

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 20, 2013

PROJECT ANALYST: Tanya S. Rupp

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: K-10124-13 / DVA Healthcare Renal Care, Inc. d/b/a Kerr Lake Dialysis / Develop a new 16-station dialysis facility in Henderson by relocating 16 existing dialysis stations from Vance County Dialysis / Vance 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. proposes to develop a new 16-station dialysis facility, Kerr Lake Dialysis, by relocating 16 existing, certified dialysis stations from Vance County Dialysis facility. DVA Healthcare Renal Care, Inc. (DVA) is a subsidiary of DaVita Healthcare Partners Inc. DVA currently owns the dialysis stations proposed to be relocated in this application, and an unaffiliated property developer will purchase the land and develop a shell building, which DVA will upfit for use as a dialysis facility. DVA will lease the building from the developer. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Neither of the two need methodologies in the *2013 State Medical Facilities Plan* (SMFP) is applicable to the review. In addition, Policy GEN-3 is not applicable to this review, since there is no identified need for additional dialysis stations in Vance County. Furthermore, Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

However, SMFP Policy ESRD-2 is applicable to this review. Policy ESRD-2, found on page 36 of the 2013 SMFP states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations to contiguous counties shall:*

- (A) Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- (B) Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate 16 existing, certified dialysis stations from Vance County Dialysis facility to develop a new 16-station in-center dialysis facility in Henderson, also in Vance County. Since the proposed relocation of stations is within the host county, there is no change in the dialysis station inventory in Vance County. Therefore the application is conforming to Policy ESRD-2, and 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 currently operates the only dialysis facility in Vance County: Vance County Dialysis Center, with 43 in-center dialysis stations. Table A, on page 9 of the January 2013 Semi Annual Dialysis Report (SDR), indicates that Vance County Dialysis Center was dialyzing 145 patients on 43 in-center dialysis stations as of June 30, 2012, for a utilization rate of 3.37 patients per station [145 / 43 = 3.372]. In this application, DVA proposes to develop a new 16-station dialysis facility, Kerr Lake Dialysis, by relocating 16 existing, certified dialysis stations from Vance County Dialysis. In Section III.3, page 19, the applicant states:

*“DVA Healthcare Renal Care, Inc. proposes to relocate sixteen dialysis stations from Vance County Dialysis to establish the sixteen-station Kerr Lake Dialysis facility in Vance County. Vance County continues to experience significant growth in the number of End Stage Renal Disease patients requiring in-center dialysis. The January 2013 Semiannual Dialysis Report indicated that there were 165 dialysis patients living in Vance County as of December 31, 2011. The US*

*Census Bureau Vance County QuickFacts ... cited that the Vance County population as of 2010 was 45,422. The incidence of End Stage Renal Disease in Vance County is one in 275 based on the information above. The ESRD patient population in Vance County has increased from 139 patients on December 31, 2007 to 165 patients on December 31, 2011. Vance County Dialysis also serves many patients living in counties contiguous to the county.”*

Population to be Served

In Section III.7, on pages 22 – 23, the applicant states it will serve dialysis patients who reside in Vance and Granville Counties, since it is a relocation of existing dialysis stations within the same county and the same town. The applicant provides a table, reproduced below, to illustrate the distribution of residents from each county.

**Projected Number of In-Center Dialysis Patients  
 First Two Operating Years**

COUNTY	OPERATING YEAR 1 (CY 2015)	OPERATING YEAR 2 (CY 2016)	COUNTY PATIENTS AS A PERCENT OF TOTAL	
			OY 1	OY 2
Henderson [Vance]	39	40	72.2%	71.4%
Granville	15	16	27.8%	28.6%
Total	54	56	100.0%	100.0%

This application is for a new dialysis facility in Henderson, which is in Vance County, close to the border of North Carolina and Virginia. There is also a Henderson County in North Carolina, which is approximately 280 miles to the West, almost at the western end of the state. It is unlikely that dialysis patients in need of hemodialysis treatments three times per week would travel nearly 600 miles round trip to receive dialysis services. Total Renal Care, Inc., which is a subsidiary of DaVita, operates the only dialysis facility in Henderson County; however, it is unreasonable to conclude that patients living in or near Vance or Granville Counties would travel to Henderson County for regular dialysis treatments. It is therefore reasonable to conclude that the applicant is referring to the town of Henderson, in Vance County, rather than the county of Henderson, as shown above and in the table on page 22 of the application.

In addition, in Section III.7, pages 22 and 23, the applicant discusses the patient populations in Vance and Granville Counties, separately. The applicant states:

**Vance County Patients**

*The January 2013 Semiannual Dialysis Report indicates that the five-year average change rate in Vance County is 4.4%. Listed below are the calculations that were performed to determine the utilization rates for the proposed Kerr Lake Dialysis facility at the end of the first and second operating years:*

*In-Center Utilization Projections using the average annual change rate for the past five years of 4.4% and starting out with 37 Vance County in-center patients*

*dialyzing at Vance County Dialysis who will transfer their treatment to Kerr Lake Dialysis as of January 1, 2015:*

*January 1, 2015 - December 31, 2015 -- 37 in-center patients X 1.044 = 38.628*

*January 1, 2016 - December 31, 2016 – 38.628 in-center patients X 1.044 = 40.327632*

*January 1, 2015-December 31, 2015 is the first operating year.*

*January 1, 2016-December 31, 2016 is the second operating year.*

...

