

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 12, 2015

PROJECT ANALYST: Gloria C. Hale
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: J-10350-14 / DVA Healthcare Renal Care, Inc. d/b/a Durham West Dialysis Center / Add four dialysis stations for a total of 30 stations upon completion of this project and Project I.D. #J-10319-14 (relocate 3 dialysis stations)/ Durham 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 Durham West Dialysis Center proposes to add four dialysis stations for a total of 30 certified dialysis stations upon completion of this project and Project I.D. #J-10319-14 (relocate 3 dialysis stations).

Need Determination

The 2014 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 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Durham County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, Durham West Dialysis Center is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate is 3.38 patients per station or

84.48%. Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table. This utilization rate was calculated based on 98 in-center dialysis patients and 29 certified dialysis stations as of December 31, 2013 (98 patients / 29 stations = 3.38 patients per station).

2014 SMFP Facility Need Methodology

Required SDR Utilization Rate		80%
Center Utilization Rate as of 12/30/13		84.48%
Certified Stations		29
Pending Stations		
Total Existing and Pending Stations		29
In-Center Patients as of 12/31/13 (SDR2)		98
In-Center Patients as of 6/30/13 (SDR1)		95
Step	Description	
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.0632
(ii)	Divide the result of step (i) by 12	0.0053
(iii)	Multiply the result of step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.0632
(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	104.1895
(v)	Divide the result of step (iv) by 3.2 patients per station	32.5592
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	3.5592

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, Durham West Dialysis Center has a need for four additional stations. The applicant proposes to add four new stations and therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles, on 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

The applicant, a subsidiary of Fresenius Medical Care Holdings, Inc., describes how it believes its proposal will promote safety and quality in Section II.3, pages 22-23, Section XI.6(g), pages 66-67, and Exhibit 23.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section VI, page 38. The applicant states in Section VI, page 39, that the majority of its dialysis patients are covered by Medicare and Medicaid and projects that greater than 90% of its in-center dialysis treatments will be covered by government payors.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize health care value for resources expended in Section III.9, pages 30-31. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize healthcare value.

The applicant adequately demonstrates that projected volumes for the proposed service incorporate the basic principles in meeting the needs of the dialysis patients to be served. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The application is consistent with the facility need determination in the 2014 SMFP and *Policy GEN-3*. Therefore, the application is conforming to this criterion.

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

C

DVA Healthcare Renal Care, Inc. d/b/a Durham West Dialysis Center currently operates a 29-station dialysis facility located in Durham County. The applicant proposes to add four dialysis stations to the existing facility for a total of 30 certified dialysis stations upon completion of this project and Project I.D. #J-10319-14 (relocate 3 dialysis stations). The applicant will continue to provide home hemodialysis or peritoneal dialysis training and support at Durham West Dialysis Center. The July 2014 SDR reports that Durham West Dialysis Center is currently certified for 29 in-center dialysis stations and had 98 in-center patients as of December 31, 2013.

Population to be Served

In Section IV.1, page 32, and in Section III.7, page 28, the applicant identifies its current in-center and home-trained patient populations as illustrated in the following table:

COUNTY OF RESIDENCE	NUMBER OF IN-CENTER PATIENTS	NUMBER OF HOME TRAINED PATIENTS
Durham	85	12
Alamance	2	3
Orange	8	1
Granville	3	4
Chatham	0	1
Person	0	1
Pitt	0	1
Vance	0	2
Wake	0	4
Total	98	28

In Section III.7, page 22, the applicant projects patient origin for Durham West Dialysis Center for the first two operating years following the completion of the project. See the following table:

COUNTY OF RESIDENCE	OPERATING YEAR ONE 2016		OPERATING YEAR TWO 2017		COUNTY PATIENTS AS A % OF TOTAL	
	In-Center Patients	Home Trained Patients	In-Center Patients	Home Trained Patients	YEAR 1	YEAR 2
Durham	83	5	85	5	77.8%	78.3%
Alamance	2	3	2	3	4.4%	4.3%
Orange	3	4	3	4	8.0%	7.8%
Granville	8	1	8	1	6.2%	6.1%
Chatham	0	1	0	1	0.9%	0.9%
Person	0	1	0	1	0.9%	0.9%
Vance	0	2	0	2	1.8%	1.7%
Wake	0	0	0	0	0.0%	0.0%
Totals	96	17	98	17	100.0%	100.0%

The applicant adequately identifies the population to be served.

