

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 29, 2013  
PROJECT ANALYST: Fatimah Wilson  
SECTION CHIEF: Craig Smith

PROJECT I.D. NUMBER: F-10040-12 / DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center / Add 10 dialysis stations to the existing facility for a total of 35 stations upon completion of this project / Mecklenburg 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

DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center currently operates a 25-station dialysis facility located at 6620 Old Statesville Road, Charlotte, NC. The applicant proposes to add 10 dialysis stations to the existing facility for a total of 35 stations upon completion of this project.

The 2012 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of 15 dialysis stations in Mecklenburg County. However, there is no need determination for additional facilities, as some are operating below 80% capacity. As of December 31, 2011, subsequent to publication of the July 2012 SDR, four stations were pending certification pursuant to Project I.D. # F-8747-11. According to the Acute and Home Care Licensure and Certification Section, the four stations pending certification were certified as of September 6, 2012. The applicant is currently eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported for North Charlotte Dialysis Center in the July 2012 SDR is 4.86 patients per station. This utilization rate was calculated based on 102 in-center dialysis

patients and 21 certified dialysis stations (102 patients / 21 stations = 4.8571 patients per station). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

**ESRD Facility Need Methodology  
 October Review**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/2011		121.43%
Certified Stations		21
Pending Stations	Certified as of September 6, 2012	4
<b>Total Existing and Pending Stations</b>		<b>25</b>
In-Center Patients as of 12/31/2011 (SDR2)		102
In-Center Patients as of 6/30/2011 (SDR1)		85
Step	Description	
(i)	Difference (SDR2 - SDR1)	17
	Multiply the difference by 2 for the projected net in-center change.	34
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/2011	0.4000
(ii)	Divide the result of Step (i) by 12	0.0333
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July [2012] SDR (12/30/11) until the end of calendar year 2012 (12 months)	0.4000
(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	142.8000
(v)	Divide the result of Step (iv) by 3.2 patients per station	44.6250
	and subtract the number of certified and pending stations as recorded in SDR2 [10] to determine the number of stations needed	<b>20</b>

*[NOTE: "Rounding" to the nearest whole number is allowed only in ... Step ... (v). In these instances, fractions of 0.5000 or greater shall be rounded to the next highest whole number.]*

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."* As shown in the table above, based on the facility need methodology for dialysis stations, the number of stations needed is 20 stations, and the applicant proposes to add 10 new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2012 SMFP is applicable to this review. Policy GEN-3 states:

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

### Promote Safety and Quality

The applicant discusses its quality index in Section I, pages 7-8. Also, in Section II.3, pages 16-17, the applicant states:

*“DaVita, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development.*

...

*The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.*

...

*Dr. Joel Bruce serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the company’s Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian.*

...

*Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes.”*

The applicant also discusses its safety measures in Section XI.6(g), pages 53-54. In Exhibit 4, the applicant provides published articles about its clinical outcomes and a copy of an article which describes DaVita’s quality index. In Exhibit 10, the applicant provides a copy of its isolation policies and procedures, in Exhibit 18, a copy of the training manual for injury prevention and safety, and in Exhibit 19, a copy of its in-service training schedule. The

applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Mecklenburg County.

### Promote Equitable Access

In Section VI, pages 30-33, the applicant provides information about accessibility to North Charlotte Dialysis Center. On page 30, the applicant states,

*“North Charlotte Dialysis 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.”*

*North Charlotte Dialysis 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. North Charlotte Dialysis Center provides dialysis six days per week with two patient shifts per day to accommodate patient need. The facility also operates a third shift on Monday, Wednesday and Friday.*

*North Charlotte Dialysis 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. North Charlotte Dialysis Center works with patients who need transportation, when necessary.”*

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

### Maximize Healthcare Value

In Section III.9, pages, 21-22, the applicant states,

*“The North Charlotte Dialysis Center promotes cost-effective approaches in the facility in the following ways:*

