

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 8, 2016

Findings Date: January 8, 2016

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Martha J. Frisone

Project ID #: K-11081-15

Facility: Vance County Dialysis

FID #: 944655

County: Vance

Applicant(s): DVA Renal Healthcare, Inc.

Project: Add two dialysis stations for a total of 35 dialysis stations upon completion of this project and Project I.D. # K-10124-13 (relocate 16 existing stations from Vance County Dialysis to develop Kerr Lake Dialysis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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 Renal Healthcare, Inc. (DVA) d/b/a Vance County Dialysis (“the applicant”) proposes to add two dialysis stations for a total of 35 stations at Vance County Dialysis upon completion of Project I.D. # K-10124-13 (relocate 16 stations from Vance County Dialysis to develop Kerr Lake Dialysis) and this project.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is neither a deficit nor a surplus of dialysis stations in Vance County, thus the applicant cannot

apply to add additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Vance County Dialysis in the July 2015 SDR is 3.2449 patients per station, or 81.12% (3.2449 / 4 patients per station = 0.8112). This utilization rate was calculated based on 159 in-center dialysis patients and 49 certified dialysis stations (159 patients / 49 stations = 3.2449 patients per station).

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

Vance County Dialysis Center – October 1 Review – July 2015 SDR

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/14		81.1%
Certified Stations		49
Pending Stations		0
Total Existing and Pending Stations		49
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR2)		159
In-Center Patients as of 6/30/14 (Jan 2015 SDR) (SDR1)		155
Step	Description	
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.0516
(ii)	Divide the result of Step (i) by 12	0.0043
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	0.0516
(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	167.2065
(v)	Divide the result of Step (iv) by 3.2 patients per station	52.2520
	and subtract the number of certified and pending stations to determine the number of stations needed	3.2520

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

Policies

There is one policy in the 2015 SMFP which is applicable to this review. POLICY GEN-3: BASIC PRINCIPLES on page 38 of the 2015 SMFP is applicable to this review because the facility need methodology 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 describes how it believes the proposed project would promote safety and quality in Section B-4(a), pages 9-10, Section O, page 52, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B-4(b), page 10, Section C, page 16, Section L, pages 45-49 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B-4(c), page 11, Section F, pages 24-30, and Section N, page 51. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

Conclusion

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

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

C

The applicant proposes to add two new stations at Vance County Dialysis, an existing facility located at 854 S. Beckford Drive in Henderson. Upon completion of Project I.D. # K-10124-13 (relocate 16 stations from Vance County Dialysis to develop Kerr Lake Dialysis) and the proposed project, Vance County Dialysis will be certified for 35 dialysis stations.

Population to be Served

On page 351, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Vance County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 19, the applicant identifies the population served as of December 31, 2014, as illustrated below in the table:

VANCE COUNTY DIALYSIS Patient Origin December 31, 2014			
County	# of In-Center Patients	# of Home Dialysis Patients	# PD Patients
Vance	119	0	9
Granville	21	0	0
Warren	8	0	2
Franklin	5	0	1
Virginia	4	0	0
Halifax	1	0	0
Other States	1	0	0
TOTAL	159	0	12

In Section C-1, page 13, the applicant identifies the patient population it proposes to serve during the first two years of operation following completion of this project and Project I.D. # K-10124-13, as illustrated below in the table:

County	Operating Year 1 2017		Operating Year 2 2018		County Patients as Percent of Total	
	In- Center Patients	Peritoneal Dialysis Patients	In- Center Patients	Peritoneal Dialysis Patients	Year 1	Year 2
Vance	89	12	92	13	78.3%	78.9%
Granville	6	0	6	0	4.7%	4.5%
Warren	8	2	8	2	7.8%	7.5%
Franklin	5	1	5	1	4.7%	4.5%
Virginia	4	0	4	0	3.1%	3.0%
Halifax	1	0	1	0	0.8%	0.8%
Other States	1	0	1	0	0.8%	0.8%
TOTAL	114	15	117	16	100.0%	100.0%

Note: Vance County Dialysis does not provide home hemodialysis.

The applicant does not project to serve any home hemodialysis patients at Vance County Dialysis. The applicant provides the assumptions and methodology for the projections above on pages 13-15.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section C-2, page 15, the applicant refers the reader to Section B-2, page 7, where the applicant states the need for the proposed project is based on the facility need methodology. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference.

