

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 20, 2013  
PROJECT ANALYST: Bernetta Thorne-Williams  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: R-10202-13/ DVA Healthcare Renal Care, Inc. d/b/a Elizabeth City Dialysis / Add nine dialysis stations for a total of 25 certified dialysis stations upon completion of this project and Project I.D # R-10176/ Pasquotank County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

DVA Healthcare Renal Care, Inc. d/b/a Elizabeth City Dialysis proposes to add nine dialysis stations for a total of 25 certified dialysis stations upon the completion of Project I.D # R-10176 (transfer 14 in-center dialysis stations, home training for peritoneal dialysis and home hemodialysis patients services to Albemarle Dialysis to establish a new End Stage Renal Facility in Pasquotank County) and this project.

According to the July 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 2 dialysis stations in Pasquotank County. However, the applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported for Elizabeth City Dialysis in the July 2013 SDR is 3.76 patients per station. This utilization rate was calculated based on

113 in-center dialysis patients and 30 certified dialysis stations (113 patients / 30 stations = 3.766 patients per station).

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

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/12		94.0%
Certified Stations		30
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>30</b>
In-Center Patients as of 12/31/12 (SDR2)		113
In-Center Patients as of 6/30/12 (SDR1)		105
Step	Description	
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12	0.1524
(ii)	Divide the result of Step (i) by 12	0.0127
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/11 until 12/31/12)	0.1524
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	130.2190
(v)	Divide the result of Step (iv) by 3.2 patients per station	40.6935
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	11

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 11 stations. Step (C) of the facility need methodology states “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add nine new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, pages 42-43 of the 2013 SMFP is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A*

*certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Promote Safety and Quality**

In Section II.3, page 17, the applicant discusses the quality of services provided at DaVita HealthCare Partners, Inc. owned and operated ESRD facilities. The applicant states that its success in providing quality services stems from a comprehensive Quality Management Program that includes the following components:

- *“Quality Improvement Methodology – utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System – integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Staff and Patient Education Program – ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program – systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team – experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team – experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance).”*

The applicant further states on page 17, that the company’s goal is to have each facility serve as a quality improvement laboratory where successful outcomes can be disseminated throughout DaVita. Exhibit 21 contains the DaVita’s Health and Safety Policy & Procedure Manual which includes a section on General Health and Safety Policies. The Health and Safety Policies state, in part:

*“The Health and Safety Policy & Procedure Manual is designed to ensure compliance and provide policy and procedure for teammate health and safety issues. Using this manual, each DaVita facility will meet Federal regulations as they relate to Risk and Occupational Safety Health and Administration (OSHA), support the corporate philosophy of consistent practice and operations of facilities within the company ...”*

The applicant adequately demonstrates that the proposal will promote safety and quality care at Elizabeth City Dialysis.

**Promote Equitable Access**

In Section VI.1, pages 30-31, the applicant states that Elizabeth City Dialysis has and will continue to provide services to all residents of the service area without regard to race, sex, age, gender, handicap, ethnic or socioeconomic groups in need of dialysis service regardless of their ability to pay. The applicant further states on page 30 that 90.4% of its patients had some or all of their services paid for by Medicare or Medicaid.

The applicant adequately demonstrates that the proposal will promote equitable access.

**Maximize Healthcare Value**

In Section III.9, pages 22-23, the applicant states that Elizabeth City Dialysis will maximize healthcare value in several ways which include utilization of a centralized purchasing department to negotiate national contracts with numerous vendors in order to secure the best product available at the best price; utilization of the reuse process that contains costs and the amount of dialyzer waste generated by the facility; the use of an electronic patient charting system that reduces the need for paper in the facility; preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule to reduce the need for repairs of the dialysis equipment; and inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand.

The applicant adequately demonstrates that the proposal will maximize healthcare value.

The applicant adequately demonstrates the proposal will incorporate the basic principles of Policy GEN 3. The application is also consistent with the facility need determination in the 2013 SMFP and is therefore 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.

The applicant, DVA Healthcare Renal Care, Inc. d/b/a Elizabeth City Dialysis proposes to add nine dialysis stations for a total of 25 certified dialysis stations upon the completion of Project I.D # R-10176 (transfer 14 in-center dialysis stations, home training for peritoneal dialysis and home hemodialysis patients services to Albemarle Dialysis to establish a new End Stage Renal Facility in Pasquotank County) and this project.