### **Granville County Patients**

*The January 2013 Semiannual Dialysis Report indicates that the five-year average change rate in Granville County is 2.9%. Listed below are the calculations that were performed to determine the utilization rates for the proposed Kerr Lake Dialysis facility at the end of the first and second operating years:*

*In-Center Utilization Projections using the average annual change rate for the past five years of 2.9% and starting out with 15 Granville County in-center patients dialyzing at Vance County Dialysis who will transfer their treatment to Kerr Lake Dialysis as of January 1, 2015:*

*January 1, 2015 - December 31, 2015 — 15 in-center patients X 1.029 = 15.435*

*January 1, 2016 - December 31, 2016 — 15.435 in-center patients X 1.029 = 15.882615.*

...

*Thus, we anticipate that there will be 54 (39 Vance County patients + 15 Granville County patients = 54 total patients) in-center patients dialyzing at the facility at the end of operating year one for a utilization rate of 84% or 3.3 patients per station and 56 (40 Vance County patients + 16 Granville County patients = 56 total patients) in-center patients dialyzing at the facility at the end of operating year two for a utilization rate of 87% or 3.5 patients per station.”*

The applicant adequately describes the population it proposes to serve.

### **Demonstration of Need**

The applicant proposes to relocate 16 certified dialysis stations from Vance County Dialysis, located in Henderson, to develop a new 16-station in-center dialysis facility, also in Henderson in Vance County. The applicant does not propose to increase the number of dialysis stations in any facility, and does not propose to acquire additional dialysis stations that would result in an increase in the inventory of dialysis stations in Vance County. Rather, the applicant proposes to reduce the number of stations in a facility that has reached operational capacity and would soon experience congestion that would interfere with the provision of quality dialysis services. As of June 30, 2012, as reported in the January 2013 SDR, which was the SDR available to the applicant at the time the application was prepared, Vance County Dialysis was certified for 43 in-center dialysis stations. Furthermore, on April 12, 2012, Vance County Dialysis was awarded a CON pursuant to Project ID # K-008574-10, to add six stations to its inventory, yielding a facility total of 49 in-center dialysis stations. Therefore, to project utilization, the applicant subtracted the 16 stations proposed to be relocated from a total of 49 in-center dialysis stations, since those 49 stations are projected to be certified by the time Kerr Lake Dialysis is certified, January 1, 2015.

In Section III.3, pages 19 – 21, the applicant describes the need the Vance County dialysis patient population has for an additional 16-station dialysis facility in Henderson. On page 19, the applicant states:

*“Fifty-two in-center patients who currently get dialysis at Vance County Dialysis have signed letters of support for the proposed Kerr Lake Dialysis facility. All of the patients have indicated in their letters that they live closer to the proposed Kerr Lake facility and that the facility will be more convenient for them.*

*Based on these letters, Kerr Lake Dialysis will have at least 52 in-center ESRD patients dialyzing in the facility January 1, 2015, which we are projecting to be the beginning of the first year of operation. Those 52 patients are projected to transfer from Vance County Dialysis. The facility is projected to have 54 in-center patients by the end of operating year one based on the current Average Annual Change Rate for the Past Five Years that is cited in the January 2013 Semiannual Dialysis Report on the second page of Table B: ESRD Dialysis Station Need Determination by Planning Area. ...*

...

*In-Center Utilization Projections using the average annual change rate for the past five years of 4.4% and starting out with 52 in-center patients dialyzing at Vance County Dialysis who will transfer their treatment to Kerr Lake Dialysis as of January 1, 2015:*

*January 1,2015-December 31,2015—52 in-center patients X 1.044 = 54.288*

*January 1,2016-December 31, 2016— 54.288 in-center patients X 1.044 = 56.676672*

***January 1, 2015-December 31, 2015 is the first operating year.***

***January 1, 2016-December 31, 2016 is the second operating year.***

*Thus, we anticipate that there will be 54 in-center patients dialyzing at the facility at the end of operating year one for a utilization rate of 84% or 3.3 patients per station and 56 in-center patients dialyzing at the facility at the end of operating year two for a utilization rate or 87% or 3.5 patients per station. The sixteen stations that will be transferred from Vance County Dialysis to Kerr Lake Dialysis will be needed for the number of projected patients that will be utilizing the new facility.” [emphasis in original]*

The applicant’s methodology, presented on page 20 of the application, includes the growth of the entire Vance County dialysis patient population, from the date of the data that was reported in the January 2013 SDR, through the end of the second project year. From that number, the applicant subtracted the number of patients and stations projected to transfer and be relocated to the proposed Kerr Lake Dialysis facility. The applicant states:

*“We have projected the growth of the entire current patient population at Vance County Dialysis by projecting the growth from the date of the most recent Southeastern Kidney Council data, which is June 30, 2012. Taking into consideration that Vance County Dialysis had 145 in-center patients as of June 30, 2012 and that Vance County had an Average Annual Change Rate for the Past Five Years of 4.4% we have projected the growth in the patient population from July 1, 2012 to the date Kerr Lake Dialysis is projected to be certified.*

*July 1, 2012-December 31, 2012 - 145 in-center patients X 1.022 = 148.19*

*January 1, 2013-Dcember 31, 2013 - 148.19 in-center patients X 1.044 = 154.71036*

*January 1, 2014-December 31, 2014 - 154.71036 X 1.044 = 161.5176158*

*Using the projections above, Vance County Dialysis would have 161 in-center patients at the point when Kerr Lake Dialysis is projected to be certified on January 1, 2015. With 52 patients and 16 dialysis stations transferring from Vance County Dialysis to Kerr Lake Dialysis, this will leave 109 patients (161 - 52 = 109) and 33 dialysis stations at Vance County Dialysis. Once the transfer takes place, using the numbers above, the Vance County Dialysis utilization rate would be 82%.*

The applicant adequately demonstrates that both dialysis facilities would be adequately utilized following the development of the new 16-station Kerr Lake Dialysis facility. Furthermore, the applicant adequately demonstrates the need the population proposed to be served has for the relocation of 16 existing dialysis stations from Vance County Dialysis to develop the proposed Kerr Lake Dialysis facility.

Access to Services

In Section VI.1, page 33, the applicant states,

*“Kerr Lake Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap.*

...

*Kerr Lake Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”*

The applicant projects that 60.9% of its patients will be covered by Medicare, Medicaid or VA and another 31.4% will be covered by Medicare/Commercial. The applicant adequately demonstrates 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.

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and the extent to which all residents of the area 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.

C

The applicant proposes to develop a new dialysis center in Henderson by relocating 16 existing, certified dialysis stations from Vance County Dialysis Center. In Section III.3, page 20, the applicant projects that 52 in-center patients will transfer from Vance County Dialysis Center to the proposed Kerr Lake Dialysis Center, because it will be closer to their home. In Exhibit 14, the applicant provides 57 letters that have been signed by existing Vance County Dialysis patients, each of which indicates the patient’s willingness to transfer care. The letters are form letters, and thus all state the same thing, which includes but is not limited to the following:

*“I am a dialysis patient. I understand that DVA Healthcare Renal Care, Inc., which is the same company that operates Vance County Dialysis, where I receive*

*treatment now, is proposing to start a second dialysis facility at another location in Henderson in Vance County.*

*I fully support a new dialysis facility in Henderson. Having my dialysis treatments in that part of the city would be much more convenient for me. I could travel between that my home [sic] and that location more easily and quickly, which would save me time and money. So I would consider transferring to Kerr Lake Dialysis for my dialysis treatments.”*

Although there are a total of 57 signed patient letters, the applicant’s projections of the number of patients it proposes to serve following the transfer of patients are based on the initial transfer of 52 in-center patients, and that is how the analyst will analyze the data in the Agency Findings.

In Section III.3 (c), page 20, the applicant states:

*“The January 2013 Semiannual Dialysis Report indicates that there were 145 ESRD in-center dialysis patients receiving their treatments at the Vance County Dialysis. The facility had 43 certified stations. At the time the SDR was published, there were six stations pending certification. The facility utilization rate identified in the SDR was 84%. The utilization rate based on 49 stations is 74%. We are projecting that 52 current in-center patients from Vance County Dialysis will transfer to Kerr Lake Dialysis.*

*With 52 patients and sixteen dialysis stations transferring from Vance County Dialysis to Kerr Lake Dialysis will leave 93 in-center patients and 33 dialysis stations at Vance County if we do not take into consideration any patient growth between January 1, 2013 and when Kerr Lake Dialysis is projected to be certified (January 1, 2015) [sic].”*

The applicant projects growth in the number of dialysis patients who receive their care in Vance County from the date of the last SDR (January 2013, which reports data as of June 30, 2012) through January 1, 2015, which is the projected certification date for the proposed Kerr Lake Dialysis facility. Thereafter, the applicant subtracts the number of patients who indicated a willingness to transfer their care to the proposed facility. In Section III.3, on page 20, the applicant states:

*“Using [those projections], Vance County Dialysis would have 161 in-center patients at the point when Kerr Lake Dialysis is projected to be certified on January 1, 2015. With 52 patients and 16 dialysis stations transferring from Vance County Dialysis to Kerr Lake Dialysis, this will leave 109 patients (161 — 52 = 109) and 33 dialysis stations at Vance County Dialysis. Once the transfer takes place, using the numbers above, the Vance County Dialysis utilization rate would be 82%.”*



Therefore, the applicant projects to serve 109 in-center dialysis patients on 33 dialysis stations at Vance County Dialysis following certification of the proposed Kerr Lake Dialysis facility. That yields a utilization of 82%, which conforms to the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2203(b) [(109 / 33 = 3.3) / 4 = 0.8258].