- *The parent corporation, DaVita, operates over 1,500 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price.*
- *The North Charlotte Dialysis Center purchases all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*
- *The North Charlotte Dialysis Center utilizes the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are*

*purchased under a national contract in order to get the best quality dialyzer for the best price.*

- *The North Charlotte Dialysis Center has installed an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility is also done on computer which reduces the need for paper.*
- *The North Charlotte Dialysis Center Bio-medical Technician assigned to the facility conducts preventive maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule that reduces the need for repair maintenance and parts. This extends the life of the dialysis machines.*
- *The North Charlotte Dialysis Center also has an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders are done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly.”*

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served.

The application is consistent with Policy GEN-3.

The application is consistent with the facility need determination in the 2012 SMFP and Policy GEN-3. Therefore, the application is conforming with 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

DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center currently operates a 25-station dialysis facility located at located at 6620 Old Statesville Road, Charlotte, NC. The applicant proposes to add 10 dialysis stations to the existing facility for a total of 35 stations upon completion of this project. The July 2012 SDR indicates a total of 21 certified stations at North Charlotte Dialysis Center, as of June 25, 2012. Based on patient origin information provided in the table in Section III.7, page 20 of the application, the applicant does not propose any home training. In Section IV.3, page 23, the applicant states, “*The*

*Charlotte Dialysis Center provides home training for patients living in Mecklenburg County under an agreement with North Charlotte Dialysis Center.”*

**Population to be Served**

In Section IV.1, page 23, the applicant states the number of in-center patients served at North Charlotte Dialysis Center as of December 31, 2012 as follows:

County of Residence	# of Patients Dialyzing In-Center
Mecklenburg	99
Cabarrus	2
Gaston	1
Total	102

In Section III.7, page 20, the applicant provided the projected patient origin for North Charlotte Dialysis Center for the first two years of operation following completion of the project as follows:

COUNTY	OPERATING YEAR 1 2014	OPERATING YEAR 2 2015	COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER PATIENTS	IN-CENTER PATIENTS	YEAR 1	YEAR 2
Mecklenburg	113	119	97.4%	97.5%
Cabarrus	2	2	1.7%	1.6%
Gaston	1	1	0.9%	0.9%
TOTAL	116	122	100.0%	100.9%

The project analyst notes that the applicant states on page 20 of the application that 100% of the in-center patients at the facility for the first two years of operation following completion of the project are from Mecklenburg County. The applicant did not provide percentages to account for the two patients from Cabarrus County or the one patient from Gaston County. The project analyst re-calculated the percentages as noted in the table above. The omission of these percentages by the applicant does not alter the need demonstrated by the applicant for the additional 10 stations.

The applicant adequately identifies the population it proposes to serve.

**Demonstration of Need**

In Section II, pages 12-13, the applicant provides the assumptions and methodology it used to project need for 10 additional dialysis stations at North Charlotte Dialysis Center. The applicant states:

*“The facility had 102 in-center patients as of December 31, 2011 based on the data reported in Table A of the July 2012 Semiannual Dialysis Report (SDR).*

*Of the 102 in-center patients cited in the SDR, 99 of the patients live in Mecklenburg County.*

*The July 2012 SDR indicates in Table B that Mecklenburg County has experienced an average annual change rate of 5.6% for the past five years.*

*The period of growth begins with July 1, 2012 through the projected operating year 2.*

