-6/30/18
Gross Patient Revenue	\$7,280,773	\$7,443,795
Contractual Allowances	\$1,195,297	\$1,218,064
Total Net Revenue	\$6,085,476	\$6,225,730
Total Operating Expenses*	\$4,835,043	\$4,943,600
Net Profit	\$1,250,433	\$1,282,131

*Includes bad debts/charity and income taxes

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. See Section X.3, pages 58-59 for the applicant’s assumptions, including number of treatments (3 treatments/week, 52 weeks/year, and 6.5% missed treatments) for in-center patients. The applicant’s projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section VII.1, page 48, the applicant provides projected staffing and salaries. The tables in Sections X.4 and X.5, pages 62-63, show budgeted operating costs adequate to cover the projected staffing.

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

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

C

The applicant proposes to add two dialysis stations to the existing BMA of Southwest Greensboro facility for a total of 33 stations upon completion of this project. The January 2015 SDR indicates there are seven dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/14	% Utilization	Patients Per Station
BMA of Greensboro (BMA)	56	70.09%	2.80
BMA of South Greensboro (BMA)	59	76.69%	3.07
BMA of Southwest Greensboro (BMA)	31	83.06%	3.32
FMC of East Greensboro (BMA)	35	76.43%	3.06
High Point Kidney Center (WFUSM)	42	79.76%	3.19
Northwest Greensboro Kidney Center (BMA)	25	86.00%	3.44
Triad Dialysis Center (WFUSM)	22	84.09%	3.36

Source: January 2015 SDR, Table A.

The applicant operates five of the seven dialysis facilities in Guilford County, as stated by the applicant on page 35 of the application. Wake Forest University School of Medicine (WFUSM) also provides dialysis services in Guilford County, as shown in the table above.

As shown in the Guilford County Dialysis Facility Data table above, BMA of Southwest Greensboro was operating at 83.06% of capacity, as of June 30, 2014. The applicant provides data demonstrating that, as of December 31, 2014, BMA of Southwest Greensboro was operating at 81.45% of capacity (101 patients / 31 stations = 3.25 patients per stations / 4 stations = .8145).

The applicant is proposing to add two additional stations at BMA of Southwest Greensboro. In Section III.7, pages 31-33, the applicant discusses the assumptions and methodology for the proposed addition of stations. The applicant demonstrates that, upon project approval, BMA of Southwest Greensboro will serve a total of 106 in-center patients on 33 stations at the end of the first operating year, which is 3.21 patients per station per week, or a utilization rate of 80.3% ($106/33 = 3.21$; $3.21/4 = .8030$).

The applicant adequately demonstrates the need to add two additional stations to its existing facility based on the facility need methodology and the number of in-center patients it proposes to serve. The discussions regarding analysis of need and competition found in Criteria (3) and (18a), respectively, are incorporated herein by reference.

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

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

C

The following table illustrates the current and projected staffing for BMA of Southwest Greensboro, as provided by the applicant in Section VII.1, page 48.

Number of Full Time Equivalent

Position	Current FTEs	Projected FTEs
RN	4.00	6.00
Technician	13.00	15.00
Clinical Manager	1.00	1.00
Medical Director*	NA	NA
Administration – FMC Director of Operations	0.20	0.20
Dietitian	0.85	0.85
Social Worker	0.90	0.90
Chief Technician	0.15	0.15
Equipment Technician	0.85	0.85
In-Service	0.20	0.20
Clerical	1.00	1.00
Total	22.15	25.15

NA*The Medical Director is a contract position, not an FTE of the facility.

In Section VII.10, page 50, the applicant provides the projected number of direct care staff for each shift offered at BMA of Southwest Greensboro at project completion.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7:00 am-12:00 pm	11	11	11	11	11	11
Afternoon	12:00 pm-5:00 pm	11	11	11	11	11	11
Evening		0	0	0	0	0	0