Projected Utilization

The applicant projects to serve 114 in-center dialysis patients at the end of the first operating year, which is 3.26 patients per station per week or an 81.4% utilization rate.

In Section C-1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Based on information in the July 2015 SDR, Vance County Dialysis had 159 in-center patients with a station utilization rate of 81.12%. This utilization was based on 159 in-center patients dialyzing on 49 stations. Eighty-nine of the 93 patients were residents of Vance County.
- The applicant proposed in Project I.D. # K-10124-13 to relocate 16 stations from Vance County Dialysis to develop Kerr Lake Dialysis. The applicant stated in the application that 37 in-center patients living in Vance County and 15 in-center patients living in Granville County would transfer their care to Kerr Lake Dialysis. The original certification date for Kerr Lake Dialysis was scheduled for January 1, 2015. Those stations at Kerr Lake Dialysis

have not been certified. The applicant assumes that those 52 patients (37 from Vance County + 15 from Granville County) will transfer on January 1, 2016.

- The applicant used a 3.2% growth rate to project future growth at Vance County Dialysis from January 1, 2015 – December 31, 2018. The applicant states the 3.2% is based on historical growth at Vance County Dialysis Center instead of the Five Year Average Annual Change Rate (AACR) for Vance County of 0.9%, as reported in the July 2015 SDR.
- The applicant projects to serve 25 patients who reside outside of Vance County. The applicant did not project growth for those 25 patients.
- The applicant projects to have 114 in-center patients by the end of Operating Year 1 (OY1) with a utilization rate of 81.4% or 3.26 patients per station per week and 117 in-center patients by the end of OY2, for a projected utilization rate of 83.6% or 3.34 patients per station per week.
- OY1 is Calendar Year 2017
- OY2 is Calendar Year 2018

The following table illustrates the historical growth rates for in-center dialysis services.

**VANCE COUNTY DIALYSIS
 HISTORICAL GROWTH RATE CALCULATIONS**

YEAR	# OF IN-CENTER PATIENTS	GROWTH RATE
12/31/14	159	2.6%
12/31/13	155	2.6%
12/31/12	151	5.6%
12/31/11	143	2.1%
12/31/10	140	-
5-yr AACR		3.2%

The applicant adequately demonstrates the use of a 3.2% annual growth rate for Vance County Dialysis is reasonable based on the historical growth at that facility.

The following table illustrates application of the assumptions and methodology.

VANCE COUNTY DIALYSIS

TIME PERIOD	CALCULATION
CY 2015	119 patients x 1.032 = 122.8
CY 2016	[122-37 (Transferring to Kerr Lake Dialysis) = 85] 85 x 1.032 = 87.82
CY 2017 (OY1)	87 x 1.032 = 89.784
CY 2018 (OY2)	89 x 1.032 = 92.657
Vance County patients only. Number of patients rounded down to nearest whole number.	

As shown in the table above, the applicant projects to serve 89 Vance County in-center patients in OY1 (2017) and 92 Vance County in-center patients in OY2 (2018). The following table includes the total in-center patient projections, including the 25 in-center patients from other counties and states.

VANCE COUNTY DIALYSIS

TIME PERIOD	CALCULATION
CY 2015	119 patients x 1.032 = 122 + 40 = 162
CY 2016	85 x 1.032 = 87.82 [40- 15 (Transferring to Kerr Lake Dialysis) = 25 87 + 25 = 112
CY 2017 (OY 1)	87 x 1.032 = 89.784 + 25 = 114
CY 2018 (OY 2)	89 x 1.032 = 92.657 + 25 = 117
All in-center patients, Vance County and the 14 patients from other counties and states. Number of patients rounded down to nearest whole number.	

As shown in the previous table, at the end of OY1 2017, the applicant projects an in-center patient census of 114 patients, which is a utilization rate of 81.4% or 3.26 patients per station per week at the end of OY1. At the end of OY2 2018, the applicant projects an in-center patient census of 117 patients, which is a utilization rate of 83.6% or 3.34 patients per station per week. The projected utilization of 3.26 patients per station per week for OY1 satisfies the 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth in the dialysis patient population in Vance County.

Peritoneal Dialysis

The applicant currently provides peritoneal dialysis (PD) but this project proposes additional in-center dialysis stations. See Section C, pages 15-16 for the applicant’s discussion of its PD services.