Population to be Served

In Section IV.1, page 24, the applicant identifies the population it served, as of December 31, 2012, as illustrated in the table below.

<b>Elizabeth City Dialysis Current Patient Origin</b>		
<b>County</b>	<b>In-Center Patients</b>	<b>Home Trained Patients</b>
Pasquotank	78	14
Currituck	4	5
Chowan	0	3
Dare	0	2
Hertford	0	4
Tyrrell	0	2
Perquimans	13	3
Bertie	0	1
Camden	15	2
Gates	3	1
<b>TOTAL</b>	<b>113</b>	<b>37</b>

In Section III.7, page 21, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

<b>Projected Dialysis Patient Origin</b>				
<b>COUNTY</b>	<b>Operating Year 1 2015</b>	<b>Operating Year 2 2016</b>	<b>County Patients as a Percent of Total</b>	
	<b>In-Center Patients</b>	<b>In Center Patients</b>	<b>Year 1</b>	<b>Year 2</b>
Pasquotank	47	51	57.3%	59.3%
Currituck	4	4	4.9%	4.7%
Perquimans	13	13	15.8%	15.1%
Camden	15	15	18.3%	17.4%
Gates	3	3	3.7%	3.5%
<b>TOTAL</b>	<b>82</b>	<b>86</b>	<b>100.0%</b>	<b>100.0%</b>

In Section III, page 21, the applicant provides the following data to support the above projected patient origin:

- Elizabeth City Dialysis had 113 in-center patients as of 12/31/2012.
- Seventy-eight of the 113 patients being served by the Elizabeth City Dialysis Center lived in Pasquotank County.
- Thirty-five of those patients receiving services at Elizabeth City Dialysis lived in four other counties.
- Elizabeth City Dialysis is applying for a nine station expansion following the completion of Project I.D # R-10176 (transfer 14 stations to establish a new ESRD facility in Pasquotank County).

The applicant adequately identified the population it proposes to serve.

### **Need Analysis**

In Section III, page 19, the applicant states the application is filed pursuant to the Facility Need Methodology. The applicant utilizes data from the July 2013 SDR and proposes to add nine dialysis stations to Elizabeth City Dialysis for a total of 25 stations upon completion of this project and Project I.D # R-10176 (transfer 14 dialysis stations and the home hemo-dialysis and training services to establish a new ESRD facility in Pasquotank County).

In Section III.7, pages 21-22, the applicant provides the following assumptions for the proposed project:

*“The Elizabeth City Dialysis Center had 113 in-center patients as of December 31, 2012... . This is a utilization rate of 94% based on the 30 certified stations in the facility. Of the 113 in-center patients cited in the SDR, 78 of those patients lived in Pasquotank County. The other 35 patients lived in four other counties. ...*

*The July 2013 SDR indicates on page 3 of Table B that Pasquotank County has experienced an average annual change rate of 7.2% for the past five years.*

*We have grown the patient population of the Elizabeth City Dialysis Center patients beginning with January 1, 2013 through the projected operating year 2. The calculations below begin with 78 in-center patients living in Pasquotank County:*

*January 1, 2013-December 31, 2013 – 78 patients X 1.072 = 83.616*

*January 1, 2014-December 31, 2014 – 83.616 patients X 1.072 = 89.636352*

*January 1, 2015 patient transfer to Albemarle Dialysis = 45 in-center patients*

*January 1, 2015 Elizabeth City Dialysis in-center patients = 89.636352  
Pasquotank patients and 35 patients living in other counties = 124.636352 –  
45 in-center patients transferring to Albemarle Dialysis = 79.6363352  
Elizabeth City Dialysis Center in-center patients*

*January 1, 2015-December 31, 2015 – 44.636358 patients X 1.072 =  
47.85016934*

*January 1, 2016-December 31, 2013 – 47.85016934 X 1.072 = 51.29538153*

*January 1, 2015 – December 31, 2015 (operating year 1)  
January 1, 2016 – December 31, 2016 (operating year 2)”*