*July 1, 2012-December 31, 2012 – 99 patients X 1.028 = 101.772*

*January 1, 2013-December 31, 2013 – 101.772 patients X 1.056 = 107.471232*

*January 1, 2014-December 31, 2014 – 101.471232 patients X 1.056 = 113.4896209*

*January 1, 2015-December 31, 2015 – 113.4896209 patients X 1.056 = 119.8450396*

*January 1, 2014-December 31, 2014 (operating year 1)*

*January 1, 2015-December 31, 2015 (operating year 2)*

*At the end of operating year one, the North Charlotte Dialysis Center is projected to have an in-center patient census of 116 patients (113 Mecklenburg County patients, 2 Cabarrus County patients and one Gaston County patient = 116 total patients for a utilization rate of 82.8% or 3.2 [3.3] patients per station. At the end of operating year two, the North Charlotte Dialysis Center is projected to have an in-center patient census of 122 patients (119 Mecklenburg County patients, 2 Cabarrus County patients and one Gaston County patient for a utilization rate of 87.1% or 3.5 patients per station. We did not calculate the growth of the patients residing outside of Mecklenburg County.”*

Projected patient utilization at the end of Year One equals 3.3 in-center patients per station per week which exceeds the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b); and the number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future growth.

#### Access

In Section VI, page 31, the applicant projects that greater than 57% of the patients at North Charlotte Dialysis Center will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for the underserved at North Charlotte Dialysis Center.

In summary, the applicant adequately identifies the population to be served and demonstrates the need for 10 additional dialysis stations based on the population it proposes to serve. Therefore, the application is conforming with 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.

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In Section III, pages 21-22, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant did not choose this alternative because North Charlotte Dialysis Center is rapidly growing. The facility is operating at 121% utilization and has a third shift as a result of capacity.
- 2) Add 10 Stations to the Existing Facility – The applicant chose this alternative to meet the growing demand for dialysis services at North Charlotte Dialysis Center. The applicant projects an annual growth rate of 5.6% with an accompanying 82.8% utilization rate by the end of the first operating year.

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 need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center shall materially comply with all representations made in its certificate of need application.**
- 2. DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center shall develop and operate no more than 10 additional dialysis stations for a total of 35 certified stations which shall include any isolation stations.**
- 3. DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center shall install plumbing and electrical wiring through the walls for no more than 10 additional dialysis stations for a total of no more than 35 dialysis stations which shall include any isolation stations.**
- 4. DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**

**5. DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis 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.

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In Section VIII.1, page 39, the applicant states that the capital cost is projected to be \$833,320. In Section IX.3, page 43, the applicant further states that there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 13 includes a letter dated September 17, 2012 from the Chief Accounting Officer of DaVita, Inc., the parent and owner of DVA Healthcare Renal Care, Inc., which states in part:

*“The project calls for a capital expenditure of \$833,320. This letter will confirm that DaVita Inc. has committed cash reserves in the total sum of \$833,320 for the project capital expenditure. DaVita Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to DVA Healthcare Renal Care, Inc.”*

In Exhibit 14, the applicant provides the audited financial statements for DaVita, Inc. for the fiscal year ended December 31, 2011. As of December 31, 2011, DaVita, Inc. had cash and cash equivalents totaling \$393,752,000 with \$8,892,172,000 in total assets and \$2,746,341,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds, if required, for the proposed project.

In Section X.1, page 44, the applicant projects the following charge per treatment for each payment source:

Payor	In-Center Charge
Medicare	\$192.00
Medicaid	\$192.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$800.00
VA	\$240.00
Medicare/Commercial	\$240.00

The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application. The applicant projects revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	Operating Year 1	Operating Year 2
Total Revenue	\$4,961,536	\$5,224,816
Total Operating Costs	\$4,461,214	\$4,664,842
Profit	\$500,322	\$559,974

Source: Application pages 44 and 47.

Assumptions:

1. Total number of treatment times 5% for missed treatments;
2. Times payor percentage; and
3. Times payor reimbursement.

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable.