The applicant demonstrates that the needs of the population presently served at Vance County Dialysis Center will continue to be adequately met following the proposed relocation of sixteen dialysis stations to develop Kerr Lake Dialysis Center. See discussion in Criterion 13 with regard to access by medically underserved groups, which is incorporated hereby as if set forth fully herein.

Therefore, the application is conforming to this criterion

- (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, pages 24 - 25, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – continue to use a 49-station facility (47 in-center and two home hemo-dialysis training stations). The applicant states the existing facility, which was certified in 1989, does not have sufficient space for facility expansion. In addition, the applicant states the existing facility is becoming congested with limited floor space as the dialysis patient population continues to increase; therefore this alternative is unacceptable.
- 2) Develop the second facility elsewhere in Vance County - The applicant states, *“Vance County has four townships identified in the Vance County census report: Henderson (population 16,095), Kittrell (population 148), Middleburg (population 162) and South Henderson (population 1,220). Henderson has the largest population, is located just south of the center point of the county and is easily accessible from anywhere in the county. Henderson is the center of the population base of the county. Over two thirds of the ESRD patients reside in Henderson. Realistically, there is no other area of the county that is more appropriate for the development of a second Vance County dialysis facility.”* Therefore, this alternative is unacceptable.
- 3) Chosen alternative – Transfer those patients who are willing to transfer their care and relocate existing stations to develop a second facility in Henderson that is easily accessible to dialysis patients who utilize Vance County Dialysis.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the following:

- Patient care will continue to be provided by the same caregivers and Nephrologist.
- Patients will not have to travel an unreasonable distance to dialyze.
- The proposed location of the Kerr Lake Dialysis facility will better serve some Vance County dialysis patients who are currently traveling to the other dialysis facility for treatment.

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.

Comments submitted regarding the proposed project included suggestions that the certification page of the application was improperly signed and that the applicant improperly identified Carolinas Medical Center as a hospital that could provide transplantation services. The analyst determined that the certification page was properly signed pursuant to 10A NCAC 14C .0203(c) and that the applicant adequately demonstrated that transplantation services will be available pursuant to 10A NCAC 14C .2204(11).

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need of its Vance County dialysis patients. Therefore, the application is conforming to this criterion and approved subject to the condition in Criterion VII, and the following conditions.

- 1. DVA Healthcare Renal Care of North Carolina, Inc. d/b/a Kerr Lake Dialysis shall materially comply with all representations made in its certificate of need application.**
- 2. DVA Healthcare Renal Care of North Carolina, Inc. d/b/a Kerr Lake Dialysis shall relocate and operate no more than 16 additional dialysis stations for a total of no more than 16 certified stations which shall include any isolation stations.**
- 3. After the certification of the sixteen dialysis stations at Kerr Lake Dialysis, DVA Healthcare Renal Care of North Carolina, Inc. shall decertify 16 dialysis stations at the Vance County Dialysis facility.**
- 4. DVA Healthcare Renal Care of North Carolina, Inc. d/b/a Kerr Lake Dialysis shall install plumbing and electrical wiring through the walls for sixteen dialysis stations which shall include any isolation stations.**
- 5. DVA Healthcare Renal Care of North Carolina, Inc. d/b/a Kerr Lake Dialysis shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
- 6. DVA Healthcare Renal Care of North Carolina, Inc. d/b/a Kerr Lake Dialysis shall acknowledge acceptance of and agree to comply with all**

**conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 43, the applicant projects the capital costs to develop the new 16-station dialysis facility will be \$1,665,296, which includes \$1,025,000 in construction costs; \$210,720 for dialysis machines; \$90,000 for RO water treatment equipment, \$64,700 for dialysis chairs, TVs, and patient computer systems; and \$274,876 for equipment, furniture, and consultant fees.

In Section IX.3, page 46, the applicant projects that there will be \$209,922 in start-up expenses and \$1,097,123 in initial operating expenses, for a total projected working capital of \$1,307,045 associated with the proposed project.

In Section VIII.3, page 43, the applicant states the entire capital cost of the project will be funded with the cash reserves of DaVita, Inc., the parent company of DVA Healthcare Renal Care, Inc. In Exhibit 19, the applicant provides an April 12, 2013 letter from DaVita's Chief Accounting Officer which confirms DaVita's commitment of cash reserves in the sum of \$2,972,341 for the proposed project [\$1,665,296 capital cost, \$209,222 start-up expense, and \$1,097,123 working capital]. DaVita's Form 10-K in Exhibit 20 confirms the availability of those cash reserves on the consolidated balance sheet, page F-6, which show cash and cash equivalents in the amount of \$533,748,000 for the year ending December 31, 2012.

