

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: December 9, 2014  
PROJECT ANALYST: Celia C. Inman  
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: G-10337-14/ Bio-Medical Applications of North Carolina, Inc. d/b/a Rockingham Kidney Center / Add 2 dialysis stations for a total of 19 stations / Rockingham County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a Rockingham Kidney Center (RKC) proposes to add two dialysis stations for a total of 19 certified dialysis stations upon completion of this project. The facility is located at 2206 Barnes Street, Reidsville, Rockingham County.

#### **Need Determination**

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 11 dialysis stations in Rockingham County; therefore, based on the county need methodology, there is no need for additional stations in Rockingham County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Rockingham Kidney Center in the July

2014 SDR is 3.23 patients per station. This utilization rate was calculated based on 55 in-center dialysis patients and 17 certified dialysis stations. (55 patients / 17 stations = 3.23 patients per station).

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

**OCTOBER 1 REVIEW-JULY 2014 SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		80.88%
Certified Stations		17
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>17</b>
In-Center Patients as of 12/31/13 (SDR2)		55
In-Center Patients as of 6/30/13 (SDR1)		51
Step	Description	
	Difference (SDR2 - SDR1)	4
(i)	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 6/30/13	0.1569
(ii)	Divide the result of Step (i) by 12	0.0131
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.1569
(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	63.62
(v)	Divide the result of Step (iv) by 3.2 patients per station	19.88
	and subtract the number of certified and pending stations as recorded in SDR2 (17) to determine the number of stations needed	2.88

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 2.88 (rounded to 3) 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**

Policy GEN-3: BASIC PRINCIPLES, page 38 of the 2014 SMFP, is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the*

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

The applicant addresses Policy GEN-3 beginning on page 19 of the application.

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, pages 38-42, 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 32-35, Section V, pages 38-42, Section VI, page 43, 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, pages 21-22, Section III, pages 32-35, Section V, page 42, 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 as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

### **Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2014 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 RKC dialysis facility for a total of 19 dialysis stations upon completion of the project.

**Population to be Served**

In Section IV.1, page 36, the applicant states the number of patients served at RKC as of June 30, 2014 as follows:

County	# Patients Dialyzing at Home	# Patients Dialyzing In-Center
Rockingham	0	43
Caswell	0	4
Guilford	0	5
Danville, VA	0	1
Total	0	53

The applicant proposes to add two dialysis stations to the existing RKC dialysis facility for a total of 19 certified dialysis stations. In Section II, page 12 and Section 111.7, page 32, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion on December 31, 2015, as summarized in the table below:

**Projected Dialysis Patient Origin**

COUNTY	IN-CENTER PATIENTS		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	Year 1	Year 2	Year 1	Year 2
Rockingham	54.6	60.1	84.5%	85.7%
Caswell	4.0	4.0	6.2%	5.7%
Guilford	5.0	5.0	7.7%	7.1%
Danville, VA	1.0	1.0	1.5%	1.4%
Total	64.6	70.1	100.0%	100.0%

The applicant adequately identifies the population to be served.

### **Analysis of Need**

The applicant describes RKC's internal need for additional stations in Section III.9, page 35, stating:

*“Failure to apply for additional stations would eventually result in the facility operating at 100% utilization. At 100% utilization the facility can not accept additional patients without opening a third dialysis shift.”*

As discussed in Criterion (1), based on the facility need methodology for adding dialysis stations, the maximum number of stations needed at RKC is three stations. The applicant proposes to add two stations.

In Section II, pages 12-13, and Section III.7, pages 32-33, the applicant provides the assumptions and methodology it uses to determine the need for additional stations and to project RKC's patient utilization, which are summarized below:

- The applicant assumes that the Rockingham County patient population at its RKC facility will increase at a rate of 10% annually, a rate equal to approximately two thirds of the one-year growth rate calculated through the facility need methodology ( $15.69\% \times 2/3 = 10.5\%$ ). The applicant states that this is a reasonable growth rate for its facility even though the Rockingham County average annual change rate for the past five years is only 1.5%, per the July 2014 SDR, because:
  - The facility need methodology demonstrates that the facility patient population increased at a rate of 15.69% in 2013.
  - RKC has had a steady increase in patient population since December 31, 2010; from 40 patients to 55 patients, an 11% compound annual growth rate (CAGR).
  - The proposed rate of growth is less than the facility need methodology rate and less than RKC's three-year CAGR.
- RKC is serving ten in-center patients residing in Caswell and Guilford counties in NC and Danville, VA. The applicant does not project any increase in this segment of the patient population.
- Operating Year One is January 1, 2016 – December 31, 2016.
- Operating Year Two is January 1, 2017 – December 31, 2017.

