

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 27, 2013
PROJECT ANALYST: F. Gene DePorter
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: R-10150-13 / DVA Healthcare Renal Care, Inc. d/b/a Edenton Dialysis Center / Relocate Edenton Dialysis Center within the City of Edenton / Chowan

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.

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The applicant, DVA Healthcare Renal Care, Inc. d/b/a Edenton Dialysis Center [EDC] proposes to relocate its current 17 dialysis station facility 0.3 miles to 312 Medical Arts Drive in Edenton. The applicant does not propose to add new dialysis stations to an existing facility or to move stations to contiguous counties. Therefore, neither of the need methodologies in the *2013 State Medical Facilities Plan [2013 SMFP]* is applicable to the review.

The North Carolina Semiannual Dialysis Report for January 2013, Table A, indicates that Edenton Dialysis Center is operating at 2.94 patients per station with a utilization rate of 73.53%. This application is for the relocation of the Edenton Dialysis facility within the town of Edenton in Chowan County. The facility will continue to provide in-center hemodialysis. Home training for peritoneal dialysis and home hemodialysis are provided by Elizabeth City Dialysis Center.

According to the January 2013 North Carolina Semiannual Dialysis Report, Table A, EDC is currently the only ESRD facility in Chowan County. The facility is certified for 17 stations as of December 21, 2012.

The applicant proposes to relocate its facility with no change in the number of dialysis stations. Therefore, neither the county need nor the facility need methodologies in the 2013 SMFP are applicable to this review. Additionally, Policy GEN-3: BASIC PRINCIPLES is not applicable because neither need methodology is applicable to the review. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable because the applicant's proposed capital expenditure is less than \$2 million.

Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS- is applicable to this review. The Policy 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:*

1. *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*
2. *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 a 17 dialysis station facility within the town of Edenton in Chowan County. Consequently, there is no change in dialysis station inventory in Chowan County. Therefore, the application is consistent with 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

The applicant, DVA Healthcare Renal Care, Inc. (DVA) d/b/a Edenton Dialysis Center (EDC) proposes to relocate the current 17 dialysis station facility from its current location at 703 Luke Street to 312 Medical Arts Drive, a distance of 0.3 mile, in Edenton. In Section III.4 and 6, pages 18-19, the applicant states,

“This application is for the relocation of the Edenton Dialysis Center. The current facility was built in the early 1990s. The building is in a poor state of repair. The proposed primary site is located 0.3 mile from the current location.

...

The relocation of the Edenton Dialysis Center will have no adverse effect on the quality of care or ability of the patients to gain access to care. The proposed location is .3 mile from the current location. The proposed facility will offer a new state-of-the-art facility for our patients.”

Population to be served

In Section III.7 page 19-20, the applicant provides the following information which identifies the patient population it proposes to serve for the first two years of operation following project completion.

In Section III, page 19, the applicant states the following:

“The January 2013 Semiannual Dialysis Report indicates that the five year average annual change rate for Chowan County is -0.004; for Perquimans County is 0.060. The calculations below show the growth of the 15 patients living in Perquimans County. The Chowan, Pasquotank and Tyrrell County patient numbers have not been calculated. We did not calculate patient growth in Chowan County since the five-year average annual growth rate is flat, at most zero. We did not calculate the Pasquotank and Tyrell patient growth since there were a small number of patients living in those counties being served by the Edenton Dialysis Center.

The period of growth begins with July 1, 2013 forward to June 30, 2015. The following are the in-center patient projections using the 6.0% Average Annual Change Rate for the Past Five Years as indicated on the first page of Table B of the January 2013 Semiannual Dialysis Report for the 15 in-center patients residing in Perquimans County.

July 1, 2013-June 30, 2014 – 15 patients X 1.06 = 15.9

July 1, 2014-June 30, 2015 – 15.9 patients X 1.06 = 16.854

July 1, 2015-June 30, 2016- 16.854 patients X 1.06 = 17.86524

July 1, 2016-June 30, 2017- 17.86524 patients X 1.06 = 18.9371544

Operating Year One is projected to begin July 1, 2015 and end June 30, 2016

Operating Year Two is projected to begin July 1, 2016 and end on June 30, 2017.”