In Section X.1, page 48, the applicant provides the projected allowable charges per treatment for each payment source, as illustrated in the following table:

SOURCE OF PAYMENT	ALLOWABLE CHARGE PER TREATMENT
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.00

Based on the calculations presented in Section X.3, page 49, the facility reimbursement is as follows:

<b>SOURCE OF PAYMENT</b>	<b>REIMBURSEMENT PER TREATMENT</b>
Medicare	\$192.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.<sup>1</sup> In Sections X.2 - X.4, pages 48 - 50, the applicant reported projected revenues and expenses. On page 50, the applicant provided a table to illustrate those projections:

	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
Total Net Revenue	\$2,527,932	\$2,623,350
Total Operating Costs	\$2,194,246	\$2,267,060
Net Profit	\$333,686	\$356,290

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X of the application for the applicant's assumptions on treatments.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating expenses of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal 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

DVA Healthcare Renal Care, Inc. d/b/a Kerr Lake Dialysis proposes to relocate 16 certified in-center dialysis stations from Vance County Dialysis to develop a new facility, Kerr Lake Dialysis, with 16 in-center dialysis stations upon project completion. As of June 30, 2012, Vance County Dialysis served 145 patients weekly on 45 dialysis stations, which is 84% of the facility's capacity  $[(145 / 43) / 4 = 0.843]$ . As of December 31, 2012, Vance County Dialysis served 151 patients weekly on 45 dialysis stations, which is 88% of the facility's capacity  $[(151 / 43) / 4 = 0.878]$ . Dialysis facilities that operate four shifts per week (2 / day on alternate days) have a capacity of four patients per station. The applicant discusses

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<sup>1</sup>[http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage\\_Renal\\_Disease\\_Prospective\\_Payment\\_System\\_ICN905143.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage_Renal_Disease_Prospective_Payment_System_ICN905143.pdf)

projections for the in-center patient population for both facilities in Section II, pages 12 – 14, and in Section III.3, pages 19 - 21 of the application. At the end of Operating Year One, Vance County Dialysis utilization will be 3.3 in-center patients per station (109 patients / 33 dialysis stations = 3.3), or 83% of capacity. In addition, at the end of Operating Year One, the proposed Kerr Lake Dialysis facility utilization will be 3.3 in-center patients per station (54 patients / 16 dialysis stations = 3.375), or 84% of capacity. The growth projections are based on the Vance County projected five-year average annual growth rate in the number of dialysis patients, as reported in the January, 2012 SDR.

The applicant adequately demonstrates the need to relocate 16 in-center dialysis stations to develop a new 16-station dialysis facility based on the number of in-center patients it proposes to serve and Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS. 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 applicant 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.

CA

In Section VII.1, page 38, the applicant provides a table to illustrate current and projected staffing for the Kerr Lake Dialysis Center. See the following table:

POSITION	PROPOSED FTEs	TOTAL FTEs
RN	3.0	3.0
Patient Care Technician	6.0	6.0
Bio-Medical Technician	0.5	0.5
Administrative	1.0	1.0
Dietician	0.5	0.5
Social Worker	0.5	0.5
Unit Secretary	1.0	1.0
Reuse Technician	0.5	0.5
<b>Total</b>	<b>13</b>	<b>13</b>

As shown in the above table, the applicant proposes to employ a total of 13.0 full-time equivalent (FTE) positions to staff Kerr Lake Dialysis upon project completion.

The following table shows the projected number of direct care staff for each shift offered in the facility following project completion, as reported by the applicant in Section VII.10, page 41:

	SHIFT TIMES	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
Morning	6 am to 11 am	4	4	4	4	4	4
Afternoon	11 am to 4 pm	4	4	4	4	4	4
Evening	N/A	0	0	0	0	0	0

In Section VII.9, page 40, the applicant states there are nine nephrologists who will be serving patients at the proposed Kerr Lake Dialysis facility. In Section V.4, page 30, the applicant states that Dr. Michael Berkoben will serve as Medical Director of the facility. In Exhibit 14, the applicant provides letters of support from area physicians, two of which are signed by a proposed Medical Director. The letters appear to be identical and therefore a duplicitous addition; however, the letters are signed by a Dr. Stephen R. Smith, who agrees to serve as Medical Director for the proposed Kerr Lake Dialysis facility. The exhibit does not contain a letter signed by Dr. Michael Berkoben. Thus it is not clear who has agreed to be the Medical Director for the facility.

The applicant documents the availability of adequate health manpower and management personnel, except for identification of the medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion, subject to the following condition:

1. **Prior to the issuance of a Certificate of Need, DVA Healthcare Renal Care of North Carolina, Inc. d/b/a Kerr Lake Dialysis shall provide a letter to the Certificate of Need Section from the Medical Director of the proposed Kerr Lake Dialysis facility which confirms his or her willingness to serve in that capacity.**

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

C

In Section V.1, page 28, the applicant provides a list of providers of the necessary ancillary and support services. Additionally, in Sections V.2 – V.7, on pages 29 – 32, the applicant provides further documentation of the availability of the necessary ancillary and support services for the patients to be served at Kerr Lake Dialysis. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