*Projected Utilization*

The following table demonstrates the calculations used to arrive at the projected in-center patient census for the first two operating years.

<b>Rockingham Kidney Center</b>	<b>In-Center Patients</b>
The applicant begins with Rockingham County patients dialyzing at the RKC facility as of June 30, 2014	43
The applicant uses a 10% growth rate to project the census forward for 6 months to December 31, 2014	$[43 \times (.10 / 12 \times 6)] + 43 = 45.2$
The applicant projects this patient population forward for 1 year to December 31, 2015.	$(45.2 \times .10) + 45.2 = 49.7$
The applicant adds the ten patients from outside Rockingham County.	$49.7 + 10 = 59.7$
The applicant projects the December 31, 2015 Rockingham County patient population forward for 1 year to December 31, 2016.	$(49.7 \times .10) + 49.7 = 54.6$
The applicant adds the ten patients from outside Rockingham County for the projected ending census for Operating Year 1, December 31, 2016.	$54.6 + 10 = 64.6$
The applicant projects the December 31, 2016 Rockingham County patient population forward for 1 year to December 31, 2017.	$(54.6 \times .10) + 54.6 = 60.1$
The applicant adds the ten patients from outside Rockingham County for the projected ending census for Operating Year 2, December 31, 2017.	$60.1 + 10 = 70.1$

At the end of Operating Year One, December 31, 2016, RKC is projecting an in-center patient census of 64.6 patients for a utilization rate of 84% or 3.36 (64 patients / 19 stations =  $3.36 / 4 = .8421$ ) patients per station. At the end of Operating Year Two, December 31, 2017, RKC is projecting an in-center patient census of 70 patients for a utilization rate of 92% or 3.68 (70 patients / 19 stations =  $3.68 / 4 = .9210$ ) patients per station.

Projected patient in-center utilization at the end of the first operating year is 3.36 in-center patients per station per week which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

**Access**

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

*“It is clear that BMA 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 RKC facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
Rockingham Kidney Center	3.8%	41.5%	62.3%	50.9%	62.3%

Note: The Medicare percentage represents the percentage of patients receiving some type of Medicare benefit, not the percentage of facility treatment reimbursement. The above percentages are not meant to total to 100% of facility utilization.

On pages 44 and 60, the applicant projects that 79.65% of its patients will be covered by some form of Medicare or Medicaid. The applicant adequately demonstrates 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.

**Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project based on reasonable and supported utilization projections and assumptions and demonstrates the extent to which all residents of the area, and in particular, underserved groups, are likely to have access to the 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, page 35, the applicant discusses the alternatives considered prior to the submission of its application, which include:

- 1) Maintain the Status Quo – the applicant states, “*BMA considered simply not applying. However, that would eventually deny patients of the area a choice of providers.*” The applicant states that the facility is approaching 100% utilization and absent a third shift, eventually patients would be forced to choose an alternate provider or travel to another county.
- 2) Apply for fewer expansion stations – the applicant states, “*... the facility is projected to exceed 80% utilization by the end of the first year of operations. Fewer stations results in higher utilization. By applying for eight [sic] stations as the need methodology demonstrates BMA will assure sufficient dialysis capacity for the ESRD patient population of the area.*”

The applicant states that the chosen alternative to apply to expand the existing Rockingham facility by adding two stations for a total of 19 certified dialysis stations is the most effective and least costly alternative for meeting the needs of the patients projected to receive treatment at the Rockingham facility.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the continued growth of Rockingham Kidney Center’s patient population. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

Furthermore, the application is 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 its 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 Rockingham Kidney Center shall materially comply with all representations made in the certificate of need application.**

- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a Rockingham Kidney Center shall develop and operate no more than two additional dialysis stations for a total of no more than 19 certified dialysis stations which shall include any home hemodialysis training or isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Rockingham Kidney Center shall install plumbing and electrical wiring through the walls for no more than two (2) additional dialysis stations for a total of 19 dialysis stations which shall include any home hemodialysis training stations or isolation stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a Rockingham Kidney Center 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 the table in Section VIII, page 51, the applicant shows the capital cost of the project is \$10,500, which includes \$1,500 for water treatment equipment and other equipment and furniture totaling \$9,000. In Section IX, page 55, the applicant states that because the project is not a proposal for a new facility, it does not involve startup or initial operating expenses.

