ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: July 24, 2014
PROJECT ANALYST: Julie Halatek
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: B-10272-14 / Total Renal Care of North Carolina, LLC d/b/a Asheville Kidney Center / Add two home hemodialysis stations for a total of 48 in-center stations and four home hemodialysis stations upon project completion / Buncombe 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.

NC

Total Renal Care of North Carolina, LLC (TRCNC) d/b/a Asheville Kidney Center (AKC) proposes to add two dialysis stations for a total of 52 certified dialysis stations upon completion of this project. The two additional stations proposed will be utilized as home hemodialysis stations.

According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 15 dialysis stations in Buncombe County. However, the applicant is eligible to apply for additional stations in its existing facility based on application of the facility need methodology because the utilization rate reported for AKC in the January 2014 SDR is 3.52 patients per station. This utilization rate was calculated based on 176 in-center dialysis patients and 50 certified dialysis stations (176 patients / 50 stations = 3.52 patients per station).

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

APRIL 1 REVIEW - JANUARY SDR

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		88.0%
Certified Stations		50
Pending Stations		0
Total Existing and Pending Stations		**50**
In-Center Patients as of 6/30/13 (SDR2)		176
In-Center Patients as of 12/31/12 (SDR1)		154
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	22
	Multiply the difference by 2 for the projected net in-center Change	44
	Divide the projected net in-center change for 1 year by the number of in-center patients as 12/31/12	0.2857
(ii)	Divide the result of Step (i) by 12	0.0238
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.1429
(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	201.1429
(v)	Divide the result of Step (iv) by 3.2 patients per station	62.8571
	and subtract the number of certified and pending stations as recorded in SDR2 [50] to determine the number of stations needed	13

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 13 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 only two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

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."

Promote Safety and Quality

In Section II.3, pages 16-17, the applicant discusses the quality of services provided at DaVita HealthCare Partners, Inc. owned and operated ESRD facilities. The applicant states that its success in providing quality services stems from a comprehensive Quality Management Program that includes the following components:

- *"Quality Improvement Methodology – utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System – integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Staff and Patient Education Program – ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program – systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team – experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team – experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance)."*

The applicant states on page 17:

"Our goal is to have each facility serve as a quality improvement laboratory where successful outcomes can be disseminated throughout DaVita."

Exhibit 22 contains DaVita's Health and Safety Policy & Procedure Manual which includes a section on General Health and Safety Policies. The Health and Safety Policies state, in part:

"The Health and Safety Policy & Procedure Manual is designed to ensure compliance and provide policy and procedure for teammate health and safety issues. Using this manual, each DaVita facility will meet Federal regulations as they relate to Risk and Occupational Safety Health Administration (OSHA), support the corporate philosophy of consistent practice and operations of facilities within the company…"

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

Promote Equitable Access

In Section VI.1(a), page 30, the applicant states:

> *"Asheville Kidney Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay."*

Based on information provided by the applicant on page 30, 80.4% of its patients had some or all of their services paid for by Medicare or Medicaid in the past year and project the same payor mix in the future.

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

Maximize Healthcare Value

In Section III.9, page 22, the applicant states that AKC will maximize healthcare value in several ways, which include: utilization of a centralized purchasing department to negotiate national contracts with numerous vendors in order to secure the best product available at the best price; utilization of the reuse process that contains costs and the amount of dialyzer waste generated by the facility; use of an electronic patient charting system that reduces the need for paper in the facility; preventative maintenance on the dialysis machines performed monthly, quarterly and semi-annually to reduce the need for repairs of the dialysis equipment; and use of an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand.

However, the applicant does not adequately demonstrate that the proposal will maximize healthcare value. See the discussion in Criterion (3) which is hereby incorporated by reference as if set forth fully herein.

The applicant does not adequately demonstrate the proposal will incorporate the basic principles of Policy GEN-3. Therefore, the application is nonconforming 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.