Analysis of Need

In Section III.2, page 24, the applicant applies the facility need methodology in the 2014 SMFP utilizing data from the July 2014 SDR, and proposes to add four dialysis stations to Durham West Dialysis Center for a total of 30 dialysis stations upon completion of this project and Project I.D. #J-10319-14 (relocate 3 stations). The applicant provides its assumptions and methodology in Section III, pages 24-30, summarized as follows:

- The facility had 98 in-center patients and 29 certified dialysis stations as of December 31, 2013, as reported in Table A of the July 2014 SDR.
- The table in Section III.2, page 24, indicates that the facility is eligible for four additional dialysis stations based on facility need methodology. The discussion of the application of the facility need methodology found in Criterion (1) is incorporated herein by reference.
- Durham West Dialysis Center is located in Durham County, which has a Five Year Average Annual Change Rate (AACR) of 2.4%, as reported in Table B of the July 2014 SDR.
- Of the 98 in-center patients as of December 31, 2013, 85 were from Durham County, two were from Alamance County, three were from Granville County, and eight were from Orange County.

- The Five Year AACR for Durham County of 2.4% is applied to the Durham County patients only as follows:

January 1, 2014 – December 31, 2014 - 85 patients X 0.024 = 87.04

January 1, 2015 – December 31, 2015 - 87.04 patients X 0.024 = 89.13

- No growth is calculated for the in-center patients from Alamance, Granville, or Orange counties, therefore the total projected number of in-center patients is 102 on December 31, 2015, illustrated as follows:

89 from Durham County
2 from Alamance County
3 from Granville County
+ 8 from Orange County
102 in-center patients

- The applicant states, on page 27, that three stations will be relocated and seven in-center patients will be transferred from Durham West Dialysis Center to East Durham Dialysis (Project I.D. #J-10319-14). The East Durham Dialysis facility is projected to be certified on January 1, 2016. Therefore, Durham West Dialysis Center is projected to have 95 in-center patients ($102 - 7 = 95$) and 26 certified stations ($29 - 3 = 26$) on January 1, 2016.
- The applicant projects the total number of in-center patients for the end of Operating Year One and Operating Year Two as follows:

89 in-center patients from Durham County as of January 1, 2016

Subtract 7 in-center patients (all from Durham County) who will transfer from Durham West Dialysis Center to East Durham Dialysis ($89 - 7 = 82$)

Operating Year One, January 1, 2016 – December 31, 2016:

82 patients X 0.024 (Durham County Five Year AACR) = 83.97

Add 13 patients from Alamance, Granville, and Orange Counties for a total of 96 in-center patients as of December 31, 2016 ($83.97 + 13 = 96.97$). The applicant states, on page 28, it will round down to the nearest whole number.

Operating Year Two, January 1, 2017 – December 31, 2017:

83.97 patients X 0.024 (Durham County Five Year AACR) = 85.98

Add 13 patients from Alamance, Granville, and Orange Counties for a total of 98 in-center patients as of December 31, 2017 ($85.98 + 13 = 98.98$).

Therefore, by the end of Operating Year One, the applicant projects to serve a total of 96 in-center dialysis patients on 30 stations for a projected utilization rate of 3.2 patients per station ($96 \text{ in-center patients} / 30 \text{ stations} = 3.2$) which meets the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C .2203(b).