In Section VIII.5, page 53, the applicant states, “*BMA is utilizing accumulated reserves to finance this project.*” The applicant further states:

*“Please refer to Exhibit 24 for letter of commitment from Mark Fawcett, Vice President and Assistant Treasurer, Fresenius Medical Care Holdings, Inc. This letter will verify the availability of the FMC funds necessary for the project.”*

The letter in Exhibit 24 commits Fresenius Medical Care Holdings, Inc. funds for the development of the proposed project. Exhibit 4 contains the consolidated financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ending December 31, 2013 and 2012, which document cash and cash equivalents of \$275,719,000 and total equity of more than \$7 million.

Thus, the applicant adequately demonstrates the availability of adequate funds to develop the project.

Based on information provided by the applicant in Section X.1, page 56, the dialysis facility's projected allowable charges per treatment for each payment source are as follows:

<b>SOURCE OF PAYMENT</b>	<b>ALLOWABLE CHARGE PER TREATMENT</b>
Private Pay	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$ 239.00
Medicaid	\$ 140.23
VA	\$ 231.12
Medicare/Medicaid	\$ 239.00
Medicare/Commercial	\$ 239.00
State Kidney Program	\$ 100.00
Other: Self/Indigent	\$1,425.00

On page 57, the applicant states:

*“In November 2013, Medicare announced further cuts to reimbursement for dialysis treatment. These cuts amount to a 12% reduction in revenues and will be phased in over several years. The following table demonstrates the projected Medicare reimbursement by calendar year. BMA will use these rates within in the application and its projections of revenues.”*

**Table X.1-2**  
**Anticipated Medicare Reimbursement by Year**

<b>YEAR</b>	<b>MEDICARE RATE</b>
2014	\$239.02
2015	\$239.02
2016	\$229.46
2017	\$220.28
2018	\$211.47
2019	\$211.47

In Sections X.2-X.4, pages 58-64, the applicant reports projected revenues and expenses as follows:

	<b>OPERATING YEAR 1 1/1/16-12/31/16</b>	<b>OPERATING YEAR 2 1/1/17-12/31/17</b>
Total Net Revenue	\$3,820,089	\$4,077,603
Total Operating Costs	\$2,878,195	\$3,049,296
Net Profit	\$941,893	\$1,028,307

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. See Section X.3, pages 59-61 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. See further discussion on the applicant's assumptions for projections in Criterion (3) which is incorporated herein by reference.

In Section VII.1, page 48, the applicant provides projected staffing and salaries. The financials in Sections X.4-5, pages 63-64, budget operating costs adequate to cover the projected staffing.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the 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 following table identifies the existing and approved kidney disease treatment centers located in Rockingham County as reported in the July 2014 SDR.

ROCKINGHAM COUNTY DIALYSIS CENTERS		
FACILITY	LOCATION	UTILIZATION
Dialysis Care of Rockingham County	Eden	79.35%
Reidsville Dialysis	Reidsville	88.16%
Rockingham Kidney Center	Reidsville	80.88%

As shown in the table above, each of the three facilities in Rockingham County are operating at above 79% of capacity as of December 2013.

The applicant proposes to add two dialysis stations to its existing Rockingham Kidney Center for a total of 19 certified dialysis stations upon completion of this project. The applicant adequately demonstrates the need for two additional stations based on the number of in-center patients it proposes to serve. The discussion regarding analysis of need found in Criterion (3) is 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. 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 projected staffing for RKC, as provided by the applicant in Section VII.1, page 48.

<b>Position</b>	<b>Total FTE Positions</b>
RN	2.50
Patient Care Technician	5.00
Clinical Manager	1.00
Administrator	0.20
Dietician	0.50
Social Worker	0.50
Chief Tech	0.10
Equipment Technician	0.90
In-Service Technician	0.30
Clerical	1.00
<b>Total</b>	<b>12.00</b>

As shown in the above table, the applicant proposes to employ a total of 12 full-time equivalent (FTE) positions to staff the RKC facility upon completion of the proposed project. In Section VII.4, page 49, the applicant states, “*BMA anticipates no difficulties in filling staff positions.*”

The following table shows the projected number of direct care staff for each shift offered at RKC after the addition of the two dialysis stations.