NC

The applicant, AKC, proposes to add two certified dialysis stations to the existing facility to be utilized as home hemodialysis stations for training and support. As of

June 30, 2013, AKC had 50 certified dialysis stations—48 in-center stations and two home hemodialysis stations.

Population to be Served

In Section III.7, page 20, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

Projected Dialysis Patient Origin - AKC						
County	Operating Year 1 2015		Operating Year 2 2016		County Patients as a Percent of Total	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Buncombe	182	25	187	25	95.4%	95.4%
Henderson	1	3	1	3	1.8%	1.8%
Rutherford	1	0	1	0	0.5%	0.5%
McDowell	0	2	0	2	0.9%	0.9%
Transylvania	0	2	0	2	0.9%	0.9%
Mitchell	0	1	0	1	0.5%	0.5%
Total	**184**	**33**	**189**	**33**	**100.0%**	**100.0%**

In Section IV.1, page 23, the applicant provides the patient origin at AKC as of June 30, 2013, as shown in the table below.

AKC Patient Origin as of 6/30/13		
County of Residence	In-Center Patients	Home Patients
Buncombe	174	25
Henderson	1	3
Rutherford	1	0
McDowell	0	2
Transylvania	0	2
Mitchell	0	1
Total	**176**	**33**

Note: In the application, both columns of this table are listed as "in-center patients"; however, the analyst inferred from information elsewhere in the application that the last column indicates home patients.

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

The applicant proposes to add two certified dialysis stations to its existing facility. In Section III.7, page 20, the applicant states:

> *"The Asheville Kidney Center had 176 in-center patients as of June 30, 2013 based on information included in Table A of the January 2014 Semiannual Dialysis Report (SDR). This is a station utilization rate of 88% based on the 50 certified stations. All but two of the patients dialyzing at the Asheville Kidney*

Center live in Buncombe County. We are applying for a two-station expansion of the Asheville Kidney Center. ..."

The applicant provides the assumptions used to demonstrate the need for two additional dialysis stations in Section III.7, pages 20-21:

"This Certificate of Need application for the expansion of the Asheville Kidney Center by five [sic] *dialysis stations is based on the following assumptions:*

- *The facility had 176 in-center patients as of June 30, 2013*
- *The table in Section III.2 indicates that the facility is eligible for up to a ten-station expansion, based* [on the] *facility need methodology*
- *Buncombe County has an average annual change rate of 2.5% over the past five years*

...

Based on the patients and stations above, Asheville Kidney Center is projected to have at least 184 in-center patients by the end of operating year 1 for a utilization rate of 88% or 3.5 patients per station and at least 189 in-center patients by the end of operating year 2 for a utilization rate of 91% or 3.6 patients per station. ...

The period of the growth begins with January 1, 2014 forward to December 31, 2016. The following are the in-center patient projections using the 2.5% Average Annual Change Rate for the Past Five Years as indicated in Table B of the January 2014 SDR.

January 1, 2014 – December 31, 2014 – 174 patients X 1.025 = 178.35

January 1, 2015 – December 31, 2015 – 178.35 patients X 1.025 = 182.80875

January 1, 2016 – December 31, 2016 – 182.80875X 1.025 = 187.3789687

Operating Year One is projected to begin January 1, 2015 and end on December 31, 2015

Operating Year Two is projected to begin January 1, 2016 and end on December 31, 2016

The number of patients stated in the chart above was rounded down to the nearest whole number."

The applicant states in Section III.7, quoted above, that AKC will have at least 184 in-center patients by the end of 2015 and at least 189 in-center patients by the end of 2016. The applicant's calculations above project 182 in-center patients by the end of 2015 and 187 in-center patients by the end of 2016. The applicant also states in Section III.7, quoted above, that all but two of the in-center patients reside in Buncombe County. The project analyst assumes that the applicant calculated the growth for only Buncombe County in-center patients and then added the two out of county in-center patients to the projected totals for Buncombe County in-center patients.

The applicant adequately demonstrates the need for two additional dialysis stations to serve in-center patients.