Access

In Section C-3, page 16, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap ... regardless of ethnic or socioeconomic situation.”

In Section L, page 49, the applicant provides its historical payor mix which indicates that Medicare and Medicaid represented 86.5% of all dialysis services in calendar year 2014. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by DVA and that the facility will conform to all federal, state and local codes and standards for handicapped access.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

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

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

NA

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

CA

In Section E-1, page 23, the applicant discusses the two alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would not support the growth rate at the facility.
2. Apply to add two stations – the applicant states the two-station expansion would help to meet the growing demand for dialysis services at Vance County Dialysis.

The applicant also considered a third shift but determined that a third shift would be inconvenient for patients; and a facility at maximum capacity eliminates patient choice. After considering the alternatives above, the applicant believes the most effective alternative is to add two stations to the existing facility to ensure adequate access for the dialysis patients of Vance County.

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

- 1. DVA Renal Healthcare, Inc. d/b/a Vance County Dialysis shall materially comply with all representations made in the certificate of need application.**

2. **DVA Renal Healthcare, Inc. d/b/a Vance County Dialysis shall add no more than two dialysis stations at Vance County Dialysis for a total of no more than 35 certified dialysis stations upon completion of Project I.D. # K-10124-13 (relocate 16 stations from Vance County Dialysis to develop Kerr Lake Dialysis) and this project, which shall include any home hemodialysis training or isolation stations.**
 3. **DVA Renal Healthcare, Inc. d/b/a Vance County Dialysis 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

The applicant proposes to add two dialysis stations to Vance County Dialysis, for a total of 35 dialysis stations at Vance County Dialysis upon completion of this project and Project I.D. # K-10124-13.

Capital and Working Capital Costs

In the table in Section F-1, page 25, the applicant states there are no capital costs associated with the proposed project. Additionally, in Section F-10, page 27, the applicant states that there are no working capital needs as Vance County Dialysis is an existing facility.

Financial Feasibility

The applicant projects revenues and expenses and provides assumptions in Section R, Form B, pages 1-2, as summarized below in the table:

VANCE COUNTY DIALYSIS		
Revenue and Expenses - Total Facility		
	OPERATING YEAR 1	OPERATING YEAR 2
	CY 2017	CY 2018
Gross Patient Revenue	\$ 6,702,280	\$ 6,890,645
Deductions from Gross Patient Revenue	(\$97,735)	(\$100,273)
Net Patient Revenue	\$ 6,604,544	\$ 6,790,372
Operating Expenses	\$ 4,210,537	\$ 4,316,278
Net Profit	\$ 2,394,007	\$ 2,474,094

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The applicant's projections of treatments and revenues are reasonable based on the number of in-center and PD patients projected for the first two operating years. The

discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section H, page 32, the applicant provides projected staffing and salaries. Form A in Section R, page 1, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add two stations to Vance County Dialysis for a total of 35 certified dialysis station at Vance County Dialysis upon completion of Project I.D. # K-10124-13 and this project.

On page 351, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Vance County. Facilities may also serve residents of counties not included in their service area.

Table A in the July 2015 SDR indicates there is one operational facility in Vance County and one facility pending certification, as illustrated in the table below:

DIALYSIS FACILITY	EXISTING AND APPROVED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Vance County Dialysis	49	159	3.24	81.12%
Kerr Lake Dialysis*	16	0	0	0.0%
Data reported in the July 2015 SDR, as of 12/31/14. *Certification Pending. The 16 stations are coming from Vance County Dialysis, which will have 33 stations once Kerr Lake Dialysis is certified.				

Both facilities are owned by DVA.

In Section C, page 13, the applicant provides the total projected patients by county of residence for the proposed project, as shown in the following table:

County	Operating Year 1 2017		Operating Year 2 2018		County Patients as Percent of Total	
	In- Center Patients	Peritoneal Dialysis Patients	In- Center Patients	Peritoneal Dialysis Patients	Year 1	Year 2
Vance	89	12	92	13	78.3%	78.9%
Granville	6	0	6	0	4.7%	4.5%
Warren	8	2	8	2	7.8%	7.5%
Franklin	5	1	5	1	4.7%	4.5%
Virginia	4	0	4	0	3.1%	3.0%
Halifax	1	0	1	0	0.8%	0.8%
Other States	1	0	1	0	0.8%	0.8%
TOTAL	114	15	117	16	100.0%	100.0%

Note: Vance County Dialysis does not provide home hemodialysis.