In Section V.4, page 40, the applicant states that Dr. Michael Mattingly will serve as the Medical Director for BMA of Southwest Greensboro. In Exhibit 21, the applicant provides a letter dated February 23, 2015 signed by Dr. Mattingly of Carolina Kidney Associates in support of the proposed project and confirming his commitment to continue to serve as Medical Director. In Section VII.4, page 49, the applicant states, “*BMA anticipates no difficulties in filling staff positions.*” In Section V.4(d), page 40, the applicant lists 11 Carolina Kidney Associates’ nephrologists who will be available to provide medical coverage for dialysis patients at BMA of Southwest Greensboro. In Section VII, page 50, the applicant states, “*There are seven nephrologists associated with Carolina Kidney Associates who provide coverage at the BMA Southwest Greensboro facility.*” The applicant further states, “*The nephrologists have hospital privileges at Moses Cone Hospital and Alamance Regional Hospital.*”

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

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

C

In Section V.1, page 38, the applicant lists the providers of the necessary ancillary and support services to be provided at BMA of Southwest Greensboro. The applicant discusses coordination with the existing health care system on pages 39-41. Exhibit 21 contains documentation of nephrology services. Exhibit 25 contains documentation of a Patient Transfer Agreement with Moses H. Cone Memorial Hospital. Exhibit 26 contains documentation of Transplantation Services Agreements with Carolinas Medical Center, UNC Hospitals, Duke University Medical Center and North Carolina Baptist Hospitals. The information in Section V and Exhibits 21, 25 and 26 is reasonable and credible. The applicant adequately demonstrates that the necessary ancillary and support services will continue to 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;

C

In Section VI.1(a), page 43, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 100 dialysis facilities in 42 North Carolina counties (including affiliations with Renal Research Institute facilities). The applicant further states, *“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”* The patient population of the BMA of Southwest Greensboro facility is expected to be comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
BMA of Southwest Greensboro	49.5%	33.7%	60.4%	38.6%	69.3%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say that 60.4% of the facility treatment reimbursement is from Medicare.

On page 43, the applicant further states:

“The historical performance does change as new patients are admitted. Commercial insurance for patients generally covers the patient for a period of 30 months from the beginning of treatment; thereafter, Medicare provides coverage for the patient. The commercial insurance population is therefore constantly changing. In addition, not every patient beginning dialysis has commercial insurance. Thus, the payor mix should be considered dynamic and not fixed.”

In Section VI.1(b), page 44, the applicant reports that as of December 30, 2014, 83.08% of the patients who were receiving treatments at BMA of Southwest Greensboro had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical payment source for those facilities.

HISTORICAL PAYOR MIX

SOURCE OF PAYMENT	BMA of SW Greensboro
Commercial Insurance	12.09%
Medicare	61.40%
Medicaid	3.79%
Medicare / Commercial	17.89%
VA	3.22%
Other: Self Pay/Indigent	1.61%
Total	100.00%

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 for Guilford County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Guilford County	15.3%	5.9%	19.5%
Statewide	16.5%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report.

(ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99.)¹

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

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis”*² (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which shows that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). 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 (p. 223). 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.” (p. 216).

The *2013 USRDS Annual Data Report* (p. 332) provides 2011 ESRD spending by payor, as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$ 30.7	62.4%
Medicare Patient Obligation	\$ 4.7	9.6%
Medicare HMO	\$ 3.6	7.3%
Non-Medicare	\$ 10.2	20.7%
Total	\$ 49.2	100.0%

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

¹<http://www.esrdnetwork6.org/utilis/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

² www.usrds.org/adr.aspx

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

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

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

C

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

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX,

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section VI.6, page 46, the applicant states, *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”*

The application is conforming to this criterion.

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

C

In Section VI.1(d), page 44, 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.”

On page 44, the applicant reports that it expects 83.08% of the in-center patients who receive treatments at BMA of Southwest Greensboro to have all or part of their services paid for by Medicare or Medicaid, as indicated below.

Projected Payor Mix

SOURCE OF PAYMENT	BMA of SW Greensboro
Commercial Insurance	12.09%
Medicare	61.40%
Medicaid	3.79%
Medicare / Commercial	17.89%
VA	3.22%
Other: Self Pay/Indigent	1.61%
Total	100.00%

The applicant projects no change from the current payor mix for in-center dialysis services. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 46, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA 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.

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

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

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

C

In Section V.3, page 39, the applicant states:

“Exhibit 19 contains a letter to Guilford Technical Community College encouraging the school to include the BMA Southwest Greensboro facility in their clinical rotations for nursing students.

...