Edenton Dialysis Center Historic Patient Origin

COUNTY	JUNE 2012		JUNE 2013		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 2012	YEAR 2013
Chowan	31	0	32	0	61.0%	60.4%
Pasquotank	4	0	4	0	7.8%	7.5%
Perquimans	14	0	15	0	27.4%	28.3%
Tyrell	2	0	2	0	3.9%	3.8%
Total	51	0	53	0	100.0%	100.0%

Source: pages 19 and 20 of the application.

The following table shows the number of in-center patients by county for operating years FY 2016 and FY 2017.

Edenton Dialysis Center Projected Patient Origin

COUNTY	OPERATING YEAR 1 FY16		OPERATING YEAR 2 FY17		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Chowan	32	0	32	0	58.2%	57.2%
Pasquotank	4	0	4	0	7.3%	7.1%
Perquimans	17	0	18	0	30.9%	32.1%
Tyrell	2	0	2	0	3.6%	3.6%
Total	55	0	56	0	100.0%	100.0%

Source: pages 19 and 20 of the application.

Based upon the above table, operating year one (FY 2016) will have a utilization rate of 80.9% and 3.2 patients per station. Operating year two (FY 2017) will have a utilization rate of 82.4% and 3.3 patients per station.

The applicant adequately identified the population it proposes to serve.

Demonstration of Need

The need to replace the facility is based upon the following;

- The current facility was built in the early 1990s.
- The building is in a poor state of repair.
- The proposed site is 0.3 mile from the current location.
- The proposed site will offer a new state-of-the-art facility for patients and is “*just the right thing to do.*”

In Section III.7, pages 19-21, the applicant provides the assumptions and methodology it used to project the proposed in-center patient utilization in operating years one and two. The January 2013 Semiannual Dialysis Report (SDR) indicates that there were 50 patients (as of 6/31/2012). The applicant states that there were 53 ESRD in-center dialysis patients receiving treatments as of June 11, 2013. The facility utilization rate identified in the January 2013 SDR is 73.53% ($50 / 17 = 2.94 / 4 = .7353$). Using the

June 2013 data, 53 patients equals 78% utilization ($53 / 17 = 3.12 / 4 = 77.9\%$). The facility is projected to have 55 patients in FY 2016 for a utilization rate of 81% ($55 / 17 = 3.24 / 4 = 81.0\%$). In operating year two (FY 2017) the applicant calculates a utilization rate of 82.4% ($56 / 17 = 3.29 / 4 = 82.4\%$).

The applicant demonstrated the need for the relocation of the facility.

Access to Services

In Section VI. 1(a) page 28-31, the applicant states,

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

...

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

The applicant projects that 69.8.9% of its patients will be covered by Medicare, Medicaid or VA and another 28.3% will be covered by Medicare/Commercial. The applicant adequately demonstrates the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

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.

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Applicant proposes to move the facility .3 mile therefore the needs of the population presently served will be adequately met by the proposed relocation.

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

CA

The applicant is relocating the facility from its current site to 312 Medical Arts Drive, Lot 6 in Edenton, a distance of 0.3 mile from the current location. The purpose of the relocation is to address physical plant issues without effecting access or quality.

In Section III.9, page 20, the applicant discusses the alternatives considered prior to the submission of its application, which include:

- 1) Maintain the Status Quo – This alternative was dismissed because the facility is in a poor state of repair and in critical need of replacement.
- 2) Relocate the facility – identify a site close to the current location of Edenton Dialysis Center on which to build a replacement facility.
- 3) Relocate the facility– Develop a new dialysis facility in Edenton, Chowan County. A site has been identified that is 0.3 mile from the existing location. The 0.3 mile difference between the old and new site will not affect access. This alternative will accommodate the building of a state-of-the-art dialysis center.

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

- The new EDC site can accommodate future growth in capacity.
- A centralized purchasing department will secure the dialysis chairs and TVs, negotiating the best product available at the best price.
- The facility will be a modern, state-of-the-art dialysis facility that will serve the needs of the ESRD dialysis patients living in the identified service area.
- An Edenton Dialysis Center Bio-Medical Technician will conduct preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule that reduces the need for repair maintenance and parts. This will extend the life of the dialysis machines.
- Patients will not have to travel an unreasonable distance to dialyze.