C

In Section XI.2, page 52 of the application, the applicant states the proposed site of Kerr Lake Dialysis is located at the corner of Ruin Creek Road and Toyota Lane in Henderson. In Section XI.1, page 52 and Section XI.6(h), page 58 of the application, the applicant states it will lease a shell building of 9,448 square feet, which Kerr Lake Dialysis will upfit for the proposed dialysis facility in Henderson. In Section XI.6(d), page 55 of the application, the applicant states that applicable energy saving features and water treatment equipment will be incorporated into the construction plans by installing “...*energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.*”

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced

difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section VI.1(b), page 33, the applicant reports that 89.7% of the Vance County dialysis patients who received treatment at Vance County Dialysis had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source of the facility:

SOURCE OF PAYMENT	PERCENTAGE
Medicare	12.2%
Medicaid	3.8%
Medicare/Medicaid	42.3%
Commercial Insurance	7.7%
VA	2.6%
Medicare/Commercial	31.4%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Vance County 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 *	2009 % UNINSURED (ESTIMATE BY CECIL G. SHEPS CENTER) *
Vance County	30%	13.4%	22.8%
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 Kerr Lake Dialysis. In fact, in 2011 only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.<sup>2</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina.

<sup>2</sup> Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16



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

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. In addition, about 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

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

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations."*<sup>3</sup>

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010: "On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy." Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

*"Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively."*<sup>4</sup>

The report provides 2010 ESRD spending by payor, as follows:

<b>ESRD SPENDING BY PAYOR<sup>5</sup></b>
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<sup>3</sup><http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>

<sup>4</sup>United States Renal Data System 2012 USRDS Report, Chapter 1, page 225:  
[http://www.usrds.org/2012/pdf/v2\\_ch1\\_12.pdf](http://www.usrds.org/2012/pdf/v2_ch1_12.pdf).

<sup>5</sup>United States Renal Data System 2012 USRDS Report, Chapter 11, page 340:  
[http://www.usrds.org/2012/pdf/v2\\_ch11\\_12.pdf](http://www.usrds.org/2012/pdf/v2_ch11_12.pdf).

Payor	Spending in Billions	Percent of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

In addition, the Southeastern Kidney Council (SKC) provides Network 6 [Georgia, North Carolina, and South Carolina] 2011 Incident ESRD patient data by age, race and gender, as shown below:

NUMBER AND PERCENT OF DIALYSIS PATIENTS BY AGE, RACE, AND GENDER		
	# of ESRD Patients	% of Dialysis Population
<b>Age</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
Total	9,342	100.0%

Source: Southeastern Kidney Council ESRD Network 6  
 2011 Annual Report; Table 3, page 16

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

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

C

In Section VI.6 (a), page 37, the applicant states, “There have been no civil rights access complaints filed within the last five years.” Therefore, 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 34, the applicant provides the projected payor mix for the proposed dialysis services at Kerr Lake Dialysis as follows:

<b>KERR LAKE DIALYSIS PROJECTED PAYOR MIX</b>	
Source of Payment	Percentage
Medicare	12.2%
Medicaid	3.8%
Medicare/Medicaid	42.3%
Commercial Insurance	7.7%
VA	2.6%
Medicare/Commercial	31.4%
<b>Total</b>	<b>100.0%</b>

The applicant projects no change from the current payor mix for dialysis visits at Vance County Dialysis, as stated in Criterion (13a) above. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion

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

C

In Section VI.5, page 36, the applicant states that:

*“Patients with End Stage Renal Disease will have access to dialysis services upon referral by a Nephrologist with privileges at Kerr Lake Dialysis. Kerr Lake Dialysis will grant privileges to all qualified nephrologists. Referrals to nephrologists most commonly come from primary care physicians or specialty physicians in Vance, Warren, Durham and Granville Counties or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the facility either directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if it were found to be medically necessary. Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies which*

*compromise Exhibit 15. The patient, again, will be referred to a qualified Nephrologist for final evaluation and then admission based on the doctor's orders." [Emphasis in original.]*

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

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

C

In Section V.3, page 30 of the application, the applicant states that "*Kerr Lake Dialysis will be offered as a clinical learning site for nursing students at the local community college.*" In addition, in Exhibit 13, the applicant provides a copy of an April 1, 2013 letter offering Kerr Lake Dialysis as a clinical training site for nursing students at Vance-Granville Community College. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity to this criterion.

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

C

DVA Healthcare Renal Care, Inc. proposes to relocate 16 existing, certified dialysis stations from Vance County Dialysis in Henderson, to develop a new 16-station dialysis facility also in Henderson. DVA is the only provider of dialysis services in Vance County. In Section V.7, pages 31 - 32, the applicant discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access to dialysis services in Vance County. On page 32, the applicant states,

*"The development of this facility will have no impact on the other outpatient dialysis facility, Vance County Dialysis. ... There are three counties contiguous to Vance County. In Franklin County, Total Renal Care of North Carolina, LLC*

*operates a twenty-three station facility. Total Renal Care of North Carolina, LLC has submitted a Certificate of Need application to develop a second dialysis facility in Youngsville in Franklin County.*