As shown in the previous table, at the end of OY1 2017, the applicant is projecting an in-center patient census of 114 patients, for a utilization rate of 81.1% or 3.26 patients per station per week (114 patients / 35 stations = 3.26 rounded; 3.26 / 4 = .8142 or 81.1%). At the end of OY2 2018, the applicant is projecting an in-center patient census of 117 patients for a utilization rate of 83.6% or 3.34 patients per station per week. The projected utilization of 3.2 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on growth of in-center patients at the facility.

The applicant adequately demonstrates the need to add two stations to Vance County Dialysis Center based on the number of in-center patients it proposes to serve. The discussion of analysis of need found in Criterion (3) is incorporated herein by reference. The discussion of competition found in Criterion (18a) is incorporated herein by reference.

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

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

C

In Section H, page 32, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for Vance County Dialysis Center. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	5.0	-	5.0
Technician (Patient Care)	14.0	-	14.0
Administrator	1.0	-	1.0
Dietician	1.0	-	1.0
Social Worker	1.0	-	1.0
Home Training RN	1.0		1.0
Bio-med Technician	1.0	-	1.0
Administrative Assistant	1.0	-	1.0
Total	25.0	0	25.0

As illustrated in the table above, the applicant does not project an increase in the total number of FTE positions at Vance County Dialysis Center.

In Section H-7, page 35, the applicant provides the projected direct care staff for Vance County Dialysis in Operating Year 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	5.0	2,080	10,400	3,120	3.3
Patient Care Tech	14.0	2,080	29,120	3,120	9.3
Total	19.0	2,080	39,520	3,120	12.6

In Section I-3(a), page 37, the applicant identifies Dr. Michael Berkoben, as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of an August 2015 letter signed by Dr. Berkoben of Duke University Medical Center, supporting the project and confirming his commitment to serve as Medical Director. In Section H-3, pages 33-34, the applicant states that vacant staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program.

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

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

In Section I-1, page 35, the applicant list the providers of the necessary ancillary and support services to be provided at the existing facility. The applicant discusses coordination with the existing health care system on pages 37-38. Exhibits I-1, and I-3 contain documents from DaVita Laboratory Services, Inc., and Dr. Berkoben (Medical Director), respectively, documenting availability of the necessary ancillary and support services. 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 care system. The information in Section I and corresponding exhibits is reasonable and 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 L-1, pages 45-46, the applicant states, *“Vance County Dialysis, by policy, makes dialysis services available to all residents in its service area. ... Vance County Dialysis helps uninsured, underinsured patients with identifying and applying for financial assistance; 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 addition, on pages 46-48, the applicant discusses its financial policies to help the above named classification of persons. In Section L-7, page 49, the applicant states that Medicare/Medicaid represented 86.5% of all dialysis services provided at Vance County Dialysis in calendar year 2014. The following table illustrates the historical payor sources for Vance County Dialysis:

PAYOR TYPE	% IN-CENTER PATIENTS	% OF PD PATIENTS	TOTAL PERCENT PATIENTS
Medicare	11.3%	8.3%	11.1%
Medicaid	6.9%	0.0%	6.4%
Commercial Insurance	10.7%	16.7%	11.1%
Medicare/ Commercial	34.6%	58.3%	35.3%
Medicare/Medicaid	34.0%	16.7%	32.7%
VA	2.5%	0.0%	2.3%
Total	100.0%	100.0%	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 Vance, Granville, Warren, Franklin and Halifax counties and statewide.

County	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) *
Vance	30.0%	13.4%	22.8%
Granville	15.0%	6.3%	18.4%
Warren	25.0%	12.6%	23.3%
Franklin	18.0%	7.3%	19.7%
Halifax	30.0%	15.7%	22.3%
Statewide	17.0%	6.7%	19.7%

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

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those persons who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).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. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*, provides prevalence data on North Carolina dialysis patients by age, race and gender, and is summarized as follows, on page 59:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	35.1%
Other, not specified	355	2.3%
Source: Southeastern Kidney Council Network6 Inc. 2014 Annual Report. ²		

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

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

C

In Section L-3(d), page 48, the applicant states:

“Vance County Dialysis 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. The facility has no obligation under the Hill Burton Act.”