The applicant further states on page 22 that it did not grow the patients living in the other four counties who receive treatment at Elizabeth City Dialysis. The applicant projects to serve 82 in-center patients (47 from Pasquotank County and 35 in-center patients from four other counties which are Currituck, Perquimans, Camden and Gates) dialyzing on 25 stations by the end of operating year 1 for a utilization rate of 82% or 3.3 patients per station [ $82 / 25 = 3.28 / 4.0 = 0.82$  or 82%]. The applicant projects 86 in-center patients (51 from Pasquotank County and 35 in-center patients from four other counties which are Currituck, Perquimans, Camden and Gates) at the end of operating year 2 for a utilization rate of 86% or 3.4 patients per station [ $86 / 25 = 3.44 / 4.0 = 0.86$  or 86%]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

### **Access to Services**

In Section VI, page 30, the applicant states:

*“Elizabeth City 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 patients without regard to race, sex, age, handicap, or other ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.*

...

*Elizabeth City Dialysis 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 54.3% of its patients will have all or part of their services covered by Medicare and or Medicaid, 6.1% will be covered by VA and another 36.1% 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.

NA

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

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In Section III.9, page 22, the applicant discusses the alternatives considered by Elizabeth City Dialysis, which include:

- 1) Maintain the Status Quo – the applicant concluded that with the transfer of 14 stations from the Elizabeth City Dialysis facility to establish a new ESRD facility (see Project I. D. # R-10176-13) in Pasquotank County the existing facility would be left with 16 certified dialysis stations. With the continued growth in Pasquotank County and the number of patients opting to have their dialysis care at Elizabeth City Dialysis doing nothing would not be in the best interest of their patients.



- 2) Adding nine stations – the applicant concluded that the proposal of nine additional dialysis stations, as proposed in the application, was its best alternative. Thus, the applicant concluded that the project as proposed was its least costly and most effective alternative

The applicant adequately demonstrates the need for nine additional stations based on the continued growth of the ESRD patient population in Pasquotank County and the facility's projected utilization. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable.

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

1. **DVA Healthcare Renal Care, Inc. d/b/a Elizabeth City Dialysis shall materially comply with all representations made in the certificate of need application.**
  2. **DVA Healthcare Renal Care, Inc. d/b/a Elizabeth City Dialysis shall develop and operate no more than nine additional stations for a total of 25 certified stations upon completion of this project and Project I.D. # R-10176-13, which shall include any isolation stations.**
  3. **DVA Healthcare Renal Care, Inc. d/b/a Elizabeth City 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.

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In Sections VIII, page 38 and IX, page 43, the applicant states there will be no capital expenses and no start-up costs or initial operating expenses associated with the proposed project.

In Exhibit 17, the applicant provides the audited financial statements for DaVita Healthcare Partners Inc. for the fiscal years ended December 31, 2012 and 2011. As of December 31, 2012, DaVita had \$533,748,000 in cash and cash equivalents, \$16,018,596,000 in total assets and \$4,508,740,000 in net assets

(total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project should the need arise.

In Section X.1, page 45, the applicant provides the allowable charges per treatment for each payment source for Elizabeth City Dialysis, as illustrated in the table below:

Payor	Allowable Charge Per In-center Treatment
Medicare	\$202.84
Medicaid	\$143.00
Medicare/Medicaid	\$253.55
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$253.55

In Sections X.2-X.4, pages 45-46, the applicant projects revenues and operating expenses for Elizabeth City Dialysis, as illustrated in the table below:

	Operating Year 1	Operating Year 2
Total Net Revenue	\$3,310,766	\$3,454,595
Total Operating Costs	\$3,051,358	\$3,162,106
<b>Net Profit</b>	<b>\$259,408</b>	<b>\$292,489</b>

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, credible and supported. See Section X, pages 45-48, for the applicant's assumptions.

The applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable and supported projections regarding revenues and operating expenses. 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 Elizabeth City Dialysis proposes to add nine dialysis stations for a total of 25 certified dialysis stations upon the completion of Project I.D # R-10176 (transfer 14 in-center dialysis stations, home training for peritoneal dialysis and home hemodialysis patients services to Albemarle Dialysis to establish a new End Stage Renal Facility in Pasquotank County) and this project. According to the July 2013 SDR, as the only provider of ESRD services in Pasquotank County, Elizabeth City Dialysis served 113

patients weekly at 3.7667 patients per station, which is 94.17% of capacity ( $113 / (4 \times 30) = .9417$ ) as of December 31, 2012. The applicant states that Elizabeth City Dialysis is located on the outskirts of the city limits of Elizabeth City and the development of a second dialysis facility in Pasquotank County will be within the city limits and will provide patients who live in the city limits of Elizabeth City easier access to dialysis services.