In Section VII.1, page 34 and Section X pages 47-48, the applicant provides projected staffing and salaries. On page 34 and 53, the applicant states that North Charlotte Dialysis Center will continue to operate within the applicable laws and regulations pertaining to staffing. Staffing by shift is provided on page 37. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

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

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

C

The applicant proposes to add 10 dialysis stations to its existing facility for a total of 35 certified dialysis stations upon completion of the proposed project. According to the July 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of 15 dialysis stations in Mecklenburg County. However, there is no need determination for additional facilities, as some are operating below 80% capacity. Although the July 2012 SDR shows there is a deficit of 15 dialysis stations in Mecklenburg County, in this

application, the applicant is applying for additional stations based on the facility need methodology. According to the July 2012 SDR, North Charlotte Dialysis Center is one of 14 dialysis facilities in Mecklenburg County with utilization rates ranging from 39% to 121%. The applicant adequately demonstrates the need for 10 additional stations based on the number of in-center patients it currently serves and proposes to serve. Per the July 2012 SDR, as of June 25, 2012, the 21 station North Charlotte Dialysis Center facility was operating at 121.43% capacity ( $102 / 21 = 4.8571$ ;  $4.8571 / 4 = 1.2143$  or 121.43%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. Based on the calculations above, the applicant is eligible to expand its facility and may apply for additional stations. Upon completion of the proposed project, the facility will have 35 stations serving 116 patients (end of year 1) which is a utilization rate of 82.86% ( $116 / 35 = 3.31$ ;  $3.45 / 4 = .8286$  or 82.86%). Therefore, the applicant is conforming with the required performance standard in 10A NCAC 14C .2203.

The applicant adequately demonstrates that the proposal would 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

In Section VII.1, page 34, the applicant provides the current and projected number of full-time equivalent (FTE) positions for North Charlotte Dialysis Center following completion of the proposed project, as illustrated in the table below:

<i>Position</i>	<i>Current # of FTEs</i>	<i>Total Positions to be Filled</i>	<i>Total FTE Positions Upon Completion</i>
<i>RN</i>	<i>4.00</i>	<i>1.00</i>	<i>5.00</i>
<i>PCT</i>	<i>11.50</i>	<i>3.00</i>	<i>14.50</i>
<i>Bio-Med Tech</i>	<i>0.75</i>	<i>0.25</i>	<i>1.00</i>
<i>MD</i>			
<i>Admin.</i>	<i>1.00</i>	<i>0.00</i>	<i>1.00</i>
<i>Dietician</i>	<i>0.75</i>	<i>0.25</i>	<i>1.00</i>
<i>Social Worker</i>	<i>0.75</i>	<i>0.25</i>	<i>1.00</i>

<i>Unit Secretary</i>	<i>1.00</i>	<i>0.00</i>	<i>1.00</i>
<i>Other-Reuse</i>	<i>1.00</i>	<i>0.50</i>	<i>1.50</i>
<b>TOTAL</b>	<b>20.75</b>	<b>5.25</b>	<b>26.00</b>

As shown in the above table, the applicant proposes to employ a total of 26.0 full-time equivalent (FTE) positions to staff the North Charlotte Dialysis Center upon completion of the proposed project. In Section VII.1, page 34, the applicant states:

*“The Medical Director is not employed by the facility. There is a signed agreement between the facility and the Medical Director. The fee to be paid is estimated to be \$100,000 annually for the Medical Director responsibilities.”*

In Section V.4(c), page 27, the applicant states that Dr. Joel Bruce serves as the medical Director of the facility and his indicated his willingness to continue to serve.

In Section VII.10, page 37, the applicant provides the direct care staff for each shift offered in the facility as shown in the table below:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6:00am to 11:00am	9	9	9	9	9	9
Afternoon	11:00am to 4:00pm	9	9	9	9	9	9
Evening	4:00pm to 9:00pm	2	0	2	0	2	0

The applicant has documented 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, page 25, the applicant lists the providers of the necessary ancillary and support services. The applicant states the method for providing these services in response to 10A NCAC 14C .2204, page 14 of the application. Emergency care, diagnostic and evaluation services, x-ray services, blood bank services, acute dialysis in an acute care setting and transplantation services will be provided by Presbyterian Hospital. The other services will be provided at the individually stated facility.

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 (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.

