

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 14, 2017

Findings Date: July 14, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Project ID #: R-11320-17

Facility: Elizabeth City Dialysis

FID #: 955812

County: Pasquotank

Applicant(s): DVA Healthcare Renal Care, Inc.

Project: Add nine stations for a total of 28 stations upon completion of this project, Project ID #R-10176-13 (relocate 14 stations to Albemarle Dialysis), Project ID #R-10202-13 (add nine stations) and Project ID #R-10264-14 (relocate six stations to Perquimans Dialysis)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Healthcare Renal Care, Inc. (DVA) d/b/a Elizabeth City Dialysis (“the applicant”) proposes to add nine dialysis stations for a total of 28 stations at Elizabeth City Dialysis upon completion of this project, Project ID #R-10176-13 (relocate 14 stations), Project ID #R-10202-13 (add nine stations) and Project ID #R-10264-14 (relocate six stations).

#### **Need Determination**

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows

there is a surplus of ten dialysis stations in Pasquotank County. Therefore, the January 2017 SDR does not indicate a need for additional stations in Pasquotank County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations.

However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations because the utilization rate reported for Elizabeth City Dialysis in the January 2017 SDR is 3.6000 patients per station, or 90.00% (3.6000 / 4 patients per station = 0.9000). This utilization rate was calculated based on 108 in-center dialysis patients and 30 certified dialysis stations (108 patients / 30 stations = 3.6 patients per station).

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

<b>ELIZABETH CITY DIALYSIS APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		90.00%
Certified Stations		25
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>25</b>
In-Center Patients as of 6/30/16 (SDR2)		108
In-Center Patients as of 12/31/15 (SDR1)		108
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.0000
(ii)	Divide the result of step (i) by 12	0.0000
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.0000
(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	108.0000
(v)	Divide the result of step (iv) by 3.2 patients per station	33.7500
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>9</b>
Pending Stations: INCLUDE all previously approved stations to be added to this facility, which includes any stations certified after the cutoff date. Do NOT subtract any stations to be transferred from this facility.		

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is nine 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, therefore the application is consistent with the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2017 SMFP which is applicable to this review, Policy GEN-3: Basic Principles. Policy GEN-3, on page 33 of the 2017 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project would promote safety and quality in Section B-4(a), pages 9-10, Section N-1, page 51 and Section O, page 52, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project would promote equitable access in Section B-4(b), page 10, Section C-3, page 16, Section L, pages 45-49, Section N-1, page 51, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

### **Maximize Healthcare Value**

The applicant describes how it believes the proposed project would maximize healthcare value in Section B-4(c), page 11, Section F, pages 25-29, and Section N, page 51. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

## **Conclusion**

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the January 2017 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

## C

The applicant proposes to add nine new stations at Elizabeth City Dialysis, an existing facility located at 1840 West City Drive in Elizabeth City. Upon completion of this project, Project ID #R-10176-13 (relocate 14 stations – certified in July 2016), Project ID #R-10202-13 (add nine stations – certified in July 2016) and Project ID #R-10264-14 (relocate six stations to Perquimans Dialysis – projected certification in January 2019).

In addition to in-center (IC) dialysis, Elizabeth City Dialysis currently provides a peritoneal dialysis (PD) home therapy program. However, this application is for nine additional in-center dialysis stations.

## **Patient Origin**

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Pasquotank County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 20, the applicant identifies the population served as of June 30, 2016, as illustrated below in the table:

<b>ELIZABETH CITY DIALYSIS PROJECTED PATIENT ORIGIN As of June 30, 2016</b>		
<b>County</b>	<b># In-Center Dialysis Patients</b>	<b># Peritoneal Dialysis Patients</b>
Pasquotank	70	14
Camden	9	3
Chowan	0	6
Currituck	6	3
Dare	1	4
Gates	2	1
Halifax	1	0
Hertford	0	1
Perquimans	15	6
Randolph	1	0
Tyrrell	0	1
Other States	3	0
<b>Total</b>	<b>108</b>	<b>39</b>

In Section C-1, page 13, the applicant provides the projected patient origin for Elizabeth City Dialysis for in-center (IC) patients for the first two years of operation following completion of the project as follows:

<b>ELIZABETH CITY DIALYSIS PROJECTED IN-CENTER PATIENT ORIGIN by COUNTY</b>				
	<b>OY1 CY2019</b>	<b>OY2 CY2020</b>	<b>Percent of Total OY1</b>	<b>Percent of Total OY2</b>
<b>County</b>	<b>IC</b>	<b>IC</b>		
Pasquotank	75	76	59.6%	60.1%
Camden	9	9	7.7%	7.6%
Chowan	0	0	3.8%	3.8%
Currituck	6	6	5.8%	5.7%
Dare	1	1	3.2%	3.2%
Gates	2	2	1.9%	1.9%
Halifax	1	1	0.6%	0.6%
Hertford	0	0	0.6%	0.6%
Perquimans	15	15	13.5%	13.3%
Randolph	1	1	0.6%	0.6%
Tyrrell	0	0	0.6%	0.6%
Other States	2	2	1.3%	1.3%
<b>Total</b>	<b>113</b>	<b>114</b>	<b>100.0%</b>	<b>100.0%</b>

Note: Project Analyst includes PD patients in the percent of total patients.

The applicant provides the assumptions and methodology used to project in-center patient origin on pages 13-15. The applicant adequately identifies the population to be served.