The application is conforming or conditionally conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. DVA Healthcare Renal Care, Inc. d/b/a Edenton Dialysis Center shall materially comply with all representations made in the certificate of need application.**
 - 2. DVA Healthcare Renal Care, Inc. d/b/a Edenton Dialysis Center shall relocate and operate no more than a total of seventeen (17) certified dialysis stations which shall include any isolation stations.**
 - 3. DVA Healthcare Renal Care, Inc. d/b/a Edenton Dialysis Center shall install plumbing and electrical wiring through the walls for no more than seventeen (17) dialysis stations which shall include any isolation stations.**
 - 4. DVA Healthcare Renal Care, Inc. d/b/a Edenton Dialysis Center shall not develop or offer home dialysis services as part of this project.**
 - 5. DVA Healthcare Renal Care, Inc. d/b/a Edenton Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII, page 36, the applicant projects that the total capital cost of the project will be \$1,452,013. In the table in Section VIII, page 36, the applicant shows that the capital cost of the project includes; \$955,500 in construction costs and \$70,000 for architect/engineering fees, \$79,020 dialysis machines, \$95,000 water treatment equipment, \$16,390 dialysis chairs, \$30,000 televisions, \$24,535 patient computer terminals and \$181,568 for other equipment and furniture.

In Section IX.3, page 40, the applicant projects that there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 17 contains a letter from the Chief Accounting Officer of DaVita Healthcare Partners, Inc. confirming DaVita's commitment of cash reserves in the sum of \$1,452,013 for capital costs of the project. DaVita's Form 10-K in Exhibit 18 confirms

the availability of said cash reserves on the consolidated balance sheet, page F-6. As of December 31, 2012 cash and cash equivalents were \$553,748,000.

Based on information provided by the applicant in Section X.1, page 41, the dialysis facility's projected allowable charges per treatment for each payment source are as follows:

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 42, the facility reimbursement is as follows:

SOURCE OF PAYMENT	REIMBURSEMENT PER TREATMENT
Medicare	\$240.00
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.¹ In Sections X.2-X.4, pages 41-45, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$ 1,956,706	\$2,011,553	\$ 2,048,838
Total Operating Costs	\$1,927,066	\$1,996,883	\$2,040,457
Net Profit	\$29,640	\$14,670	\$8,381

The applicant projects that revenues 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, page 42 of the

¹ http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage_Renal_Disease_Pro prospective_Payment_System_ICN905143.pdf

application for the applicant's assumptions on number of treatments (3 days/week, 52 weeks/year with 5% missed treatments).

The applicant's projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. In Section VII.1, page 32 and Section X.5, page 45, the applicant provides projected staffing and salaries. The applicant states compliance with all staffing requirements in 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 34. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and revenues. 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.

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DVA Healthcare Renal Care, Inc. d/b/a Edenton Dialysis Center proposes to relocate a 17 dialysis station facility a distance of 0.3 mile within the community of Edenton. EDC is the only dialysis facility in Chowan County.

With the relocation of the 17 stations, Edenton Dialysis Center's dialysis station inventory will not change, nor will the inventory of Chowan County.

The applicant adequately demonstrates the need to relocate the 17 dialysis stations of Edenton Dialysis Center within Chowan County. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

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The following table illustrates the projected staffing for Edenton Dialysis Center, as provided by the applicant in Section VII.1, page 32.

Position	Current FTE Positions	Projected FTE Positions
RN	2.5	2.5
PCT	7.5	7.5
Bio-Med Tech	0.5	0.5
MD	Contract	Contract
Admin	1.0	1.0
Dietician	0.5	0.5
Social Worker	0.5	0.5
Unit Secretary	1.0	1.0
Other-Reuse	1.0	1.0
Total	14.5	14.5

As shown in the above table, the applicant proposes to retain the current staffing level of 14.5 FTEs to staff the Edenton Dialysis Center upon completion of the proposed project. In Section VII.1, page 32-33, the applicant states,

“The Regional Operations Director is responsible for the overall operation of the facility and serves as liaison to the governing body. She is also responsible for ensuring compliance with 42 C.F.R. and budgetary compliance.