	<b>Shift Times</b>	<b>Monday</b>	<b>Tuesday</b>	<b>Wednesday</b>	<b>Thursday</b>	<b>Friday</b>	<b>Saturday</b>
Morning	7:00 am to 12:00 pm	5	5	5	5	5	5
Afternoon	12:00 pm to 5:00 pm	5	5	5	5	5	5
Evening	N/A	0	0	0	0	0	0

In Section V.4, page 41, the applicant states that Alvin Powell, M.D., of Carolina Kidney Associates, P.A. will continue to serve as Medical Director of the facility. Exhibit 21 contains a letter signed by Dr. Powell, expressing support for the addition of dialysis stations and agreeing to continue his relationship with the facility. In Section V, page 41, the applicant lists 10 nephrologists from Carolina Kidney Associates who will have privileges to admit patients and perform rounds on dialysis patients at the RKC facility. In Section VII, page 50, the applicant states

that the Carolina Kidney Associates nephrologists have admitting privileges at Moses Cone Health System.

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.

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In Section V.1, page 38, the applicant provides a list of providers of the necessary ancillary and support services. Annie Penn Hospital and/or Moses Cone Health System will provide acute dialysis in an acute care setting. See Exhibit 25 for the back-up hospital services agreement with Moses Cone. Annie Penn Hospital will provide blood bank, diagnostic evaluation and X-ray services. Transplantation services will be provided by North Carolina Baptist Hospital, Duke University Medical Center and University of North Carolina Hospitals (Exhibit 26). Rockingham County Mental Health will provide psychological counseling. Pediatric nephrology will be referred to University of North Carolina Hospitals. Vascular surgery will be provided by Carolina Kidney Vascular or Vein and Vascular Specialist. All BMA staff are trained to respond to emergencies and there is a fully stocked crash cart available on-site. If needed, patients will be transported by ambulance to the hospital for further acute care. Spectra will provide laboratory services (Exhibit 15). Self care training, including hemodialysis, peritoneal dialysis, CAPD and CCPD will be provided by BMA Greensboro, also referred to as Greensboro Kidney Center (Exhibit 20). 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 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

NA

- (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 43, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 102 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 RKC facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
Rockingham Kidney Center	3.8%	41.5%	62.3%	50.9%	62.3%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say 62.3% of the treatment reimbursement is from Medicare.

On pages 43-44, the applicant further states:

*“BMA notes that the historical performance as reported here represents the payor mix for Rockingham Kidney Center as of June 30, 2014. The historical performance is not a guarantee of future performance as the payor source 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 Section VI.1(b), page 44, the applicant reports that 79.65% of the patients who were receiving treatments at RKC as of June 30, 2014, 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 the facility.

**ROCKINGHAM KIDNEY CENTER PAYOR MIX**

SOURCE OF PAYMENT	IN-CENTER %
Commercial Insurance	15.93%
Medicare	56.65%
Medicaid	3.15%
VA	4.43%
Medicare/Commercial	19.85%
Total	100.00%

Totals may not sum due to rounding.

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 Rockingham, Caswell and Guilford, counties and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Rockingham County	20.0%	9.3%	19.0%
Caswell County	21.0%	10.8%	20.0%
Guilford County	15.0%	5.9%	19.5%
Statewide	17.0%	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.*)<sup>1</sup>

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 ....”*<sup>2</sup> (p. 216)

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 (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*

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

<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

*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:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
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%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

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:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
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%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
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.<sup>3</sup>

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

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

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

C

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

In Section VI.6 (a), page 46, the applicant states, *“There have been no Civil Rights complaints lodged against 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 45, 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 over 79% of the in-center patients who receive treatments at RKC to have all or part of their services paid for by Medicare or Medicaid as indicated below.

**ROCKINGHAM KIDNEY CENTER PAYOR MIX**

<b>SOURCE OF PAYMENT</b>	<b>IN-CENTER %</b>
Commercial Insurance	15.93%
Medicare	56.65%
Medicaid	3.15%
VA	4.43%
Medicare/Commercial	19.85%
Total	100.00%

Totals may not sum due to rounding.