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

Exhibit 19 contains a copy of a letter from Fresenius Medical Care to the Practical Nursing Program at Guilford Technical Community College inviting the college to include BMA of Southwest Greensboro in the clinical rotation for its nursing students.

The information provided in Section V.3 and referenced exhibits is reasonable and credible and supports a finding of conformity with 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 for a total of 33 stations upon project completion. According to the January 2015 SDR, there are seven dialysis facilities in Guilford County, listed as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/14	% Utilization	Patients Per Station
BMA of Greensboro (BMA)	56	70.09%	2.80
BMA of South Greensboro (BMA)	59	76.69%	3.07
BMA of Southwest Greensboro (BMA)	31	83.06%	3.32
FMC of East Greensboro (BMA)	35	76.43%	3.06
High Point Kidney Center (WFUSM)	42	79.76%	3.19
Northwest Greensboro Kidney Center (BMA)	25	86.00%	3.44
Triad Dialysis Center (WFUSM)	22	84.09%	3.36

Source: January 2015 SDR, Table A.

As the table above illustrates, the five BMA Guilford County facilities, on average, are highly utilized. BMA of Southwest Greensboro is operating at 83.06% of capacity, as of June 30, 2014.

In Section V.7, pages 41-42, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states,

“BMA does not anticipate that this proposal will have any effect upon dialysis facilities in Guilford County. BMA projections of patients to be served by the

facility are a function of the existing patient population served by BMA coupled with growth of that population. 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. BMA also anticipates that the patient population of the Wake Forest affiliated dialysis facilities clinic will increase at the same rate proposed by BMA.

This facility will have added value stemming from the strength of our relationship with the nephrology physicians at Carolina Kidney Associates.

...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments.

...

The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ... Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This facility will be no different.

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives."

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates BMA will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates BMA will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA of Southwest Greensboro has operated in compliance with all 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.

CA

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming or conditionally conforming to all applicable criteria, as discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

- C- In Section II.1, page 10, and Exhibit 5 (copy of the January 2015 SDR, Tables A and B), the applicant provides the utilization rates for BMA of Southwest Greensboro. As of June 30, 2014, the facility had a utilization rate of 83.06% with 103 in-center patients dialyzing on 31 stations ($103 / 31 = 3.32$; $3.32 / 4 = 0.8306$)

.2202(a)(2) Mortality rates;

- C- In Section II.1, page 10, the applicant reports 2012, 2013 and 2014 facility mortality rates for BMA of Southwest Greensboro, as 6.8%, 14.5% and 12.0%, respectively.

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

- NA- In Section II.1, page 10, the applicant states that BMA of Southwest Greensboro is not certified to provide home dialysis services.

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

- C- In Section II.1, page 10, the applicant reports that BMA of Southwest Greensboro referred 22 patients for transplant evaluation in 2014, and three patients received transplants in 2014.

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

- C- In Section II.1, page 10, the applicant states that BMA of Southwest Greensboro has 15 patients on the transplant waiting list.

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

- C- In Section II.1, page 10, the applicant reports BMA of Southwest Greensboro had a total of 126 hospital admissions in 2014; 4% were dialysis related and 96% 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.

-CA- In Section II.1, page 11, the applicant reports that BMA of Southwest Greensboro had two Hepatitis B conversions in 2012 and zero in 2013. The applicant shows that the facility has two patients who currently have Hepatitis B. The applicant does not show the number of patients with infectious disease or the number who converted to infectious status during the last calendar year (2014).

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

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

-NA- The applicant does not propose a new facility. BMA of 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- The applicant does not propose a new facility. BMA of 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- The applicant does not propose a new or replacement facility. BMA of 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 excerpts from Fresenius’ Clinical Services Integrated Policy and Procedure Manual Volume II which includes Guidelines for Use of Emergency Generators Policy 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- The applicant does not propose a new facility. BMA of 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 states, in Section II, page 12, that BMA, its parent company, “will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations.” See also Sections I, pages 4-7, VII.2, page 49, and Exhibits 12 and 13.

.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.1, page 13, the applicant provides BMA of Southwest Greensboro’s projected in-center patient origin by county, based on the facility’s existing patient origin.