However, the applicant states that the two additional dialysis stations will be used as home hemodialysis training stations. In Section I.8, page 3, the applicant states:

> *"The facility is currently certified for fifty End Stage Renal Disease dialysis stations. This application is for the expansion of the facility by two stations. The two stations will be utilized in the home training department as home hemodialysis stations for training and support. When the project is complete, there will be 48 certified stations on the in-center treatment floor and four hemodialysis stations for training and support. …"*

In Section II.1, pages 12-13; again in Section II.1, at the bottom of page 13; and in Section III.7, page 20, the applicant states:

> *"We are applying for a two-station expansion of the Asheville Kidney Center. The two stations will be utilized in the home hemodialysis training and support suite."*

In the January 2014 SDR, under the *Methodology* section on page 8, paragraph #2 states:

> *"(2) Facility Need*
>
> *A dialysis facility located in a county for which the result of the County Need methodology is zero in the current SDR is determined to need additional stations to the extent that:*
>
> *(A) Its utilization, reported in the current SDR, is 3.2 patients per station or greater.*
>
> *(B) Such need, calculated as follows, is reported in an application for a certificate of need:*
>
> *(i) The facility's number of* ***in-center*** *dialysis patients reported in the previous SDR (SDR1) is subtracted*

from the number of ***in-center*** *dialysis patients reported in the current SDR (SDR2). The difference is multiplied by 2 to project the net* ***in-center*** *change for 1 year. Divide the projected net* ***in-center*** *change for the year by the number of* ***in-center*** *patients from SDR1 to determine the projected annual growth rate.*

(ii) The quotient from (2)(B)(i) is divided by 12.

(iii) The quotient from (2)(B)(ii) is multiplied by 6 (the number of months from June 30, 2013 until December 31, 2013) for the January 2014 SDR.

(iv) The product from (2)(B)(iii) is multiplied by the number of the facility's ***in-center*** *patients reported in the current SDR and that product is added to such reported number of* ***in-center*** *patients.*

(v) The sum from (2)(B)(iv) is divided by 3.2, and from the quotient is subtracted the facility's current number of certified stations as recorded in the current SDR and the number of pending new stations for which a certificate of need has been issued. The remainder is the number of stations needed." (emphasis added)

The facility need methodology in the January 2014 SDR calculates the number of additional stations needed by applying the methodology rules to the number of in-center patients. Thus, the applicant has adequately demonstrated the need for two additional in-center stations.

However, in the January 2014 SDR, under the *Basic Principles* section on page 6, paragraph #5 states:

> *"Home patients will not be included in the determination of need for new stations. Home patients include those that receive hemodialysis or peritoneal dialysis in their home."*

Because home patients are excluded from the calculations used to determine the number of stations needed under the facility need methodology, the demonstration that additional stations are needed, based solely on the need by in-center patients, does not adequately demonstrate that additional stations are needed to serve home hemodialysis patients.

In the January 2014 SDR, under the *Basic Principles* section on page 5, paragraph #1 states:

> *"Increases in the number of facilities or stations should be done to meet the specific need for either a new facility or an expansion."*

The facility need methodology calculations show the need for additional stations to serve the in-center patient population. However, the applicant does not propose to serve the in-center patient population with the additional stations. The applicant is required to demonstrate the need that home hemodialysis patients have for two additional home hemodialysis stations. However, the applicant does not provide any information to demonstrate the need for two additional home hemodialysis stations.

In Section III.7, page 20, the applicant provides the county of residence for the patients projected to utilize the facility in the first two operating years following project completion. In both Operating Year One and Operating Year Two, the applicant projects a total of 33 home hemodialysis patients will utilize the facility. Later in the same section, on page 21, the applicant states:

> *"**Home Training in Hemodialysis***
>
> *The Asheville Kidney Center had 33 home hemodialysis patients as of December 31, 2014* [sic]. *For the purpose of this application TRC has chosen to forgo growing the HHD* [home hemodialysis] *patient population. It is projected that Asheville Kidney Center will treat 33 HHD patients during operating years one and two."* (emphasis in original)

Thus, since the applicant does not project an increase in the number of home hemodialysis patients, the application does not demonstrate the need for two additional home hemodialysis stations.