In addition, the applicant proposes to continue to serve both home hemodialysis and home peritoneal dialysis patients and provides its assumptions and methodology for the proposed home-trained patients on pages 28 – 30, summarized as follows:

- Durham West Dialysis Center begins with 28 home-trained patients as of December 31, 2013, based on the December 2013 ESRD facilities Data Collection Form. The applicant's home-trained patients are from eight counties as follows:

- 12 patients from Durham County
- 3 patients from Alamance County
- 4 patients from Granville County
- 1 patient from Orange County
- 1 patient from Chatham County
- 1 patient from Person County
- 2 patients from Vance County
- 4 patients from Wake County

- The applicant calculates the average Five Year AACR based on each of the counties' Five Year AACRs from the July 2014 SDR, as follows:

County	Five Year AACR
Durham	2.40%
Alamance	2.80%
Granville	8.10%
Orange	-3.20%
Chatham	2.60%
Person	4.30%
Vance	0.90%
Wake	4.10%
Total	22.00%
Average	$22/8 = 2.75\%$

- The average Five Year AACR of 2.75% is applied to project the number of home-trained patients for 2014 and 2015 as follows:

January 1, 2014 – December 31, 2014 - $28 \text{ patients} \times 0.0275 = 28.77$

January 1, 2015 – December 31, 2015 - $28.77 \text{ patients} \times 0.0275 = 29.56$

- The applicant subtracts 12 home-trained patients who will transfer to East Durham Dialysis (Project I.D. #J-10319-14) on January 1, 2016. Therefore, the number of home-trained patients at the start of Operating Year One is 17 ($29 - 12 = 17$).
- The average Five Year AACR of 2.75% is applied to project the total number of home-trained patients in Operating Years One and Two, as follows:

January 1, 2016 – December 31, 2016 - $17 \text{ patients} \times 0.0275 = 17.47$

January 1, 2017 – December 31, 2017 - $17.46 \times 0.0275 = 17.95$

- The applicant states, on page 30, that it rounds down to the nearest whole number, therefore, Durham West Dialysis Center is projected to have 17 home-trained patients at the end of Operating Year One and 17 home-trained patients at the end of Operating Year Two.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth of Durham County patients at Durham West Dialysis Center. The applicant adequately demonstrates the need to add four dialysis stations.

Access to Services

In Section VI.1, page 38, the applicant states:

“Durham West 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.”

The applicant projects 90.9% of its patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the service area, including the medically underserved, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need for four additional dialysis stations at Durham West Dialysis Center, and adequately demonstrates the extent to which all residents in the service area, in particular underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section III.9, page 30, the applicant discusses one alternative it considered other than the proposal to add four dialysis stations. The alternative considered was to maintain the status quo. The applicant states that this alternative was dismissed because demand at the facility is growing and therefore doing nothing would not meet the demand.

The applicant adequately demonstrates the need for four additional dialysis stations based on the continued growth of the ESRD patient population of Durham County and the facility's projected utilization. The discussion regarding need found in Criterion (3) is incorporated herein by reference. Furthermore, the application is conforming to all other statutory and regulatory review criteria. An application that is not approvable cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the 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 Durham West Dialysis Center shall materially comply with all representations made in the certificate of need application.**
- 2. Prior to issuance of the certificate of need, DVA HealthCare Renal Care, Inc. d/b/a Durham West Dialysis Center shall provide the CON Section with a copy of a letter from Dr. Stephen Smith indicating his willingness to continue to serve as medical director of Durham West Dialysis Center.**
- 3. Prior to issuance of the certificate of need, DVA HealthCare Renal Care, Inc. d/b/a Durham West Dialysis Center shall provide the CON Section with documentation of an ongoing program of training for nurses and technicians in dialysis techniques at Durham West Dialysis Center.**

4. **DVA Healthcare Renal Care, Inc. d/b/a Durham West Dialysis Center shall develop no more than four additional dialysis stations at Durham West Dialysis Center for a total of no more than 30 dialysis stations upon completion of this project and Project I.D. #J-10319-14 (relocate 3 stations), including any home hemodialysis or isolation stations.**
 5. **DVA Healthcare Renal Care, Inc. d/b/a Durham West Dialysis Center shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations.**
 6. **DVA Healthcare Renal Care, Inc. d/b/a Durham West Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, pages 48, the applicant states there will be no capital cost for the project.