County	Operating Year One	Operating Year Two	County Patients as a Percent of Total	
			Year One	Year Two
Guilford	100	102	94.34%	94.45%
Davidson	3	3	2.83%	2.78%
Randolph	2	2	1.89%	1.85%
Virginia	1	1	0.94%	0.93%
Total	106	108	100.00%	100.00%

The applicant’s assumptions and methodology for its projections are provided on pages 12-13 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

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

-NA- The applicant does not propose a new facility. BMA of 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, 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- The applicant does not propose a new facility. BMA of 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- In Section II.1, page 15, the applicant projects that it will serve a total of 106 in-center patients on 33 stations at the end of the first operating year, which is 3.21 patients per station per week, or a utilization rate of 80.3% ($106 / 33 = 3.21$; $3.21 / 4 = 0.8030$). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section II.1, pages 12-13, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) Diagnostic and evaluation services;

- C- The applicant states, in Section II, page 16, and Section V, page 38, that diagnostic and evaluation services will be referred to Moses Cone Hospital.

.2204(2) Maintenance dialysis;

- C- The applicant states, in Section II, page 16, and Section V, page 38, that the facility will provide in-center maintenance dialysis.

.2204(3) Accessible self-care training;

- C- In Section II, page 16, and Section V, page 38, the applicant states that patients who are candidates for self-care will be referred to the BMA Greensboro home training department for self-care training.

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

- C- The applicant states, in Section II, page 16, that patients who are candidates for home dialysis will be referred to the BMA Greensboro home training department.

.2204(5) X-ray services;

- C- The applicant states, in Section II, page 16, that x-ray services will be referred to Moses Cone Hospital or Greensboro Diagnostics. Section V, page 38, lists Moses Cone Hospital as the provider of x-ray services.

.2204(6) Laboratory services;

- C- Laboratory services will be provided on-site by the applicant through a contract with Spectra Labs, as stated by the applicant in Section II, page 16, and Section V, page 38. Exhibit 15 contains documentation of a current Laboratory Services Agreement with Spectra Laboratories.

.2204(7) Blood bank services;

- C- The applicant states, in Section II, page 17, and Section V, page 38, that blood bank services will be provided by Moses Cone Hospital.

.2204(8) Emergency care;

- C- The applicant states, in Section II, page 17, and Section V, page 38, that facility staff provide emergency care on site until emergency responders arrive and that a fully stocked 'crash cart' is available for use at the facility. Patients in need of emergency care at a hospital are transported via emergency services.

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

- C- The applicant states, in Section II, page 17, and Section V, page 38, that acute dialysis in an acute care setting will be provided by Moses Cone Hospital.

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

- C- The applicant states, in Section II, page 17, that patients needing vascular surgery will be referred to Vein & Vascular Specialists (Greensboro) or Carolina Kidney Vascular Center. In Section V, page 38, the applicant lists Vascular Vein Specialists of Greensboro as providing vascular surgery services.

.2204(11) Transplantation services;

- C- In Section II, page 17, and Section V, page 38, the applicant states that candidates for transplantation services will be referred to Carolinas Medical Center. Exhibit 26 contains a copy of a Transplantation Agreement between the applicant and Carolinas Medical Center.

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

- C- Vocational rehabilitation counseling and services will be provided by the Division of Vocational Rehabilitation of Guilford County, as stated by the applicant in Section II, page 17, and Section V, page 38.

.2204(13) Transportation

- C- The applicant states, in Section II, page 17, that transportation services will be provided by Specialty Community Area Transportation, Greensboro Transit Authority, Guilford County Transportation, or MNZ Transportation. Section V, page 38, lists Specialized Community Area Transit and Piedmont Authority Regional Transportation for providing 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 (Replaced with 42 CFR Part 494).*
- C- In Section VII.1, page 48, the applicant provides a current and proposed staffing chart. In Section VII.2, page 49, the applicant states the proposed facility will comply with all staffing requirements as stated in 42 C.F.R. Part 494 (formerly 42 C.F.R., Section 405.2100). The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.
- .2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- In Sections II, page 18 and VII.5, page 49, the applicant discusses the required training for staff and states that training at BMA facilities is continually updated, as needed, by the In-Service Coordinator and RN Manager. Exhibit 9 contains an outline of the training program and Exhibit 10 contains an outline of continuing education programs.