After the relocation of the 14 stations in January of 2015 to Albemarle Dialysis, 16 certified stations would remain at the Elizabeth City Dialysis. The proposed addition of nine stations would give the dialysis facility a total of 25 dialysis stations. The applicant projects to serve 82 in-center patients in operating year 1 (2015) dialyzing on 25 stations for a utilization rate of 82% or 3.2 patients per station [ $82 / 25 = 3.28 / 4.0 = 0.82$  or 82%]. The applicant projects 86 in-center patients in operating year 2 for a utilization rate of 86% or 3.4 patients per station [ $86 / 25 = 3.44 / 4.0 = 0.86$  or 86%]. The growth projections are based on Pasquotank County’s projected five-year average annual growth rate in the number of dialysis patients.

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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In Section VII.1, page 34, the applicant states that Elizabeth City Dialysis currently employs 23 full time equivalent staff (FTEs). The applicant does not propose to hire additional staff as a result of the proposed project. The applicant further states on page 34, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405 .2100.*”

In Section VII.10, pages 36-37, the applicant provides the following table that illustrates the current and projected number of direct care staff per shift offered:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning*	6am to 11am	7	7	7	7	7	7
Afternoon	11am to 4pm	7	7	7	7	7	7
Evening	N/A	0	0	0	0	0	0

\*The applicant indicates on page 37, that the projected schedule for the morning shift will operate from 6:00 a.m. – 10:30 a.m. The applicant does not provide an explanation as to why there is a projected shift of 30 minutes from the current schedule and the projected schedule following project completion.

In Section V.4, page 28, the applicant states that Dr. Karl Brandspigel, of Albemarle Nephrology, currently serves as the Medical Director of Elizabeth

City Dialysis and he has expressed his willingness to continue serving in that role.

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

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

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In Section V.1, page 26, 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. See Exhibit 9 for a copy of the acute care agreement and Exhibit 10 for a copy of the Transplant Agreement with Duke University Medical Center. The applicant adequately demonstrates the necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare 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.

NA

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

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

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In Section VI.1(a), page 30, the applicant states Elizabeth City Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), page 30, the applicant reports that 90.4% of the patients who received treatments at Elizabeth City 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 for the existing facility:

<b>ELIZABETH CITY DIALYSIS PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Medicare	21.9%
Medicaid	2.6%
Medicare/Medicaid	29.8%
Commercial Insurance	3.5%
VA	6.1%
Medicare/Commercial	36.1%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Onslow County and statewide.

	<b>2011 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2011 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured CY (Estimate by Cecil G. Sheps Center) *</b>
Pasquotank County	19%	8.4%	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.<sup>1</sup>

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

<sup>1</sup> Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.

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 prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”<sup>2</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>3</sup>*

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

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<sup>2</sup> <http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>

<sup>3</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).

<b>ESRD Spending by Payor<sup>4</sup></b>		
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:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<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%
<b>Total</b>	<b>9,342</b>	<b>100.0%</b>

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.<sup>5</sup>

Elizabeth City Dialysis 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

<sup>4</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)

<sup>5</sup> Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16.



programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

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

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

In Section VI.6 (a), page 33, the applicant states, *“There have been no civil rights access complaints filed within the last five years.”*

The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.1(c), page 31, the applicant provides the projected payor mix for the proposed services at the existing facility, as follows:

<b>ELIZABETH CITY DIALYSIS PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Medicare	21.9%
Medicaid	2.6%
Medicare/Medicaid	29.8%
Commercial Insurance	3.5%
VA	6.1%
Medicare/Commercial	36.1%
<b>Total</b>	<b>100.0%</b>

As illustrated in the table above, the applicant does not project a change in its payor mix.