In Section IX, page 53, the applicant indicates that there will be no start-up or initial operating expenses associated with this project.

The applicant provides the audited financial statements for DaVita Healthcare Partners Inc. in Exhibit 19. The report shows that, as of December 31, 2013, DaVita Health Care Partners Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$4,605,541,000 in net assets (total assets less total liabilities).

In Section X.1, page 54, the applicant projects the following charges per treatment for each payment source as follows.

DURHAM WEST DIALYSIS CENTER	
PAYMENT SOURCE	IN-CENTER CHARGE
Medicare	\$239.02
Medicaid	\$143.00
Medicare/Medicaid	\$239.02
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.02

The applicant projects net revenue in Section X.2, page 55, and operating expenses in Section X.4, page 59, of the application. The applicant projects revenues will exceed expenses in each of the first two operating years (OY) following completion of the project, as illustrated in the following table:

DURHAM WEST DIALYSIS CENTER		
	OY1 (CY 2016)	OY2 (CY 2017)
Total Projected Net Revenue	\$5,208,706	\$5,273,901
Total Projected Operating Costs	\$4,661,254	\$4,759,202
Projected Net Profit	\$547,452	\$514,699

In Section X.3, pages 54, 56-58, the applicant provides the following assumptions to project revenue for OY1 and OY2:

Assumptions

1. With regard to the first operating year, an average of 95.5 in-center patients and 17 home patients are used to project revenues. The number of in-center patients is based on 95 patients treated at the beginning of the year with growth during the year to 96 in-center patients. The number of home patients is based on 17 patients treated at the beginning of the year with growth during the year rounded down to 17 patients.
2. With regard to the second operating year, an average of 97 in-center patients and 17 home patients are used to project revenues. The number of in-center patients is based on 96 in-center patients treated at the beginning of the year with growth during the year to 98 in-center patients. The number of home patients is based on 17 patients treated at the beginning of the year with growth during the year rounded down to 17 patients.
3. For both operating years and for both in-center and home patients, the total number of treatments includes the number of patients multiplied by an average of three treatments per week, per patient, for 52 weeks;
4. For both operating years and for both in-center and home patients, the total number of treatments is reduced by five percent to account for missed treatments; and
5. For both operating years and for both in-center and home patients, the average reimbursement per treatment is based on the applicant's historical experience and expected future reimbursement.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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

DVA Healthcare Renal Care, Inc., d/b/a Durham West Dialysis Center proposes to add four dialysis stations to the existing facility for a total of 30 certified dialysis stations upon the completion of this project and Project I.D. #J-10319-14 (relocate 3 stations). The applicant does not propose to establish a new facility. The applicant adequately demonstrates the need for four additional stations based on the number of in-center patients it proposes to serve. The discussion regarding need found in Criterion (3) is incorporated herein by reference.

According to Table A in the July 2014 SDR, as of December 31, 2013, Durham West Dialysis Center was operating at 84.48% of capacity, with 98 in-center patients on 29 stations ($98 / 29 = 3.38$; $3.38 / 4 = 0.845$). The target utilization rate is 80% or 3.2 patients per station, per week, at the end of the first operating year. Therefore, the applicant is eligible to expand its facility and may apply for additional stations, consistent with the facility need methodology in the 2014 SMFP. In Section III.7, page 26, the applicant states that at the end of Operating Year One, the facility will have 30 stations serving 96 patients, which is a utilization rate of 80% ($96 / 30 = 3.2$; $3.2 / 4 = 0.80$).