C

The applicant proposes to renovate/construct 4,330 (3,158 new space and 1,172 renovation) square feet of space to the existing dialysis facility. In Section VIII.1, page 39, the applicant provides the estimated construction cost for the proposed project to include \$450,000 for construction costs and \$45,000 for architect and engineering fees. A cost estimate from an architect or engineer was not provided by the applicant to verify estimates provided in Section VIII. In Section XI.6(d), page 53, the applicant states that the facility is constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating and confirms that the expansion of the dialysis facility will continue to operate within the applicable laws and regulations pertaining to fire safety equipment, physical environment and other relevant health safety requirements. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the project proposed, and that the construction costs will not unduly increase costs and charges for health

services at North Charlotte Dialysis Center. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. Therefore, the application is conforming to this criterion.

- (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 discusses North Charlotte Dialysis Center's history of providing dialysis services to the underserved populations of North Carolina. The applicant states:

*"...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.*

*North Charlotte Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as handicapped. ...*

*North Charlotte Dialysis 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. ..."*

In Section VI.1, page 30, the applicant states that historically, 78.8 % of patients at North Charlotte Dialysis Center have some or all of their services paid for by Medicare or Medicaid and an additional 5.8 % are covered by VA. Thus, 84.6% of the center revenue is derived from government payors. The table below illustrates the current historical payor mix for the facility.

**Historical Payor Source**

<b>Payor Source</b>	<b>In-Center</b>
Medicare	26.0%
Medicaid	4.8%
Medicare/Medicaid	26.8%
Commercial Insurance	13.5%

VA	5.8%
Self/Indigent	1.9%
Medicare/Commercial	21.2%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Mecklenburg County 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>2008-2009 % Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)</b>
Mecklenburg	15.0%	5.1%	20.1%
Statewide	17.0%	6.7%	19.7%

Source: <http://www.ncdhhs.gov/dma/countyreports/index.htm>

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 North Charlotte Dialysis Center. In fact, only 5.8% of all 2011 Incident ESRD patients in North Carolina's Network 6 were under the age of 35.

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 and gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The Centers for Medicare & Medicaid Services (CMS) website states,

*“Although the ESRD population in less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...*

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population.*

*In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”<sup>1</sup>*

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010:

*“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy...”*

The report validates the statistical constancy reported by CMS above. Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

*“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”*

The report provides 2010 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	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender demonstrating the following:

<b>Number and Percent of Dialysis Patients by Age, Race and Gender</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%

<sup>1</sup> [www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorgainziations/downloads/esrdnetworkprogrambackgroundpublic.pdf](http://www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorgainziations/downloads/esrdnetworkprogrambackgroundpublic.pdf)

75+	1,872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6  
 Includes North Carolina, South Carolina and Georgia

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

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

C

In Section VI.1(f), page 31 applicant states:

*“North Charlotte Dialysis 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 does not anticipate any change to the future payor mix as indicated in this table.

<b>Payor Source</b>	<b>In-Center</b>
Medicare	26.0%
Medicaid	4.8%
Medicare/Medicaid	26.8%
Commercial Insurance	13.5%
VA	5.8%
Self/Indigent	1.9%
Medicare/Commercial	21.2%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, the applicant projects that 78.8% of all in-center patients will have some or all of their services paid for by Medicare or Medicaid with VA covering another 5.8%.

In Section VI.1(d), page 31, the applicant states, “The North Charlotte Dialysis Center maintains an open-door policy of accepting all patients, regardless of ability to pay, who develop end stage renal disease while residing in the service area of the North Charlotte Dialysis Center..” [emphasis in original]

In Section VI, page 32, the applicant states the facility design satisfies all state requirements and local building codes to allow equal access for handicapped patients and ensures access by these individuals by providing wheelchair ramps, handicapped bathrooms, wheelchair scales and ADA complaint doors.

The applicant demonstrates it will provide adequate access to elderly and medically underserved populations. 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 North Charlotte Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Mecklenburg County or transfer referrals from other Nephrologists outside of the immediate areas.*

...