...

The UA [unit administrator] is responsible for the quality dialysis care for all patients in the facility on a daily basis through planning and teammate scheduling. ... The UA also ensures that direct patient care is provided. The UA also supervises orientation and training of new teammates and ensures that teammates adhere to facility policies and procedures”

The following table shows the projected number of direct care staff for each shift offered in the Edenton Dialysis Center facility after the relocation of the 17 stations.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11am	5	5	5	5	5	5
Afternoon	11am to 4pm	5	5	5	5	5	5
Evening	N/A	0	0	0	0	0	0

In Section V.4(c), page 26, the applicant states that Dr. Ravi Ramsamooj serves as the Medical Director of the facility and has indicated his willingness to continue to serve (See Exhibit 12). In Section VII.2, page 33, the applicant states Dr. Ravi Ramsamooj is board-certified in Nephrology with several years of experience in the care of ESRD patients.

The information provided in Section VII is reasonable and credible. The applicant adequately demonstrates the availability of resources, including health manpower and

management personnel, including a medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion.

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

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In Section V.1, page 24, the applicant provides a list of providers of the necessary ancillary and support services. Acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services, blood bank and vascular surgery will be provided by Albemarle Hospital. Exhibit 9 contains a letter from Albemarle Hospital agreeing to provide support services. In addition, Exhibit 10 contains a letter from Sentara Norfolk General Hospital agreeing to serve as a renal transplant center.

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. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

- (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and

- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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The applicant proposes to construct a 7,774 square foot dialysis facility, with 160 square feet per dialysis station on a 1.37 acre lot currently zoned for dialysis use. In Section III, page 36, the applicant provides a breakdown of the total capital costs of \$1,452,013.

Capital Cost Breakdown

Site Costs	\$ 0
Construction Contract:	
Cost of Materials	\$573,300
Cost of Labor	\$382,200
Sub-Total-Construction Contract	\$955,500
Miscellaneous Project Costs:	
Dialysis Machines	\$79,020
(RO) Water Treatment Equipment	\$95,000
Equipment/Furniture	\$181,568
A&E Fees	\$70,000
Dialysis Chairs	\$16,390
Televisions	\$30,000
Chair side Computer Terminals	\$24,535
Sub-Total Miscellaneous	\$496,513
Total Capital Cost of Project	\$1,452,013

In Section XI.6 (d), page 49, the applicant states the facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating. This project is estimated to be 7,774 SF [3,011 SF for support services and 4,763 SF for treatment areas].

The applicant adequately addresses energy efficiencies and notes that costs will not unduly increase the costs and charges for providing the proposed services. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1 (a), page 28, the applicant states Edenton Dialysis Center will utilize a policy of making dialysis services available to all residents in its service area without qualifications.

In Section VI.1 (b), page 28, the applicant reports that 96.2% of the patients who received treatments at EDC had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source for the existing facility:

EDENTON DIALYSIS CENTER HISTORIC PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Private Pay	-
Medicare	17.0%
Medicaid	13.2%
Medicare/Medicaid	37.7%
Commercial Insurance	1.9%
VA	1.9%
Medicare/Commercial	28.3%
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 Chowan County and statewide.

	2011 Total # of Medicaid Eligibles as % of Total Population *	2011 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Chowan County	22.7%	11.0%	20.8%
Perquimans	18.6%	8.6%	21.1%
Statewide	17%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. 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 35.²

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

² Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”³

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.”⁴

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

ESRD Spending by Payor⁵		
Payor	Spending in Billions	% 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%

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender, as shown below:

³ <http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>

⁴ United States Renal Data System 2012 USRDS Report, Chapter 1, page 225:
http://www.usrds.org/2012/pdf/v2_ch1_12.pdf.