Additionally, the applicant provides no information to demonstrate that the existing 33 home hemodialysis patients are not adequately served on the two existing home hemodialysis stations.

In Section III.9, page 21, in response to a question about alternatives considered to the proposed project, the applicant states:

> *"There were only two alternatives of meeting the needs of the proposed project considered. The first was to do nothing. This alternative was dismissed since the facility is rapidly growing. The second was to apply for the two-station expansion of the facility. We chose the second alternative in order to help meet the growing demand for dialysis services at the Asheville Kidney Center."*

The applicant demonstrated the projected in-center population growth supports the need for two additional in-center stations. However, the applicant specifically chooses not to show growth in the home hemodialysis patient population, and therefore does not adequately demonstrate the need for two additional home hemodialysis stations.

Access

In Section VI.1(a), page 30, the applicant states:

> *"Asheville Kidney Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.*
>
> *Asheville Kidney Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. Asheville Kidney Center provides dialysis six days per week with two patient shifts per day to accommodate patient need. The facility also provides a third shift on Monday, Wednesday and Friday for patients who have a need for an evening treatment time.*
>
> *Asheville Kidney Center does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. Asheville Kidney Center works with patients who need transportation, when necessary."*

In Section VI.1(c), page 31, the applicant projects that 80.4% of its patients will be covered by Medicare or Medicaid and 7.4% of its patients will be covered by the VA.

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.

The applicant adequately identifies the population it proposes to serve 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. However, the applicant does not adequately demonstrate the need the population proposed to be served (i.e., home hemodialysis patients) has for the services proposed for all of the following reasons:

- The applicant provides no information to demonstrate the need that the home hemodialysis population has for additional stations.

- The applicant states that the population to be served by the additional stations is not projected to grow, and therefore, the applicant does not adequately demonstrate a need for additional stations.

- The applicant does not adequately demonstrate that the population utilizing the existing stations is not adequately served by the existing stations, and therefore, has a need for additional stations.

Therefore, the application is nonconforming 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.

NC

In Section III.9, page 21, the applicant describes the alternatives it considered to meet the need for the proposed services, which were to maintain the status quo or to increase the number of dialysis stations at the facility.

However, the applicant does not adequately demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. See discussion in Criterion (6), which is hereby incorporated by reference as if set forth fully herein. Thus, the applicant does not adequately demonstrate that the least costly or most effective alternative was chosen.

Furthermore, the application is not conforming to all other applicable statutory and regulatory review criteria, and thus, is not approvable. See Criteria (1), (3), (5), (6), (18a), and (21b). A project that cannot be approved cannot be an effective alternative.

In summary, the applicant does not adequately demonstrate that this proposal is the least costly or most effective alternative to meet the stated need. Therefore, the application is nonconforming to this criterion and cannot be approved.

(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.

NC

In Section VIII.1, page 39, the applicant states that the proposed capital cost of the project is $25,550: $22,000 for dialysis machines and $3,550 for other equipment. In Section IX.1, page 43, the applicant projects no start-up or initial operating expenses, as the facility is already in operation. In Section VIII.2 and VIII.3, page 40, the applicant states that cash reserves of DaVita HealthCare Partners, Inc., the parent company of Total Renal Care of North Carolina, Inc., will be used to finance the capital costs.