*By policy, the North Charlotte Dialysis Center admits new patients only from a Board Certified Nephrologist with admission privileges as determined by Medical Staff Bylaws and who have agreed to provide Nephrology coverage for the patient.”*

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

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

### C

In Section V.3, page 27, the applicant states the North Charlotte Dialysis Center will provide access to any area health professional training programs upon execution of an agreement. The applicant states that the facility has an established Student Training Agreement with Everest Institute. The information provided in Section V.3 is reasonable and credible. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

### C

The applicant proposes to add 10 dialysis stations to its existing facility for a total of 35 certified dialysis stations upon completion of the proposed project. According to the July 2012 SDR, North Charlotte Dialysis Center is one of 14 dialysis facilities in Mecklenburg County with utilization rates ranging from 39% to 121%.

In Section V.7, page 28, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access.

The applicant states its proposal is not intended to be a competitive venture. The applicant further states:

*“The effect of other facilities in Mecklenburg County and surrounding counties would be difficult to determine since most patients from Mecklenburg County already receive treatment in established facilities operated by several different providers.*

*The effect upon competition is unknown. However, patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. The North Charlotte Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”*

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding 10 dialysis stations to the existing North Charlotte Dialysis Center facility will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- ◆ The applicant adequately demonstrates the need, based on “Facility Need”, to add 10 dialysis stations for a total of 35 certified dialysis stations upon completion of the proposed project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to North Charlotte Dialysis Center patients;
- ◆ The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 and VII, pages 25-26, 27-28, respectively, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.

On page 16, the applicant states, *“DaVita, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program.”*

- ◆ The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 30, the applicant states:

*“North Charlotte Dialysis 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.”*

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

The applicant currently provides dialysis services at North Charlotte Dialysis Center. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, North Charlotte Dialysis Center has operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

**10A NCAC 14C .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 IV.1, page 23, the applicant provides the utilization rate as reported in the July 2012 SDR (Exhibit 7, Tables A and B) of 121.43% with 4.56 ( $102 / 21 = 4.8571$ ) patients per station.
  - (2) Mortality rates;
    - C- In Section IV.2, page 23, the applicant provides the mortality rates as 16.3%, 6.7% and 8.0% for 2009, 2010 and 2011, respectively.

- (3) The number of patients that are home trained and the number of patients on home dialysis;
- NA- In Section IV.3, page 23, the applicant states, "*The Charlotte Dialysis Center provides home training for patients living in Mecklenburg County under an agreement with North Charlotte Dialysis Center.*" However, the applicant does not propose to have any home hemodialysis patients at the facility.
- (4) The number of transplants performed or referred;
- C- In Section IV.4, page 23, the applicant states North Charlotte Dialysis Center referred 41 transplants in 2011. One transplant was performed in 2011.
- (5) The number of patients currently on the transplant waiting list;
- C- In Section IV.5, page 24, the applicant states "*North Charlotte Dialysis 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.6, page 24, the applicant states that there were 124 total hospital admissions in 2011, 30 (24.2%) of which were dialysis related and 94 (75.8%) 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 there were five patients at the facility as of December 31, 2011 with an infectious disease.

(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- North Charlotte Dialysis Center 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- North Charlotte Dialysis Center is an existing facility.

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

-NA- North Charlotte Dialysis Center 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 8 for a copy of North Charlotte Dialysis Center's Power Supply Documentation and Backup Agreement which has policies and procedures for back-up electrical service 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- North Charlotte Dialysis Center 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 XI.6(g), page 53, the applicant states, "*North Charlotte Dialysis 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 safety requirements.” See also Sections II.3, pages 16-17; VII.2, pages 34-35 and, XI.6(e), page 53.*

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

-C- See Section III.7, pages 20-21 for the methodology and assumptions the applicant uses to project patient origin as presented in the following table:

County	Operating Year 1 2014	Operating Year 2 2015	County Patients as a Percent of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
Mecklenburg	113	119	97.4%	97.5%
Cabarrus	2	2	1.7%	1.6%
Gaston	1	1	0.9%	0.9%
<b>Total</b>	116	122	100.0%	100.0%

The project analyst notes that the applicant states on page 20 of the application that 100% of the in-center patients at the facility for the first two years of operation following completion of the project are from Mecklenburg County. The applicant did not provide percentages to account for the two patients from Cabarrus County or the one patient from Gaston County. The project analyst re-calculated the percentages as noted in the table above. The omission of these percentages by the applicant does not alter the need demonstrated by the applicant for the additional 10 stations.

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth 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- North Charlotte Dialysis Center is an existing 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, pages 11, the applicant states, “*DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis 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 rates for such services.”*

**10A NCAC 14C .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- North Charlotte Dialysis Center does not propose to establish a new End Stage Renal Disease 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 Sections II.1, pages 12-13 and Section III.7, page 20, North Charlotte Dialysis Center projects utilization of 116 patients as of the end of the first operating year (3.31 patients per station per week). Assumptions are provided in Section II.1, pages 11-13 and Section III.7, pages 20-21.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 12-13 and Section III.7, pages 20 -21. The applicant projects an increase in its current Mecklenburg County patient utilization using the county 5-year AACR.

**10A NCAC 14C .2204 SCOPE OF SERVICES**

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

(1) diagnostic and evaluation services;

-C- In Section V.1, page 25, the applicant states that diagnostic and evaluation services will be provided by Presbyterian Hospital.

(2) maintenance dialysis;

- C- In Section V.1, page 25, the applicant states that dialysis/maintenance will be provided by the applicant.
- (3) accessible self-care training;
- C- Based on patient origin information provided in the table in Section III.7, page 20 of the application, the applicant does not propose any home training. In Section IV.3, page 23, the applicant states, *“The Charlotte Dialysis Center provides home training for patients living in Mecklenburg County under an agreement with North Charlotte Dialysis Center.”*
- (4) accessible follow-up program for support of patients dialyzing at home;
- C- Based on patient origin information provided in the table in Section III.7, page 20 of the application, the applicant does not propose any home training. In Section IV.3, page 23, the applicant states, *“The Charlotte Dialysis Center provides home training for patients living in Mecklenburg County under an agreement with North Charlotte Dialysis Center.”*
- (5) x-ray services;
- C- In Section V.1, page 25, the applicant states that x-ray services will be provided by Presbyterian Hospital.
- (6) laboratory services;
- C- In Section V.1, page 25, the applicant states that laboratory services will be provided by Dialysis Laboratories.
- (7) blood bank services;
- C- In Section V.1, page 25, the applicant states that blood bank services will be provided by Presbyterian Hospital.
- (8) emergency care;
- C- In Section V.1, page 25, the applicant states that emergency care will be provided by Presbyterian Hospital.
- (9) acute dialysis in an acute care setting;
- C- In Section V.1, page 25, the applicant states that acute dialysis in acute care setting will be provided by Presbyterian Hospital.
- (10) vascular surgery for dialysis treatment patients;

- C- In Section V.1, page 25, the applicant states that vascular surgery will be provided by Presbyterian Hospital.
- (11) transplantation services;
- C- In Section V.1, page 25, the applicant states that transplantation services will be provided by Presbyterian Hospital.
- (12) vocational rehabilitation counseling and services; and
- C- In Section V.1, page 25, the applicant states that vocational rehabilitation services will be provided by the North Carolina Division of Vocational Rehabilitation Services.
- (13) transportation.
- C- In Section V.1, page 25, the applicant states that transportation services will be provided by DSS/Various Providers.

#### **10A NCAC 14C .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. In Section VII.2, pages 34-35, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.

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

- C- See Section VII.5, page 36 and Exhibits 12, 18 and 19.