*Fresenius Medical Care operates facilities in Granville County (FMC of Neuse River and FMS of Oxford) and Warren County (FMC of Warren Hills). None of these facilities are in close proximity of the proposed Kerr Lake Dialysis.*

*The development of Kerr Lake Dialysis is a proposal to relocate stations and a number of the patients receiving their dialysis treatments at Vance County Dialysis. The growth projections for Vance County Dialysis are based on that existing patient population. Therefore, our projections for the proposed Kerr Lake Dialysis facility do not depend on any change in existing referral patterns. Our goal is to locate a second in-center dialysis facility in Henderson to provide easy access to the Vance County patient population who live in the southern portion of Henderson and the southern portion of Vance County. ...*

*For these reasons, we do not believe that this new facility will have an impact on any Fresenius facility located in contiguous counties. Kerr Lake Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burden 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 other[s] involved in the dialysis process to receive services.”*

Furthermore, see Sections II, III, V, VI and VII of the application. The information provided by the applicant in the sections above is reasonable and credible and adequately demonstrates that relocating 16 existing, certified dialysis stations to develop a new 16-station dialysis facility in Vance County will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis services because:

- The applicant adequately demonstrates need based on Policy ESRD-2: Relocation of Dialysis Stations, to relocate 16 dialysis stations from Vance County Dialysis to develop the proposed Kerr Lake Dialysis facility;
- The applicant adequately demonstrates that the proposed project is a cost-effective alternative to meet the need to provide access to dialysis services for patients in Vance County;
- The applicant has and will continue to provide quality services. In addition, the information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care dialysis services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 and VII, pages 28 - 31 and 38 - 41 respectively, and referenced exhibits is reasonable and credible and demonstrates that the applicant provides quality care; and

- The applicant has and will continue to provide adequate access to medically underserved populations (more than 80% are Medicare or Medicaid patients).

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Reidsville Dialysis Center operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

C

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

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

C

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

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

**.2202 INFORMATION REQUIRED OF APPLICANT**

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

(1) *Utilization rates;*

- C- In Section II.1, page 10, the applicant refers to the utilization rates for Vance County Dialysis as reported in the January 2013 SDR (provided in Exhibit 7 of the application). See also Section III.3, page 19. The utilization rate applied by the applicant was calculated based on 145 in-center dialysis patients and 43 certified dialysis stations as of June 30, 2012 (145 patients / 43 stations = 3.37 patients per station; 3.4 patients per station / 4.00 patients per station = 84%).

(2) *Mortality rates;*

- C- In Section IV.2, page 26, the applicant reports the 2010, 2011 and 2012 facility mortality rates for Vance County Dialysis as 12.1%, 8.1% and 10.8%, respectively.

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

- C- In Section IV.3, page 26, the applicant states, “*Vance County Dialysis had one home trained patient as of December 31, 2012.*”

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

- C- In Section IV.4, page 26, the applicant states, “*Vance County Dialysis had one patient receive a transplant in 2012. Twenty-four patients were referred for transplant evaluation in 2012.*”

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

- C- In Section IV.5, page 27, the applicant states, “*Vance County Dialysis has eleven patients 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 27, the applicant states that there were 275 hospital admissions in CY 2012 for Vance County Dialysis, 31 of which (11.3%) were dialysis related, and 244 (88.7%) were non-dialysis related.

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

- C- In Section IV.7, page 27, the applicant states that there were no patients dialyzing in Vance County with hepatitis B during 2012. The applicant further states there were four patients who had AIDS. There were no patients treated with infectious disease who converted to infectious status within the last year at Vance County Dialysis.

- (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.*
- C- In Exhibit 8, the applicant provides an April 8, 2013 letter signed by a representative of Maria Parham Medical Center, which states the medical center will provide the following services to the proposed Kerr Lake Dialysis facility:
- Acute dialysis
  - Emergency room care
  - Diagnostic evaluation services
  - X-Ray services
  - Special, immunological and routine laboratory services
  - Blood banking services
  - Surgical services including vascular surgery
- (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.*
- C- In Exhibit 9, the applicant provides an April 2, 2013 letter signed by the Assistant Vice President of Carolinas Medical Center (CMC) which describes the relationship the hospital will have with Kerr Lake Dialysis and the specific services that the hospital will provide to patients of Kerr Lake Dialysis.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- In Section XI.6(e) and Section XI.6(f), on page 56 of the application, the applicant states that power and water will be available at the proposed site for the Kerr Lake Dialysis



facility. The applicant refers to Exhibits 9 and 10 for the documentation of the provision of these services; however, the documentation is actually provided in Exhibit 22.

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

-C- See Exhibit 9, in which the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.

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

-C- In Section XI.1, page 52, the applicant provides information which identifies the location of the site on which the services are to be operated. In addition, in Exhibit 22, the applicant provides a copy of an April 11, 2013 letter signed by a representative of Hill/Gray Seven, LLC which evidences that DVA Healthcare Renal Care, Inc. will lease the building in which it will provide dialysis services. In Section XI.3, page 53, and in Exhibit 22, the applicant identifies a secondary site on which the facility could be built.