Exhibit 18 contains the United States SEC Form 10-K for DaVita HealthCare Partners, Inc. for the year ending December 31, 2013. As of December 31, 2013, DaVita had $946,249,000 in cash and cash equivalents. Exhibit 17 contains a letter dated March 3, 2014, from the Chief Accounting Officer for DaVita HealthCare Partners, Inc., which states in part:

> "*I am the Chief Accounting Officer of DaVita HealthCare Partners, Inc., the parent company and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care, Inc., which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC.*
>
> *We are submitting a Certificate of Need application to expand our Asheville Kidney Center by two ESRD dialysis stations. The project calls for a capital expenditure of $25,550. This letter will confirm that DaVita HealthCare Partners Inc. has committed cash reserves in the total sum of $25,550. for the project capital expenditure. DaVita HealthCare Partners Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina.*
>
> *…*"

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

In Section X.1, page 45, the applicant provides the facility's allowable charge per treatment by payment source:

AKC Allowable Charge per Treatment by Payor Source	
Medicare	$240.00
Medicaid	$143.00
Medicare/Medicaid	$240.00
Commercial Insurance	$1,175.00
VA	$193.00
Medicare/Commercial Insurance	$240.00

The applicant notes that the reimbursement rates above are the same whether the treatment is performed in-center or done at home by home-trained patients.

In Section X.2, page 46, and Section X.4, page 49, the applicant provides projected revenues and operating costs (expenses), as illustrated in the following table:

Asheville Kidney Center		
	Operating Year 1	**Operating Year 2**
Total Net Revenue	$10,715,454	$10,940,324
Total Operating Costs	$8,251,763	$8,433,687
Net Profit	$2,463,691	$2,506,637

Although the net revenues are projected to exceed total operating costs in each of the first two operating years, revenues and expenses are not based on reasonable and supported assumptions regarding projected utilization. Specifically, the applicant bases the projections on utilization of the proposed stations by in-center patients; however, the proposed stations are not proposed to serve in-center patients. See Criterion (3) for discussion regarding need and projected utilization which is hereby incorporated by reference as if set forth fully herein. Therefore, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, the application is nonconforming 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.

NC

The applicant, AKC, proposes to add two certified dialysis station to the existing facility to be utilized as home hemodialysis stations for training and support.

In Section IV.1, page 23, the applicant documents 33 home hemodialysis patients being served on two existing home hemodialysis stations as of June 30, 2013. The applicant discusses projections for the home hemodialysis patient population in Section III.7, pages 20-21, of the application. The applicant states that it projects no growth in the home hemodialysis population and projects the home hemodialysis patient population at the end of Operating Year to remain at 33. The applicant provides no information to demonstrate that the existing patient population is not adequately served by the existing home hemodialysis stations.

Additionally, the applicant does not adequately demonstrate that the patients proposed to be served need two additional home hemodialysis stations. See the discussion regarding need in Criterion (3) which is hereby incorporated by reference as if set forth fully herein. Therefore, the applicant did not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing and approved home hemodialysis training and support services. Consequently, the application is nonconforming 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 AKC as provided by the applicant in Section VII.1, page 34:

AKC Projected Staffing	
Position	**Total FTEs**
RN	9
HTRN	2
PCT	21
Bio-Med Tech	1.5
MD	
Admin	1
Dietician	1.5
Social Worker	1.5
Unit Secretary	3
Other-Reuse	3
Total	**43.5**

As shown in the above table, the applicant proposes to employ a total of 43.5 full-time equivalent (FTE) positions to staff the AKC facility upon completion of the proposed project. The medical director is a contract position. In Section VII.2, pages 34-35, the applicant states:

> *"... The Regional Operations Director is responsible for the overall operation of the facility and serves as liaison to the governing body. He is also responsible for ensuring compliance with 42 C.F.R. and budgetary compliance.*
>
> *... The UA is responsible for the quality dialysis care for all patients in the facility on a daily basis through planning and teammate scheduling. The UA ensures that patients are properly assessed through physician rounds, patient monitoring and charting. The UA also ensures that direct patient care is provided. The UA also supervises orientation and training of new teammates and ensures that teammates adhere to facility policies and procedures. ..."*

The following table shows the projected number of direct care staff for each shift offered at AKC:

AKC Direct Care Staff Per Shift							
	Shift Times	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
Morning	6am to 11am	13	13	13	13	13	13
Afternoon	11am to 4pm	13	13	13	13	13	13
Evening	4pm to 8pm	3	0	3	0	3	0

In Section V.4(c), page 27, the applicant states that John Manley, M.D., currently serves as medical director and has expressed his willingness to continue in that role. Exhibit 12 contains a letter signed by Dr. Manley, expressing support for the expansion of the dialysis facility by two stations and agreeing to continue as the medical director for the facility. In Section VII.2, page 35, the applicant states Dr. Manley is board-certified in nephrology with several years of experience in the care of ESRD patients.