In Section L-6, page 48, the applicant states, *“There have been no civil rights equal access 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 C-3, page 16, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. ...

Payment will not be required upon admission. 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 L-3(c), page 48, the applicant states:

“Vance County Dialysis makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.”

In Section L-1(b), page 46, the applicant reports that it expects 86.8% of the in-center patients who receive treatments at Vance County Dialysis to have all or part of their services paid for by Medicare and Medicaid, as indicated below in the table.

PAYOR TYPE	% IN-CENTER PATIENTS	% OF PD PATIENTS	TOTAL PERCENT PATIENTS
Medicare	11.3%	8.3%	11.1%
Medicaid	6.9%	0.0%	6.4%
Commercial Insurance	10.7%	16.7%	11.1%
Medicare/ Commercial	34.6%	58.3%	35.3%
Medicare/Medicaid	34.0%	16.7%	32.7%
VA	2.5%	0.0%	2.3%
Total	100.0%	100.0%	100.0%

On page 46, the applicant states it assumes the payor mix for Vance County Dialysis will remain the same as its historical payor mix.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L-4, page 48, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a nephrologist with privileges at Vance County Dialysis. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies, found at Exhibit L-3. ...”

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

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

C

In Section M-1, page 50, the applicant states that Vance County Dialysis has been offered as a clinical training site for student nurses attending Vance-Granville Community College.

Exhibit M-2 contains a copy of the student training agreement with Vance-Granville Community College. The information provided in Section M and referenced exhibits is reasonable and supports a finding of conformity to this criterion.

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

C

The applicant proposes to add two dialysis stations to Vance County Dialysis for a total of 35 stations upon completion of Project I.D. # K-10124-13 (relocate 16 stations from Vance County Dialysis to develop Kerr Lake Dialysis) and this project.

On page 351, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Vance County. Facilities may also serve residents of counties not included in their service area.

Table A in the July 2015 SDR indicates there one operational facility in Vance County and one facility pending certification, as illustrated in the table below:

DIALYSIS FACILITY	EXISTING AND APPROVED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Vance County Dialysis	49	159	3.24	81.12%
Kerr Lake Dialysis*	16	0	0	0.0%
Data reported in the July 2015 SDR, as of 12/31/14. *Certification Pending. The 16 stations are coming from Vance County Dialysis which will have 33 stations once Kerr Lake Dialysis is certified.				

Both facilities are owned by DVA.

In Section N-1, page 51, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

“The expansion of Vance County Dialysis will have no effect on competition in Vance County. The addition of two stations at this facility serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DVA Renal Healthcare, Inc. and not any other providers in the service area.

The expansion of Vance County Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive

impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

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

Therefore, the application is conforming to this criterion.

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

C

In Section O, page 52, the applicant refers the reader to Section B-4(a), for its discussion regarding the methods it uses to ensure and maintain quality. The discussion is found on pages 9-12. In Section O-3, page 52, the applicant states:

“Exhibit O-3 lists facilities located in NC owned by the parent company DaVita HealthCare Partners Inc. that did not operate in compliance with the Medicare conditions of participation during the 18 month look back period. Each facility is currently in compliance.”

In Exhibit O-3, the applicant states that three facilities were cited for deficiencies that resulted in a finding of Immediate Jeopardy, during the 18 months immediately preceding submittal of the application, as shown in the table below:

DVA Quality Care			
Facility	Survey Date	Back in Compliance	
Burlington Dialysis	6/16/2014	Yes	7/29/2014
Dialysis Care of Edgecombe County	7/1/2014	Yes	7/30/2014
Dialysis Care of Rowan County	9/17/2014	Yes	10/22/2014

Based on a review of the information in the application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 application is conforming to all applicable criteria, as discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

- C- In Section P, page 54, the applicant refers the reader to Section G-1, page 31 where the applicant provides the utilization rates for Vance County Dialysis. The December 31, 2014 utilization rate was reported as 81.12% with 159 in-center patients dialyzing on 49 stations.

.2202(a)(2) Mortality rates;

- C- In Section P, page 54, the applicant refers the reader to Section C-9, page 20 where it provides the Vance County Dialysis mortality rates, as follows:

Vance County Dialysis	Beginning In-center Patients	Ending In-center Patients	Average	Deaths	% Gross Mortality
2014	155	159	157	17	10.83%
2013	151	155	153	18	11.76%
2012	143	151	147	17	11.56%

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

-C- In Section P, page 54, the applicant refers the reader to Section C-8, page 19. Vance County Dialysis reports having 12 PD patients and no home hemodialysis patients.