In Section VI.1(a), page 30, the applicant states,

*“Elizabeth City Dialysis 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 demonstrates that medically underserved populations will continue to 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(a), page 32, the applicant states that:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at the Elizabeth City Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Pasquotank County and other counties surrounding Pasquotank County 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 Elizabeth City 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 Elizabeth City Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Elizabeth City Dialysis Center transfer and transient policies which comprise **Exhibit 13**. The patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission, if medically necessary.”* [Emphasis in original]

The applicant adequately demonstrates that it provides a range of means by which a person can access services at Elizabeth City Dialysis. 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(a), page 28, the applicant states,

*“Elizabeth City Dialysis Center is utilized as a clinical training site by the College of the Albemarle nursing students.”*

Exhibit 11 includes a copy of an agreement between Vivra Renal Care (currently Elizabeth City Dialysis) and the College of Albemarle for the ESRD facility to be included in its clinical rotation schedule for student nurses. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

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

C

The applicant proposes to add nine dialysis stations for a total of 25 certified dialysis stations upon the completion of Project I.D # R-10176 (transfer 14 in-center dialysis stations, home training for peritoneal dialysis and home hemodialysis patients services to Albemarle Dialysis to establish a new End Stage Renal Facility in Pasquotank County) and this project. Elizabeth City Dialysis is currently the only ESRD facility in Pasquotank County and upon completion of Project I.D # R-10176-13, DVA Healthcare Renal Care, Inc. will continue to be one of two providers of ESRD services within Pasquotank County. The July 2013 SDR reported the utilization rate Elizabeth City Dialysis was 3.76 patients per station. This utilization rate was calculated based on 113 in-center dialysis patients and 30 certified dialysis stations (113 patients / 30 stations = 3.766 patients per station).

In Section V.7, page 29, the applicant discusses the impact of the proposed project on competition as it relates to promoting cost-effectiveness, quality and access, the applicant states:

*“Pasquotank County is a rural county served by Albemarle Hospital. The proposed expansion of the facility is an effort to provide dialysis services to this rural community and surrounding rural communities that do not have a dialysis facility and is not intended to be a competitive venture. The Elizabeth City Dialysis Center is currently the only dialysis facility located in Pasquotank County. The effect of other facilities in surrounding counties would be difficult to determine since most patients from Pasquotank County already receive treatment in Elizabeth City. Many of the patients who live in Camden, Currituck, Perquimans and Gates Counties depend on the Elizabeth City Dialysis Center for their in-center treatments. The proposed Albemarle Dialysis [see Project I.D # R-10176-13] will primarily serve patients living in Elizabeth City. The Elizabeth City Dialysis Center will serve Elizabeth City patients as well as most of the patients who travel from out of county for their treatments. ...*

*There is no competitive provider in North Carolina that has a facility in close proximity of Pasquotank County. We have no knowledge of ill effect on competitors who operate in North Carolina. ...”*

According to the July 2013 SDR there is not a provider of ESRD services in the four other counties (Currituck, Perquimans, Camden and Gates) in which the applicant has historically served patients and projects to serve patients in the future.

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding nine dialysis stations to the existing Elizabeth City Dialysis facility will have a positive impact on cost-effectiveness, quality and access to the proposed service based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to add nine additional stations to the existing facility based on facility need methodology. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to Elizabeth City Dialysis patients;
- The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 (pages 26-29), and VII (pages 34-37), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.

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

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

Therefore, the application is conforming to this criterion.

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

C

DVA Healthcare Renal Care, Inc. currently provides dialysis services at Elizabeth City Dialysis. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Elizabeth City Dialysis 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- In Section II.1, page 10, the applicant states the utilization rate is reported in the July 2013 SDR provided in Exhibit 7. The July 2013 SDR reports a utilization rate of 94.17% which was calculated based on 113 in-center dialysis patients and 30 certified dialysis stations as of December 31, 2012. See Exhibit 1 for the Medicare Certification letter for Elizabeth City Dialysis.