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

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

C

In Section V.1, pages 25-26, the applicant provides a list of providers of the necessary ancillary and support services. The applicant states that acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services, blood bank services, and vascular surgery will be provided by Mission Hospitals. Transplantation services for AKC patients are provided by Duke University Medical Center, Piedmont Hospital, Carolinas Medical Center, Emory, and Wake Forest University Hospital. Dr. John Manley, a board-certified nephrologist, is the medical director of AKC and expressed support for the project in Exhibit 12. 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;

C

In Section VI.1(a), page 30, the applicant states:

> *"Asheville Kidney Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age,*

handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay."

In Section VI.1(b), page 30, the applicant reports that 80.4% of the patients who received treatments at AKC had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source for the existing facility:

AKC – Current Payor Mix	
Source of Payment	**Percentage**
Medicare	13.8%
Medicaid	7.9%
Medicare/Medicaid	27.5%
Commercial Insurance	12.2%
VA	7.4%
Medicare/Commercial	31.2%
Total	**100.0%**

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Buncombe 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)***
Buncombe County	36%	16.1%	18.3%
Statewide	17%	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 dialysis services offered by AKC. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

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

OSBM's website does not include information on the number of handicapped persons.

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

> "*The December 31, 2011 prevalent population included 430,273 patients on dialysis ...*"[1] (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 of primary Medicare coverage, compared to just 53 percent of those with a transplant*."(p. 216)

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

[1] www.usrds.org/adr.aspx

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

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

The 2013 United States Renal Data System (USRDS) Annual Data Report 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%**

*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 332.

AKC 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 applicant;

C

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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 31, the applicant states:

> *"Asheville Kidney Center has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993."*

In Section VI.6(a), page 33, the applicant states, *"There have been no civil rights equal access complaints filed within the last 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(c), page 31, the applicant provides the projected payor mix for the proposed services at the new facility as follows:

AKC – Projected Payor Mix	
Source of Payment	**Percentage**
Medicare	13.8%
Medicaid	7.9%
Medicare/Medicaid	27.5%
Commercial Insurance	12.2%
VA	7.4%
Medicare/Commercial	31.2%
Total	**100.0%**

The applicant projects no change from the current AKC payor mix as stated in Criterion (13a) above.

In Section VI.1(a), page 30, the applicant states,

> *"Asheville Kidney Center does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. Asheville Kidney Center works with patients who need transportation, when necessary."*

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(a), page 32, the applicant states:

> *"Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Asheville Kidney Center. These referrals most commonly come from primary care physicians or specialty physicians in Buncombe and Henderson Counties. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact Asheville Kidney Center directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Asheville Kidney Center catchment area requesting transfer to this facility are processed in accordance with the Asheville Kidney Center transfer and transient policies which comprise* ***Exhibit 13****. The patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary."* (emphasis in original)

The applicant adequately demonstrates that it provides 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(a), page 27, the applicant states:

> "*Asheville Kidney Center serves as a clinical learning site for nursing students from AB Tech Community College in Asheville. The Area Health Education Center at Mission Hospitals has an ongoing renal education program that provides health care professionals with the opportunity to expand their knowledge of End Stage Renal Disease. See* ***Exhibit 11****. The facility also serves as a clinical learning site for the Patient Care Technician Training Program at McDowell Community College, located in Marion in McDowell County."* (emphasis in original)

While Exhibit 11 does not contain any information, because AKC is an existing facility, the information provided in Section V.3(a), page 27, is reasonable and credible and supports a finding of conformity to this criterion.