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 that:

*“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. Rockingham Kidney Center 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 offers a range of means by which a person can access 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, pages 39-40, the applicant states:

*“Exhibit 19 contains letters to Rockingham Community College encouraging the school to include the Rockingham Kidney Center 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 Dean of the Division of Health Sciences at Rockingham Community College inviting the college to include RKC in the clinical rotation for its nursing students. The information provided in Section V.3 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 to its existing Rockingham County facility for a total of 19 certified dialysis stations upon completion of this project. According to the July 2014 SDR, Rockingham County has three dialysis centers, as shown below:

ROCKINGHAM COUNTY DIALYSIS CENTERS		
FACILITY	LOCATION	UTILIZATION
Dialysis Care of Rockingham County	Eden	79.35%
Reidsville Dialysis	Reidsville	88.16%
Rockingham Kidney Center	Reidsville	80.88%

In Section V.7, page 42, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states it does not expect this proposal to have an effect on the competitive climate in Rockingham County. The applicant states that RKC is operated by BMA and the other two facilities in the county are operated by DaVita Dialysis. The applicant also states that the physicians associated with DaVita do not have rounding privileges in the BMA facility; and the Carolina Kidney Associates nephrologists which serve BMA facilities do not have privileges in the DaVita facilities. The applicant further states:

*“This facility also has added value stemming from the strength of our relationship with the physicians of 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. In this application, BMA projects that greater than 84% of the In-center patients will be relying upon government payors. 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.*

...

*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 in the application 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 discussion regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, is incorporated herein by reference.

- The applicant adequately demonstrates it will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates it will continue provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

RKC currently provides dialysis services. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Rockingham Kidney Center facility operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of the decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183(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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

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

### **.2202 INFORMATION REQUIRED OF APPLICANT**

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

(1) *Utilization rates;*

-C- In Section II.1, page 10, the applicant states that the utilization rate is reported in the July 2014 SDR. The July 2014 SDR shows a utilization rate of 80.88% for RKC. The rate was calculated based on 55 in-center dialysis patients and 17 certified dialysis stations as of December 31, 2013 (55 patients / 17 stations = 3.2352 patients per station; 3.2352 patients per station / 4.00 patients per station = 80.88%). In Section II, page 12, the applicant projects serving 64 dialysis patients on 19 stations for a utilization rate of 84% ( $64 / 19 = 3.36 / 4 = 0.8421$ ) in operating year one and 70 dialysis patients on 19 stations for a utilization rate of 92% ( $70 / 19 = 3.68 / 4 = 0.921$ ) in year two.

(2) *Mortality rates;*

-C- In Section II, page 10, the applicant reports the 2011, 2012 and 2013 facility mortality rates as 10.4%, 17.6% and 13.2%, respectively.

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

-NA- In Section II, page 10, the applicant states, “Rockingham Kidney Center is not certified to offer home training. Patients who are candidates for home dialysis are referred to the BMA Greensboro dialysis facility.”

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

-C- In Section II, page 10, the applicant provides information showing RKC referred nine patients for transplant in 2012 and ten patients in 2013; RKC did not have any transplants performed in 2012, but had three transplants performed in 2013.

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

-C- In Section II, page 10, the applicant states, “Rockingham Kidney Center has eight patients on the transplant waiting list.”

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

- C- In Section II, page 10, the applicant states that there were 85 hospital admissions in 2013, two (2.3%) of which were dialysis related and 83 (97.6%) non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section II, page 11, the applicant provides information that shows there were no patients dialyzing at RKC with Hepatitis B Conversions during 2012 and 2013 and no current patients with infectious disease (Hepatitis B).
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
- NA- RKC is an existing facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- RKC is an existing facility.

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

-NA- RKC is an existing facility.

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

-C- See Exhibit 12, in which the applicant provides copies of written policies and procedures, including back up procedures in the event of a power outage.

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

-NA- RKC is an existing facility.

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

-C- In Section II, page 12, the applicant states:

*“BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at Rockingham Kidney Center.”*

In Section XI.6(g), page 69, the applicant states,

*“BMA of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements. Information detailing conformity can be found in Sections II and VII and exhibits referenced therein. Additionally, this applicant has confirmed its commitment to provide services in conformity with the law on the Certification page provided in the front of the application.”*

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

-C- The applicant provides the following projected patient origin for Operating Years One and Two (January 1, 2016 – December 31, 2016 and January 1, 2017 – December 31, 2017, respectively) on page 12 of the application, as shown below.

**Projected Dialysis Patient Origin**

COUNTY	IN-CENTER PATIENTS		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	Year 1	Year 2	Year 1	Year 2
Rockingham	54.6	60.1	84.5%	85.7%
Caswell	4.0	4.0	6.2%	5.7%
Guilford	5.0	5.0	7.7%	7.1%
Danville, VA	1.0	1.0	1.5%	1.4%
Total	64.6	70.1	100.0%	100.0%

The applicant’s assumptions and methodology are provided on pages 12-14.

(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 is not proposing a new facility.