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

-C- In Section P, page 54, the applicant refers the reader to Section C-10, page 20, and states the number of transplants performed or referred by Vance County Dialysis in 2014 was 7.

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

-C- In Section P, page 54, the applicant refers the reader to Section C-10, page 20, and states that Vance County Dialysis had seven patients on the transplant waiting list.

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

-C- In Section P, page 54, the applicant refers the reader to Section C-11, page 20 and states hospital admission rates as: Dialysis related 66 or 20.9%; Non-dialysis related 150 or 79.1%.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- In Section P, page 55, the applicant refers the reader to Section C-10, page 20 and states that at Vance County Dialysis, there were 11 persons with infectious disease and zero patients converted to an infectious status during the last calendar year.

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

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

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
 - (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- In Section P, page 55, the applicant refers the reader to Section K-1(f), page 40, and there refers the reader to Exhibit K-1(f) where the applicant provides copies of written policies and procedures for back up electrical service in the event of a power outage.

- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section P, page 56, the applicant refers the reader to Section K-1(g), page 41, where it states: “Vance County Dialysis will provide service in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply and other relevant health and safety requirements” See also Section H-2, page 33.

.2202(b)(7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.

-C- In Section P, page 56, the applicant refers the reader to Section C-1, page 13, where the applicant provides projected patient origin by county for Vance County Dialysis, based on the patients who currently dialyze there. The applicant's assumptions and methodology for its projections are provided on pages 13-15 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

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

-NA- This application is to add stations and does not propose a new facility.

.2202(b)(9) A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.

-C- In Section P, page 56, the applicant refers the reader to Section L-3(c), page 48, where the applicant states, "Vance County Dialysis makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status."

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- This application is to add stations and does not propose a new facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section P, page 57, the applicant refers the reader to Section C-1, pages 13-14, where the applicant documents the need for the project and demonstrates that it will serve a total of 114 in-center patients on 35 stations at the end of the first operating year, which is 3.25 patients per station per week, or a utilization rate of 81.4%. The

discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

- C- In Section P, page 57, the applicant refers the reader to Section C.1, pages 13-15, where the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) Diagnostic and evaluation services;

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that diagnostic and evaluation services will be referred to Maria Parham Medical Center.

.2204(2) Maintenance dialysis;

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that in-center maintenance dialysis is provided at Vance County Dialysis.

.2204(3) Accessible self-care training;

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that self-care training is provided at Vance County Dialysis.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that an accessible follow-up program for support of patients dialyzing at home is provided Vance County Dialysis.

.2204(5) X-ray services;

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that patients in need of x-ray services will be referred to Maria Parham Medical Center.

.2204(6) Laboratory services;

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that laboratory services will be provided by DaVita Laboratory Services, Inc.

.2204(7) Blood bank services;

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that patients in need of blood bank services will be referred to Maria Parham Medical Center.

.2204(8) Emergency care;

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that patients in need of emergency care will be referred to Maria Parham Medical Center.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that patients in need of acute dialysis services will be referred to Maria Parham Medical Center.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that patients in need of vascular surgery services will be referred to Granville Heart and Vascular.

.2204(11) Transplantation services;

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that patients in need of transplantation services will be referred to Duke University Medical Center. Exhibit I-3 contains a copy of the August 2015 letter from Dr. Berkoben the medical director at Vance County Dialysis which documents the provision of transplantation services to the proposed facility.

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

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that vocational rehabilitation counseling services are provided by the North Carolina Division of Vocational Rehabilitation Services.

.2204(13) Transportation

- C- In Section P-1, page 57, the applicant refers the reader to Section I-1, page 35, where the applicant states that transportation services will be provided by the Vance County Department of Social Services (DSS).

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).

- C- In Section P-1, page 57, the applicant refers the reader to Section H-2, page 33, where the applicant states that it will comply with *42 C.F.R. Section 405.2100* (Replaced with 42 CFR Part 494). In Section H-1, page 32, the applicant provides a staffing chart. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

.2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

- C- In Section P-1, page 57, the applicant refers the reader to Section H-4, page 34, where the applicant discusses its training at DVA facilities.