(2) *Mortality rates;*

-C- In Section IV.2, page 24, the applicant reports the 2010, 2011 and 2012 facility mortality rates as 13.7%, 16.5% 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 25, the applicant states, “*Elizabeth City Dialysis Center had 37 home-trained patients as of December 31, 2012.*”

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

-C- In Section IV.4, page 25, the applicant states, “*Elizabeth City Dialysis Center had 6 patients receive a transplant in 2012. 12 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 25, the applicant states, “*Elizabeth City Dialysis Center has 24 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 25, the applicant states that Elizabeth City Dialysis had 205 hospital admissions in 2012 for, 32 (15.6%) of which were dialysis related and 173 (84.4%) of which 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 25, the applicant states that there were no patients dialyzing at Elizabeth City Dialysis with AIDS or Hepatitis B, as of December 31, 2012. The applicant also states that the number of patients treated with infectious disease who have converted to infectious status within the last year is zero.
- (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- Elizabeth City Dialysis is an existing facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- Elizabeth City Dialysis is an existing facility.

- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- Elizabeth City Dialysis is an existing facility.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 8, in which the applicant provides copies of written policies and procedures for back up electrical service in the event of a power outage.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- Elizabeth City Dialysis is an existing facility.
- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- In Section XI.6(g), page 53, the applicant states, “Elizabeth City Dialysis has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health safety requirements.”
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section III.7, pages 21-22, the applicant provides the projected patient origin, including all assumptions, the methodology by which the patient origin is projected, as illustrated in the table below.



**Projected Dialysis Patient Origin**

COUNTY	Operating Year 1 2015	Operating Year 2 2016	County Patients as a Percent of Total	
	In-Center Patients	In Center Patients	Year 1	Year 2
Pasquotank	47	51	57.3%	59.3%
Currituck	4	4	4.9%	4.7%
Perquimans	13	13	15.8%	15.1%
Camden	15	15	18.3%	17.4%
Gates	3	3	3.7%	3.5%
TOTAL	82	86	100.0%	100.0%

See Section III.7, pages 21–23 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- Elizabeth City Dialysis is an existing facility.

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

-C- In Section II. 1, page 12, the applicant states, “DVA Healthcare Renal Care, Inc. d/b/a Elizabeth City 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.*

-NA- Elizabeth City Dialysis 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.*
- C- In Section II, pages 12-13, the applicant states that there were 113 in-center patients dialyzing on 30 stations as of December 31, 2012 which resulted in a utilization rate of 94%. The applicant projects to have 82 in-center patients by the end of year one for a utilization rate of 82% or 3.2 patients per station per week [ $82 / 25 = 3.28 / 4.0 = 0.82$  or 82%].

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

(2) *maintenance dialysis;*

- C- The table in Section V.1, page 26, states the applicant will provide in-center maintenance dialysis.

(3) *accessible self-care training;*

- C- The table in Section V.1(d), page 26, the applicant does state that in-center hemodialysis, intermittent peritoneal dialysis, CAPD and CCPD will be provided by the applicant.

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

- C- The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V.2(d), page 27. The applicant states:

*“The Elizabeth City Dialysis Center 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."*

The home training program currently located at Elizabeth City Dialysis will be relocated to Albemarle Dialysis, (see Project I.D. # R-10176).

- (5) *x-ray services;*
  - C- The table in Section V.1, page 26, states patients will be referred to Albemarle Hospital for x-ray services.
- (6) *laboratory services;*
  - C- The table in Section V.1, page 26, states 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 26, states patients will be referred to Albemarle Hospital for blood bank services.
- (8) *emergency care;*
  - C- The table in Section V.1, page 26, states 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 26, states patients will be referred to Albemarle Hospital for acute dialysis in an acute care setting.
- (10) *vascular surgery for dialysis treatment patients;*
  - C- The table in Section V.1, page 26, states dialysis patients will be referred to Albemarle Hospital for vascular surgery.
- (11) *transplantation services;*

-C- The table in Section V.1, page 26, states patients will be referred to Pitt County Memorial Hospital and Duke University Medical Center for transplantation services. See Exhibit 10 for documentation of transplantation agreements.

(12) *vocational rehabilitation counseling and services; and*

-C- The table in Section V.1, page 26, states patients will be referred to the NC Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1, page 26, states patients will be referred to Inter-County Public Transportation 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 34, the applicant provides the current staffing for Elizabeth City Dialysis. The applicant states, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 as evidenced below.*” Elizabeth City Dialysis plans for two dialysis shifts; direct care staffing of 7.0 FTE per shift on Monday through Saturday as noted in response to VII.10.

(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 36, 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 Teammates. Exhibit 22 contains the Elizabeth City Dialysis Annual In-Service Calendar.