Durham West Dialysis Center is one of nine existing or approved dialysis facilities located in Durham County. Of the nine facilities, only eight were operational as of December 31, 2013 as indicated in the July 2014 SDR. The applicant operates three dialysis centers in Durham County, Duke University Hospital operates one, and BioMedical Applications (BMA), a subsidiary of Fresenius Medical Care (FMC), operates four, as illustrated in the following table:

Facility	Location	Number of Certified Stations 12/31/2013	Utilization Rate 12/31/2013	Patients Per Station
Duke Hospital Dialysis	Durham	16	79.69%	3.19
Durham Dialysis (DaVita)	Durham	24	94.79%	3.79
Durham West Dialysis (DaVita)	Durham	29	84.48%	3.38
FMC Dialysis Briggs Avenue	Durham	29	68.97%	2.76
FMC Dialysis West Pettigrew	Durham	20	76.25%	3.05
FMC South Durham Dialysis	Durham	12	97.92%	3.92
Freedom Lake Dialysis Unit (BMA)	Durham	22	81.82%	3.27
Southpoint Dialysis (DaVita)	Durham	12	97.92%	3.92
East Durham Dialysis*	Durham	0	0.00%	0.00

Source: July 2014 SDR, Table A, page 11.

*According to the July 2014 SDR, Table A, page 11, East Durham Dialysis is a “Proposed new site consisting of existing stations”.

As shown in the table above, as of December 31, 2013, five of the eight operational Durham County dialysis facilities were operating above 80% utilization (3.2 patients per station), and all eight were operating above 75% utilization (3.0 patients per station).

Table B of the July 2014 SDR indicates there are no additional dialysis stations needed in Durham County. The county need methodology requires that there be a deficit of at least 10 stations and that all existing facilities operate at or above 80% capacity. However, the applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported is 84.48%. The applicant adequately demonstrates the need to develop four additional dialysis stations at the existing Durham West Dialysis facility based on the number of in-center patients projected to utilize the facility.

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

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

In Section VII.1, page 44, the applicant provides the current and projected number of full-time equivalent (FTE) positions as shown in the following table:

DURHAM WEST DIALYSIS CENTER		
POSITION	NUMBER OF CURRENT FTES	TOTAL FTES
Registered Nurse	1.5	1.5
HTRN	1.0	1.0
Patient Care Technician	12.0	12.0
Bio-Medical Technician	0.5	0.5
Administrator	1.0	1.0
Dietician	1.0	1.0
Social Worker	1.0	1.0
Unit Secretary	1.0	1.0
Total	19.0	19.0

As shown in the table above, the applicant proposes to continue to employ a total of 19.0 full-time equivalent (FTE) positions to staff Durham West Dialysis Center upon completion of the proposed project and Project I.D. #J-10319-14 (relocate 3 stations). In Section V.4, page 36, the applicant states that Dr. Stephen Smith will continue to serve as medical director of the facility and refers to Exhibit 13. There is no documentation in Exhibit 13. The applicant does not provide written documentation of Dr. Smith's commitment to continue to serve the facility as medical director.

The applicant adequately demonstrates the availability of sufficient health manpower, but does not demonstrate the availability of sufficient management personnel for the services proposed to be provided. Therefore, the application is conforming to this criterion subject to Condition 2 found at the end of Criterion (4).

- (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 Sections V.1 and V.2, on pages 34-35, the applicant lists the providers of the necessary ancillary and support services that will serve the patients dialyzing at Durham West Dialysis Center. Duke University Medical Center provides the following services: emergency care, acute hemodialysis, diagnostic evaluation, transplantation, X-ray, blood bank, pediatric nephrology, and vascular surgery. The other services are provided by the individual providers listed in the table provided on page 34. The applicant discusses coordination with the existing health care system in Section V.2-V.6, pages 35-37, and states that it has established relationships with many agencies in Durham County and the surrounding counties.

The information the applicant provides in those sections is reasonable and adequately supports a finding of conformity to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.1, page 38, the applicant states,

“Durham West 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.”