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

-C- In Section II, 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.”*

**.2203 PERFORMANCE STANDARDS**

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2*

*patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

- NA- The applicant proposes to add stations to an existing facility.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section II, page 12, the applicant projects serving 64 dialysis patients on 19 stations for a utilization of 3.36 ( $64 / 19 = 3.36$ ) patients per station per week at the end of the first operating year, based on the methodology and assumptions found in Section II, pages 12-14 and in Section III of the application. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**.2204 SCOPE OF SERVICES**

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

- (1) *diagnostic and evaluation services;*
  - C- Section II, page 16 and the table in Section V.1, page 38 state patients will be referred to Annie Penn Hospital for diagnostic and evaluation services.
- (2) *maintenance dialysis;*
  - C- Section II, page 16 and the table in Section V.1, page 38, state the applicant will provide in-center maintenance dialysis.
- (3) *accessible self-care training;*
  - C- In Section II, page 16, the applicant states, “*Patients who are candidates for self-care are referred the BMA Greensboro dialysis home training department.*” The table in Section V.1, page 38, shows patients will receive in-center hemodialysis, intermittent peritoneal dialysis, CAPD and CCPD at BMA Greensboro.

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

-C- In Section II, page 16, the applicant states, “*Patients who are candidates for home dialysis are referred to the BMA Greensboro dialysis home training department.*” The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 39, stating,

*“Currently, patients who desire to perform home dialysis will be trained and referred to the BMA Greensboro dialysis home training program. Patients who are candidates for home dialysis are referred by their attending nephrologists to facility BMA Greensboro Home Training Clinic. The applicant will provide back-up hemodialysis treatments to any home patient in need of temporary hemodialysis.*

*Services offered to home patients include home visitation, assistance with problems that patients have with catheters; diagnosis of infections and assistance with placing orders of needed supplies. Social work and dietary assessments are provided for those patients on an ongoing basis. Patients are given EPO at the facility or taught to administer it to themselves at home. Laboratory testing of blood samples may be provided by the facility as prescribed by the physician.”*

(5) *x-ray services;*

-C- Section II, page 16 and the table in Section V.1, page 38, state patients will be referred to Annie Penn Hospital for x-ray services.

(6) *laboratory services;*

-C- Section II, page 16 and the table in Section V.1, page 38, state the facility provides on-site laboratory services through contract with Spectra Labs. Exhibit 15 contains a laboratory services agreement.

(7) *blood bank services;*

-C- Section II, page 16 and the table in Section V.1, page 38, state patients will be referred to Annie Penn Hospital for blood bank services.

(8) *emergency care;*

-C- Section II, page 16 and the table in Section V.1, page 38, state emergency care is provided on site from the trained staff and fully

stocked crash cart. Emergency services will be summoned via phone call to 911 in the event transport by ambulance to a hospital is required.

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

-C- Section II, page 16 and the table in Section V.1, page 38, state patients will be referred to Annie Penn Hospital or Moses Cone Hospital for acute dialysis in an acute care setting.

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

-C- Section II, page 17 and the table in Section V.1, page 38, state dialysis patients will be referred to Carolina Kidney Vascular or Vein and Vascular Specialists for vascular surgery.

(11) *transplantation services;*

-C- In Section II, page 17, the applicant states, “A copy of an executed transplant agreement is included in Exhibit 26. The facility has executed transplant agreements with Duke, Wake Forest Baptist, and UNC Medical Center.” Exhibit 26 contains an executed transplant agreement between RKC and Duke University Medical Center.

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

-C- Section II, page 17 and the table in Section V.1, page 38, state patients will be referred to Vocational Rehabilitation, Wentworth, NC for vocational counseling and services.

(13) *transportation.*

-C- Section II, page 17 and the table in Section V.1, page 38, state transportation services for RKC dialysis patients are provided by Rockingham County Council on Aging.

## **.2205 STAFFING AND STAFF TRAINING**

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

-C- In Section VII.1, page 48, the applicant provides the proposed staffing for RKC. On page 49, the applicant states, “Rockingham Kidney Center will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100).” See additional staffing details in Section 1.13(c), pages 7-8, and Section II.2, pages 22-23.

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

-C- In Section VII.5, page 49, the applicant refers to Exhibit 9 for an outline of the training program and Exhibit 10 for an outline of continuing education programs. The applicant also states that each new employee will be required to successfully complete a 10-week training program, including training in the clinical aspects of their job, facility and corporate policies and procedures, safety precautions, OSHA regulations, and CPR.