(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 56, the applicant states, “Kerr Lake Dialysis will operate within the applicable laws and regulations pertaining to staffing and the fire safety equipment, physical environment and other relevant health safety requirements.” See Exhibit 25 for excerpts from the Health and Safety Policy and Procedure Manual and Exhibit 26 for the In-service Calendar with mandatory training classes.

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

-C- The applicant provides the following projected patient origin in Section III.7, page 22 of the application (see the analyst’s conclusions regarding the stated counties to be served by the facility):

**Projected Number of In-Center Dialysis Patients  
 First Two Operating Years**

COUNTY	OPERATING YEAR 1 (CY 2015)	OPERATING YEAR 2 (CY 2016)	COUNTY PATIENTS AS A PERCENT OF TOTAL	
			OY 1	OY 2
Vance	39	40	72.2%	71.4%

Granville	15	16	27.8%	28.6%
Total	54	56	100.0%	100.0%

See Section III.7, pages 22 - 24 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

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

-C- In Section III.8, page 24, the applicant states that 100% of the patients to be served at Kerr Lake Dialysis will reside within 30 miles of the proposed facility.

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

-C- In Section II.1, page 12, the applicant states,

*“DVA Healthcare Renal Care, Inc. d/b/a Kerr Lake Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

**.2203 PERFORMANCE STANDARDS**

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

-C- In Section II, pages 12 – 13, and Section III.3, pages 19 – 21, the applicant adequately documents that the relocation of 16 existing, in-center dialysis stations from Vance County Dialysis to develop the new 16-station Kerr Lake Dialysis facility is needed, based on projected utilization of 3.3 patients per station per week dialyzing on 16 certified stations at the end of the first operating year. See also the discussion in Criterion (3), which is incorporated hereby as if set forth fully herein. The application is conforming to this rule.

(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.*

-NA-

**.2204 SCOPE OF SERVICES**

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

(1) *diagnostic and evaluation services;*

-C- The table in Section V.1, page 28, shows patients will be referred to Maria Parham Medical Center for diagnostic and evaluation services.

(2) *maintenance dialysis;*

-C- The table in Section V.1, page 28, shows the facility will provide dialysis and maintenance.

(3) *accessible self-care training;*

-C- The table in Section V.1, page 28, shows self-care training will be provided by Vance County Dialysis.

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

-C- In response to this rule, the applicant states, “*Addressed in Section V, Question 1 of the application.*” However, the applicant instead addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), on page 29, stating,

*“Vance County Dialysis provides protocols and routines for patient follow-up. The social workers and dieticians contact the home-trained patients monthly. The patients are supported by monthly visits to their Board Certified Nephrologist for examination. The Home Training nursing teammates perform monthly medication reviews, nursing assessments and laboratory review of blood work in order to continuously monitor the well being of home patients. Patient’s blood chemistries are sent to a Medicare certified laboratory where they are analyzed. The results are reviewed by the teammates for adequacy and then reviewed by the dietitian and Nephrologist. Home trained patients are monitored by our Quality Management team.”*

(5) *x-ray services;*

- C- The table in Section V.1, page 28, shows patients will be referred to Maria Parham Medical Center for x-ray services.
- (6) *laboratory services;*
- C- The table in Section V.1, page 28, shows patients will be referred to Dialysis Laboratories for routine and special laboratory services.
- (7) *blood bank services;*
- C- The table in Section V.1, page 28, shows patients will be referred to Maria Parham Medical Center for blood bank services.
- (8) *emergency care;*
- C- The table in Section V.1, page 28, shows patients will be referred to Maria Parham Medical Center for emergency care.
- (9) *acute dialysis in an acute care setting;*
- C- The table in Section V.1, page 28, shows patients will be referred to Maria Parham Medical Center for acute dialysis in an acute care setting. See Exhibit 8 for a copy of the proposed hospital transfer agreement.
- (10) *vascular surgery for dialysis treatment patients;*
- C- The table in Section V.1, page 28, shows patients will be referred to Maria Parham Medical Center for vascular surgery for dialysis patients.
- (11) *transplantation services;*
- C- The table in Section V.1, page 28, shows patients will be referred to Carolinas Medical Center for transplantation services. See Exhibit 9 for a letter from CMC which documents the transplantation services it will provide to Kerr Lake Dialysis patients.
- (12) *vocational rehabilitation counseling and services; and*
- C- The table in Section V.1, page 28, shows patients will be referred to North Carolina Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.
- (13) *transportation.*

- C- The table in Section V.1, page 28, shows patients will be referred to KARTS for transportation.

**.2205 STAFFING AND STAFF TRAINING**

- (a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*
  - C- In Section VII.1, page 38, the applicant provides the proposed staffing. The applicant states, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 as evidenced below.*” Kerr Lake Dialysis proposes two dialysis shifts, six days per week, and direct care staffing as noted in response to application question VII.10, page 41.
- (b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
  - C- In Section VII.5, page 40, the applicant refers to Exhibit 18 for a copy of the training program outlines.