The applicant’s dialysis policies, procedures and guidelines with regard to accepting patients for dialysis care are provided in Exhibit 14.

In Section VI.1, page 38, the applicant reports that 90.9% of the patients who received treatments at Durham West Dialysis Center had some or all of the services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payor mix for the facility, as reported by the applicant.

DURHAM WEST DIALYSIS CENTER HISTORICAL PAYOR MIX	
PAYOR SOURCE	PERCENTAGE
Medicare	29.6%
Medicaid	7.1%
Medicare/Medicaid	13.3%
Commercial Insurance	7.1%
VA	2.0%
Medicare/Commercial	40.9%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Durham 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 *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Durham County	15.6%	5.8%	20.1%
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 dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/31/2012*, page 99).¹

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

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

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

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show 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)

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

² www.usrds.org/adr.aspx

The 2013 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%

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

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

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

The applicant demonstrates that medically underserved populations currently have adequate access to services available at Durham West Dialysis Center. 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

³ www.esrdnetwork6.org/publications/reports.html

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 41, the applicant states, “*Durham West Dialysis Center has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons...*” In Section VI.6(a), page 42, 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 39, the applicant provides the projected payor mix for the proposed dialysis services at the facility, as follows:

Durham West Dialysis Center		
Source of Payment	In-Center Percentage	Home-Trained Percentage
Medicare	29.6%	7.7%
Medicaid	7.1%	0.0%
Medicare/Medicaid	13.3%	15.4%
Commercial Insurance	7.1%	19.2%
VA	2.0%	0.0%
Medicare/Commercial	40.9%	57.7%
Total	100.0%	100.0%

The applicant projects no change from the current payor mix for both in-center and home-trained patients. The applicant projects that 90.9% of its in-center patients and 80.8% of its home-trained patients will be Medicare or Medicaid recipients. The applicant demonstrates that the elderly and medically underserved populations will continue to have adequate access to the proposed dialysis 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, pages 41-42, the applicant describes the range of means by which patients will have access to the proposed dialysis services. Patients obtain access through referrals to a Nephrologist who has privileges at the facility. The information provided in Section VI.5 is reasonable and supports a finding of conformity 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.

CA

In Section V.3, page 36, and Exhibit 12, the applicant states that Durham West Dialysis Center has an existing clinical training agreement with Education Corporation of America d/b/a Virginia College. In addition, the applicant states it will provide access to area health training programs upon establishment of agreements. Exhibit 12 contains a copy of an agreement with Education Corporation of America d/b/a Virginia College.

The applicant adequately demonstrates that the facility will accommodate the clinical needs of area health professional training programs. Therefore, 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

DVA Healthcare Renal Care, Inc., d/b/a Durham West Dialysis Center proposes to add four dialysis stations to the existing facility for a total of 30 certified dialysis stations upon completion of this project and Project I.D. #J-10319-14 (relocate 3 stations). The applicant does not propose to establish a new facility. The applicant adequately demonstrates the need for four additional stations based on the number of in-center patients it proposes to serve. The discussion regarding need found in Criterion (3) is incorporated herein by reference.

According to Table A in the July 2014 SDR, as of December 31, 2013, Durham West Dialysis Center was operating at 84.48% of capacity, with 98 in-center patients on 29 stations (98 / 29

= 3.3793; $3.3793 / 4 = 0.8448$). The target utilization rate is 80% or 3.2 patients per station, per week, at the end of the first operating year. Therefore, the applicant is eligible to expand its facility and may apply for additional stations, consistent with the facility need methodology in the 2014 SMFP. In Section III.7, page 22, the applicant states that at the end of Operating Year One, the facility will have 30 stations serving 96 patients, which is a utilization rate of 80% ($96 / 30 = 3.2$; $3.2 / 4 = 0.80$).