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

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

NC

According to the January 2014 SDR, there are two other dialysis facilities in Buncombe County—Swannanoa Dialysis Center in Swannanoa and Weaverville Dialysis in Weaverville. TRCNC is the owner of all three facilities. According to the January 2014 SDR, Swannanoa Dialysis Center is not currently being utilized. Weaverville Dialysis has a utilization rate of 53.75%. TRCNC proposes to add two certified dialysis station to the existing facility to be utilized as home hemodialysis stations for training and support. The applicant projects that 76% of the patients expected to utilize the proposed stations will be residents of Buncombe County.

In Section V.7, pages 28-29, the applicant discusses how any enhanced competition will have a positive impact on the cost effectiveness, quality, and access to the proposed home hemodialysis training and support services. 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 in the application regarding quality and access is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on 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 that it will continue to provide quality services; and

- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

However, the applicant did not adequately demonstrate that any enhanced competition includes a positive impact on the cost effectiveness of the proposed services based on the following analysis:

- The applicant did not adequately demonstrate the need that the proposed population to be served has for the additional stations. See Criterion (3) for discussion regarding need which is hereby incorporated by reference as if set forth fully herein.

- The applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of revenues and costs because projected revenues and costs are based, in part, on projected utilization. See Criterion (5) for discussion regarding projected utilization which is hereby incorporated by reference as if set forth fully herein.

- Development of stations that are not needed is not cost effective.

Therefore, the application is nonconforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, AKC operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) 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.

NC

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 not 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 the utilization rate is addressed in the January 2014 SDR provided in Exhibit 7. The January 2014 SDR utilization rate of 88% was calculated based on 176 in-center dialysis patients and 50 certified dialysis stations as of June 30, 2013 (176 patients / 50 stations = 3.52 patients per station; 3.52 patients per station / 4.00 patients per station = 0.88).

(2) Mortality rates;

-C- In Section IV.2, page 23, the applicant states that the mortality rates for years 2013, 2012, and 2011 are 15.3%, 15.4%, and 14.7%, respectively.

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

-C- In Section IV.3, page 23, the applicant states that AKC had 33 home hemodialysis trained patients.

(4) The number of transplants performed or referred;

-C- In Section IV.4, page 24, the applicant states AKC referred 23 patients for transplant evaluation in 2013 and four AKC patients received transplants in 2013.

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

-C- In Section IV.5, page 24, the applicant states that there are eight AKC patients currently on the transplant waiting list.

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

-C- In Section IV.6, page 24, the applicant states that there were 288 hospital admissions in 2013. 29 admissions were dialysis related and 259 were 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 IV.7, page 24, the applicant states that, as of December 31, 2013, there were five patients dialyzing at AKC with AIDS and two patients dialyzing with hepatitis B. Two patients with infectious disease converted to infection status during 2013.

(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- This application does not involve a new 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- The application does not involve a new facility.

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

-NA- The application does not involve a new or replacement facility.

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

-C- See Exhibit 8 for copies of written policies and procedures for back up for electrical service in the event of a power outage provided by the applicant.

(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 application does not involve a new 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 XI.6(g), page 55, the applicant states: *"Asheville Kidney Center has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health and safety requirements.* "

See Exhibit 22 for excerpts from the Health & Safety Policy and Procedure Manual and Exhibit 23 for the In-Service Calendar with mandatory training classes.

(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 in Section III.7, page 20, of the application as shown below:

Projected Dialysis Patient Origin - AKC						
County	Operating Year 1 2015		Operating Year 2 2016		County Patients as a Percent of Total	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Buncombe	182	25	187	25	95.4%	95.4%
Henderson	1	3	1	3	1.8%	1.8%
Rutherford	1	0	1	0	0.5%	0.5%
McDowell	0	2	0	2	0.9%	0.9%
Transylvania	0	2	0	2	0.9%	0.9%
Mitchell	0	1	0	1	0.5%	0.5%
Total	**184**	**33**	**189**	**33**	**100.0%**	**100.0%**

See Section III.7, pages 20-21, of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is hereby incorporated by reference as if set forth fully herein.