⁵ United States Renal Data System 2012 USRDS Report, Chapter 11, page 340:
http://www.usrds.org/2012/pdf/v2_ch11_12.pdf

Number and Percent of Dialysis Patients by Age, Race, and Gender		
	# of ESRD Patients	% of Dialysis Population
Age		
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%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
Total	9,342	100.0%

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.⁶

EDC 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 VI.1 (f), page 29, the applicant states,

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

In Section VI.6 (a), page 31, the applicant states, *“There have been no civil rights access complaints filed within the last five years.”*

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

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 29, the applicant provides the projected payor mix for the proposed services at the replacement facility as follows:

EDENTON DIALYSIS CENTER PROJECTED PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	17.0%
Medicaid	13.2%
Medicare/Medicaid	37.7%
Commercial Insurance	1.9%
VA	1.9%
Medicare/Commercial	28.3%
Total	100.0%

The applicant projects no change in the projected Edenton Dialysis Center payor mix from the current payor mix.

In Section VI.1 (a), page 28, the applicant states,

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

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

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

C

In Section VI.5, page 30, the applicant states that:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Edenton Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Chowan and surrounding 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 Edenton Dialysis Center directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Edenton Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Edenton Dialysis Center transfer and transient policies which comprise **Exhibit 13**. The patient, again, will be referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary.”*

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

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

CA

In Section V.3, pages 25-26, the applicant states,

“Edenton Dialysis Center has an agreement with the Kaplan nursing programs. See Exhibit 11 for a copy of the agreement.”

However, Kaplan nursing programs are not physically located in the Edenton area.

Prior to issuance of the certificate of need, DVA Healthcare Renal Care, Inc. d/b/a Edenton Dialysis Center shall provide the CON Section with a copy of a letter sent to a local health professional training program indicating an interest in establishing a training program relationship at Edenton Dialysis Center.

- (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 relocate a 17-station dialysis facility in Edenton, Chowan County from its current location to a new site 0.3 miles from the current site. EDC is currently the only dialysis facility in Chowan County. In Section V.7, page 27, the applicant discusses the impact of the project on competition as it relates to promoting cost-effectiveness, quality and access. On page 27, the applicant states,

“Chowan County is a rural county. The proposed relocation of the facility to a site 0.3 miles from the existing facility is not intended to be a competitive venture. The effect of other facilities in surrounding counties would be difficult to determine. The effect upon competition is unknown. However, patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. The Edenton Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”

The applicant further states that relocating the facility will maintain dialysis services close to where many of the Edenton Dialysis Center patients live, particularly those in Chowan County where a large concentration of dialysis patients live.

See also Sections II, III, V, VI and VII. The information provided by the applicant in the sections above is reasonable and credible and adequately demonstrates that the expected effects of relocating the existing dialysis facility will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis services. The determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need to relocate a 17 dialysis station facility within Edenton and that it is a cost effective alternative to meet that need;
- The applicant adequately demonstrates it will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V and

VII, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care; and

- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations. Currently more than 90% of the payor mix at EDC is comprised of Medicare/ Medicaid recipients.

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

EDC currently provides dialysis services at 703 Luke Street in Edenton. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Edenton Dialysis Center facility 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.

G.S. 131E-183(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

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- The January 2013 SDR, provided in Exhibit 7, shows a utilization rate of 73.53%. It was calculated based on 50 in-center dialysis patients and 17 certified dialysis stations as of June 30, 2012 (50 patients / 17 stations = 2.9412 patients per station; 2.9412 patients per station / 4.00 patients per station = 73.53%).

(2) *Mortality rates;*

-C- In Section IV.2, page 22, the applicant reports the 2010, 2011 and 2012 facility mortality rates as 26.8%, 19.4% and 20.0%, respectively.

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

-C- In Section IV.3, page 22, the applicant states, “*The Elizabeth City Dialysis Center provides home training for patients under an agreement with Edenton Dialysis Center.*”

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

-C- In Section IV.4, page 23, the applicant states, “*The Edenton Dialysis Center referred 8 patients for transplant evaluation in 2012. None of these patients received a transplant in 2012.*”

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

-C- In Section IV.5, page 23, the applicant states, “*The Edenton Dialysis Center has 2 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 23, the applicant states that there were 126 hospital admissions in 2012 for Edenton Dialysis Center: 44 (34.9%) of which were dialysis related and 82 (65.1%) 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 23, the applicant states that there were 2 patients dialyzing at Edenton Dialysis Center with AIDS and no patients with Hepatitis B, as of December 31, 2012. No patients converted to infectious status within the last 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:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
- NA- EDC is an existing facility, with an existing agreement with Albemarle Hospital of Elizabeth City. See Exhibit 9.
- (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- EDC is an existing facility with an existing agreement with Sentara Norfolk General Hospital Renal Transplant Center. See Exhibit 10.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- Exhibit 22 provides site specific documentation of the availability of water and sewer from the Town of Edenton.

- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 8, 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- See Section XI.2-3, pages 46-47 and Exhibit 20, where the applicant provides the required information regarding the primary and secondary sites.
 - (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), pages 46-53, the applicant states, *“Edenton Dialysis Center has and will operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health safety requirements.”*
 - (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 on page 19 of the application;

**Edenton Dialysis Center
 Projected Dialysis Patient Origin**

COUNTY	OPERATING YEAR 1 FY 2016		OPERATING YEAR 2 FY 2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Chowan	32	0	32	0	58.2%	57.2%
Pasquotank	4	0	4	0	7.3%	7.1%
Perquimans	17	0	18	0	30.9%	32.1%
Tyrrell	2	0	2	0	3.6%	3.6%
Total	55	0	56	0	100.0%	100.0%

See Section III.7, pages 19-20 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.*

-NA- EDC is an existing facility.

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

-C- In Section VI. 1(a), page 28, the applicant states,

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

.2203 PERFORMANCE STANDARDS

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

-NA- EDC is an existing facility.

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

-NA- Edenton Dialysis Center is not proposing to add dialysis stations.

.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 24, states patients will be referred to Albemarle Hospital for diagnostic and evaluation services.

(2) *maintenance dialysis;*

-C- The table in Section V.1, page 24, states the applicant will provide in-center maintenance dialysis.

(3) *accessible self-care training;*

-C- To be provided at Elizabeth City Dialysis Center.

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

-C- In Section V.1, page 24, the applicant states that Elizabeth City Dialysis Center will provide support for patients dialyzing at home. The applicant also addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 25.

The home training program currently offered through Elizabeth City Dialysis Center will continue.

(5) *x-ray services;*

-C- The table in Section V.1, page 24, states patients will be referred to Albemarle Hospital for x-ray services.

(6) *laboratory services;*

-C- The table in Section V.1, page 24, indicates patients will be referred to Dialysis Laboratories for routine and immunological special laboratory services.

(7) *blood bank services;*

-C- The table in Section V.1, page 24, indicates patients will be referred to Albemarle Hospital for blood bank services.

(8) *emergency care;*

-C- The table in Section V.1, page 24, indicates patients will be referred to Albemarle Hospital for emergency care.

- (9) *acute dialysis in an acute care setting;*
- C- The table in Section V.1, page 25, indicates patients will be referred to Albemarle Hospital for acute dialysis in an acute care setting. See Exhibit 9 for a copy of the hospital's patient transfer agreement with Edenton Dialysis Center.
- (10) *vascular surgery for dialysis treatment patients;*
- C- The table in Section V.1, page 24, indicates dialysis patients will be referred to Albemarle Hospital for vascular surgery.
- (11) *transplantation services;*
- C- The table in Section V.1, page 24, indicates patients will be referred to Sentara Virginia Beach General Hospital for transplantation services. See Exhibit 10 for documentation from Sentara Virginia Beach General Hospital.
- (12) *vocational rehabilitation counseling and services; and*
- C- The table in Section V.1, page 24, indicates patients will be referred to the North Carolina Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.
- (13) *transportation.*
- C- The table in Section V.1, page 24, indicates patients will be referred to "DSS/Various Providers" 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 32, the applicant provides the proposed staffing for Edenton Dialysis Center. The applicant states, "*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 as evidenced below.*" Edenton Dialysis Center plans for two dialysis shifts; direct care staffing of 5.0 FTE per shift on Monday through Saturday as noted in response to VII.10, page 34.
- (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 34, the applicant refers to Exhibit 16 for a copy of the training program description/outline. Exhibit 16 contains a copy of DaVita's Training Programs for New Patient Care Provider. Exhibit 24 contains the Edenton Dialysis Center Annual In-Service Calendar.