Durham West Dialysis Center is one of nine existing or approved dialysis facilities located in Durham County. Of the nine facilities, only eight were operational as of December 31, 2013 as indicated in the July 2014 SDR. The applicant operates three dialysis centers in Durham County, Duke University Hospital operates one, and BioMedical Applications (BMA), a subsidiary of Fresenius Medical Care (FMC), operates four, as illustrated in the following table:

Facility	Location	Number of Certified Stations 12/31/2013	Utilization Rate 12/31/2013	Patients Per Station
Duke Hospital Dialysis	Durham	16	79.69%	3.19
Durham Dialysis (DaVita)	Durham	24	94.79%	3.79
Durham West Dialysis (DaVita)	Durham	29	84.48%	3.38
FMC Dialysis Briggs Avenue	Durham	29	68.97%	2.76
FMC Dialysis West Pettigrew	Durham	20	76.25%	3.05
FMC South Durham Dialysis	Durham	12	97.92%	3.92
Freedom Lake Dialysis Unit (BMA)	Durham	22	81.82%	3.27
Southpoint Dialysis (DaVita)	Durham	12	97.92%	3.92
East Durham Dialysis*	Durham	0	0.00%	0.00

Source: July 2014 SDR, Table A, page 11.

*According to the July 2014 SDR, Table A, page 11, East Durham Dialysis is a “Proposed new site consisting of existing stations”.

As shown in the table above, as of December 31, 2013, five of the eight operational Durham County dialysis facilities were operating above 80% utilization (3.2 patients per station), and all eight were operating above 75% utilization (3.0 patients per station).

Table B of the July 2014 SDR indicates there are no additional dialysis stations needed in Durham County. The county need methodology requires that there be a deficit of at least 10 stations and that all existing facilities operate at or above 80% capacity. However, the applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported is 84.48%.

In Section V.7, page 37, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“Durham County is a metropolitan area. The proposed expansion of the facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture.

...

The addition of four stations to the Durham West facility is focused on serving our every [sic] increasing patient population.

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. Durham West Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”

See also Sections II, III, V, VI and VII, in which the applicant discusses the cost-effectiveness, quality and access to the proposed services.

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

- The applicant adequately demonstrates the need for the proposed project and that the proposed project is a cost-effective alternative. The discussions regarding need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13), respectively, are incorporated herein by reference.

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 Durham West Dialysis Center. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during 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.

CA

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conditionally 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 Sections II.1 and III.7, pages 14 and 26, respectively, the applicant states the utilization rate was 84.48% or 3.38 patients per station ($98 / 29 = 3.38$) as of 12/31/2013.
- (2) *Mortality rates;*
-C- In Section IV.2, page 32, the applicant states the mortality rates were 10.2% in 2011, 6.0% in 2012, and 15.0% in 2013.
- (3) *The number of patients that are home trained and the number of patients on home dialysis;*
-C- In Section IV.3, page 33, the applicant states that there were 16 home-trained patients.

- (4) *The number of transplants performed or referred;*
-C- In Section IV.4, page 33, the applicant states that in 2013 Durham West Dialysis Center referred 15 patients for transplant evaluation and three patients received transplants.
- (5) *The number of patients currently on the transplant waiting list;*
-C- In Section IV.5, page 33, the applicant states that Durham West Dialysis Center has 23 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 33, the applicant states that there were 222 hospital admissions in 2013; 12.6% dialysis-related and 87.4% 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 33, the applicant states that there were no patients at the facility with an infectious disease or who had converted to infectious status in 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- Durham West Dialysis Center is an existing facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with 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- Durham West 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- Durham West 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 the policies and procedures for back-up electrical service in the event of a power outage for Durham West Dialysis Center.

(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- Durham West 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 52, the applicant states, “*Durham West 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.*” In addition, the applicant describes how it complies with applicable laws on page 53 and in Section VII.2, pages 44-45.