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

-NA- This application does not involve 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.1, page 12, the applicant states:

"Total Renal Care of North Carolina d/b/a Asheville Kidney Center will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is 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- This application does not involve a new 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.

-NC- In Section II.1, page 13, the applicant states that it projects to have a utilization rate of 88%, or 3.5 patients per station, at the end of operating year one. However, the applicant does not adequately demonstrate that the projected increase in patient population will be as a result of using the additional stations for their proposed purpose. The projected population increase is for in-center patients, but the proposed additional stations are to be utilized for home hemodialysis training and support. The applicant does not project any increase in the home hemodialysis patient population during operating years one and two. See further discussion on need, utilization, and methodology in Criterion (3) which is hereby incorporated by reference as if set forth fully herein.

.2204 SCOPE OF SERVICES

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

(1) diagnostic and evaluation services;

-C- The table in Section V.1, page 25, states patients will be referred to Mission Hospitals for diagnostic and evaluation services.

(2) maintenance dialysis;

-C- The table in Section V.1, page 25, states the applicant will provide in-center maintenance dialysis.

(3) accessible self-care training;

-C- The table in Section V.1, page 25, states the applicant will provide in-center hemodialysis self-care training.

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

-C- The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V.2(d), page 26:

> *"Asheville Kidney Center provides protocols and routines for patient follow-up. The social workers and dieticians contact the home-trained patients monthly. The patients are supported by*

monthly visits to their Board Certified Nephrologist for examination. The Home Training Nursing teammates perform monthly medication reviews, nursing assessments and laboratory review of blood work in order to continuously monitor the well being of home patients. Patient's blood chemistries are sent to a Medicare certified laboratory where they are analyzed. The results are reviewed by the teammates for adequacy and then reviewed by the dietitian and Nephrologist. Home trained patients are monitored by our Quality Management team."

(5) x-ray services;

-C- The table in Section V.1, page 25, states patients will be referred to Mission Hospitals for x-ray services.

(6) laboratory services;

-C- The table in Section V.1, page 25, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.

(7) blood bank services;

-C- The table in Section V.1, page 25, states patients will be referred to Mission Hospitals for blood bank services.

(8) emergency care;

-C- The table in Section V.1, page 25, states patients will be referred to Mission Hospitals for emergency care

(9) acute dialysis in an acute care setting;

-C- The table in Section V.1, page 25, states patients will be referred to Mission Hospitals for acute dialysis in an acute care setting.

(10) vascular surgery for dialysis treatment patients;

-C- The table in Section V.1, page 25, states dialysis patients will be referred to Mission Hospitals for vascular surgery.

(11) transplantation services;

-C- The table in Section V.1, page 25, states patients will be referred to Duke University Medical Center, Piedmont Hospital, Carolinas Medical Center, Emory, or Wake Forest University for transplantation services.

(12) vocational rehabilitation counseling and services; and

-C- The table in Section V.1, page 25, states patients will be referred to the North Carolina Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.

(13) transportation.

-C- The table in Section V.1, page 26, states patients will be referred to the Department of Social Services or Round A Bout transportation services.

.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 34, the applicant provides the proposed staffing for AKC. On the same page, the applicant states: *"The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100* [now 42 C.F.R. Section 494] *as evidenced below."* In Section VII.10, page 36, the applicant documents plans for three dialysis shifts. On the morning and afternoon shifts, the applicant provides direct care staffing of 13 FTE per shift, Monday through Saturday. On the evening shift, the applicant provides direct care staffing of 3 FTE per shift, on Mondays, Wednesdays, and Fridays.

(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 36, the applicant refers to Exhibit 16 for a copy of the training program outlines. Exhibit 16 contains a copy of DaVita's Training Programs for New Patient Care Provider Teammates. Exhibit 23 contains the AKC Annual In-Service Calendar.