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

-C- In Section II.1, pages 14-20, and Section III.7, pages 26-30, the applicant provides the methodology and assumptions for projecting patient origin for both in-center and home-trained patients. Projected patient origin is presented in the following table:

COUNTY OF RESIDENCE	OPERATING YEAR ONE 2016		OPERATING YEAR TWO 2017		COUNTY PATIENTS AS A % OF TOTAL	
	In-Center Patients	Home Trained Patients	In-Center Patients	Home Trained Patients	YEAR 1	YEAR 2
Durham	83	5	85	5	77.8%	78.3%
Alamance	2	3	2	3	4.4%	4.3%
Orange	3	4	3	4	8.0%	7.8%
Granville	8	1	8	1	6.2%	6.1%
Chatham	0	1	0	1	0.9%	0.9%
Person	0	1	0	1	0.9%	0.9%
Vance	0	2	0	2	1.8%	1.7%
Wake	0	0	0	0	0.0%	0.0%
Totals	96	17	98	17	100.0%	100.0%

Also see the discussion regarding population to be served in Criterion (3) which is incorporated herein by reference.

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

-NA- Durham West 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, page 13, the applicant states, “DVA Healthcare Renal Care, Inc. d/b/a Durham West 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 rate 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- Durham West 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- Durham West Dialysis Center projects utilization at 3.2 patients per station per week as of the end of the first operating year. The methodology and assumptions used to project utilization are provided in Section II.1, pages 14-18, and Section III.7, pages 26-28. The discussion regarding need found in Criterion (3) is incorporated herein by reference.

(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 14-18, and Section III.7, pages 26-28. The discussion regarding need found in Criterion (3) is incorporated herein by reference.

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 34, the applicant states patients will receive diagnostic and evaluation services from Duke University Medical Center.

(2) maintenance dialysis;

-C- In Section V.1, page 34, the applicant states patients will receive maintenance dialysis services at the facility.

(3) accessible self-care training;

-C- In Section V.1, page 34, the applicant states that Durham West Dialysis Center provides self-care training in hemodialysis, CAPD and CCPD.

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

-C- In Section V.2, page 35, the applicant describes its follow-up program for support of patients dialyzing at home, including monthly contact by social workers and dieticians as well as monthly assessments and monitoring by the facility's Home Training Nurses.

(5) x-ray services;

- C- In Section V.1, page 34, the applicant states x-ray services will be provided by Duke University Medical Center.
- (6) *laboratory services;*
 - C- In Section V.1, page 34, the applicant states laboratory services will be provided by Dialysis Laboratories.
- (7) *blood bank services;*
 - C- In Section V.1, page 34, the applicant states blood bank services will be provided by Duke University Medical Center.
- (8) *emergency care;*
 - C- In Section V.1, page 34, the applicant states emergency care services will be provided by Duke University Medical Center.
- (9) *acute dialysis in an acute care setting;*
 - C- In Section V.1, page 34, the applicant states acute dialysis services will be provided by Duke University Medical Center.
- (10) *vascular surgery for dialysis treatment patients;*
 - C- In Section V.1, page 34, the applicant states vascular surgery services will be provided by Duke University Medical Center.
- (11) *transplantation services;*
 - C- In Section V.1, page 34, the applicant states transplantation services will be provided Duke University Medical Center and University of North Carolina Medical Center Chapel Hill.
- (12) *vocational rehabilitation counseling and services; and*
 - C- In Section V.1, page 34, the applicant states vocational rehabilitation counseling and services will be provided by the North Carolina Division of Vocational Rehabilitation Services.
- (13) *transportation.*
 - C- In Section V.1, page 34, the applicant states transportation services will be provided by the Department of Social Services.

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, on pages 44-45, the applicant states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

(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.

-CA-In Exhibit 17, the applicant provides an outline of its training program for new patient care provider teammates but does not provide documentation that an ongoing program of training for nurses and technicians in dialysis techniques will be provided at the facility. Therefore, the application is conforming to this Rule subject to Condition 3 found at the end of Criterion (4).