### **Analysis of Need**

In Section B-2, page 7, the applicant states that the need for the proposed project is based on the facility need methodology in the 2017 SMFP utilizing data from the January 2017 SDR, and it proposes to add nine dialysis stations to Elizabeth City Dialysis for a total of 28 stations at the facility upon completion of this project and the other projects previously named in these findings. The applicant uses the following assumptions in Section C-1, pages 13-14 of the application:

- Based on information in the January 2017 SDR, as of June 30, 2016, the utilization rate for Elizabeth City Dialysis was 90.00% or 3.6 patients per station per week. This utilization was based on 108 in-center patients dialyzing on 30 stations. Ninety of the 108 patients were residents of Pasquotank County, 15 were from Perquimans County (outside the Pasquotank County service area), and the remaining 23 patients were from other counties (also outside the service area) and out of state.
- The applicant was approved to develop Albemarle Dialysis (also in Pasquotank County) by transferring 14 stations from Elizabeth City Dialysis in Project ID #R-10176-13. Those 14 stations were transferred on July 7, 2016, leaving Elizabeth City Dialysis with 16 stations.
- In Project ID #R-10202-13, DVA was approved to add nine stations at Elizabeth City Dialysis. Those stations were certified on July 8, 2016 for a total of 25 dialysis stations.
- In Project ID #R-10264-14, DVA was approved to transfer six stations from Elizabeth City Dialysis to develop Perquimans County Dialysis. The transfer of six stations will leave Elizabeth City Dialysis with 19 stations. In the application, the applicant indicated that 13 in-center patients would transfer their care from Elizabeth City Dialysis to Perquimans County Dialysis when it is certified in January 2019.
- The applicant uses a growth rate of 2.0% for the Elizabeth City Dialysis facility, which is Pasquotank County's Five Year Average Annual Change Rate (AACR) as published in Table B of the January 2017 SDR for the 70 Pasquotank County in-center patients. Thus, the applicant assumes a 2.0% growth rate for the facility through the second operating year (see chart of projected center growth rate on page 13 of the application). The applicant projects no growth for patients living outside of Pasquotank County.
- The applicant projects that after the growth period beginning January 1, 2018 and ending December 31, 2018, Elizabeth City Dialysis will have 111 in-center patients, 99 of whom will be from Pasquotank County. After subtracting 13 in-center patients who are projected to transfer to Perquimans County Dialysis, 86 patients from Pasquotank County will be dialyzing at Elizabeth City Dialysis, and 25 patients will be from outside of Pasquotank County beginning with the 2019 Calendar Year (CY)/Operating Year 1 (OY).
- The applicant projects Elizabeth City Dialysis will have 100 in-center patients by the end of OY1 for a utilization rate of 89.3% or 3.57 patients per station per week and 101 in-

center patients by the end of OY2 for a utilization rate of 90.2% or 3.61 patients per station per week.

- OY1 is CY 2019
- OY2 is CY 2020

Projected Utilization

The applicant’s methodology from Section C-1, page 15, is illustrated in the following table.

<b>ELIZABETH CITY DIALYSIS IN-CENTER PATIENT PROJECTIONS</b>					
	<b>Start Date</b>	<b># SA* Patients x Growth Rate</b>	<b>SA Year End Census + # out of SA existing patients</b>	<b>Total Year End Census</b>	<b>Year End Date</b>
Beginning SA census	6/31/2016	# SA patients = 70			
Interim Period	7/1/2016	70 x 1.01 = 70.7	70.7 + 38	108.7	12/31/2016
Current Year	1/1/2017	70.7 x 1.02	72.114 + 38	110.114	12/31/2017
Interim Period	1/1/2018	72.114 x 1.02	73.55628 + 38	111.5563	12/31/2018
OY1	1/1/2019	73.55628 x 1.02	**75.02741 + (38-13) = 25	100.0274	12/31/2019
OY2	1/1/2020	75.02741 x 1.02	76.52795 + 25	101.528	12/31/2020

\*SA = service area = Pasquotank County. \*\*13 patients transferring to Perquiman’s Dialysis.

The applicant projects to serve 100 in-center patients or 3.57 patients per station per week (100/28 = 3.57) by the end of OY1 and 101 in-center patients or 3.61 patients per station per week (101/28 = 3.61) by the end of OY2 for the proposed 28-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C.2203(b). The January 2017 SDR indicates that Elizabeth City Dialysis operated at a utilization rate of 90.00 percent (3.6 patients per station) as of June 30, 2016. Based on data reported in the SDR, during the period from June 30, 2015 to June 30, 2016, the in-center census at Elizabeth City Dialysis increased from 106 to 108 patients, which is an annual rate of growth of 1.8% percent. In this application, the applicant assumes a projected annual rate of growth of 2.0 percent for the in-center patient census at Elizabeth City Dialysis, which equals the Pasquotank County Five Year Average Annual Change Rate of 2.0 percent. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L-1(a), pages 45-46, the applicant states that Elizabeth City Dialysis makes its services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L-7, page 49, the

applicant reports that 88.1% of the in-center patients who received treatments at Elizabeth City Dialysis had some or all of their services paid for by Medicare or Medicaid in CY2016. In Section L-1(b), page 46, the applicant projects 88.1% of its in-center patients will be Medicare or Medicaid recipients; no change from its current payor mix. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

### **Conclusion**

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

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

NA

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

CA

In Section E-1, page 24, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would not support the growth rate at the facility.
2. Apply to add nine stations – the applicant states that the nine-station expansion would help to meet the growing demand and ensure access for dialysis services at Elizabeth City Dialysis.

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

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

- 1. DVA 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 add no more than nine dialysis stations at Elizabeth City Dialysis for a total of no more than 28 certified dialysis stations upon completion of this project, Project ID #R-10176-13 (relocate 14 stations – certified in July 2016), Project ID #R-10202-13 (add nine stations – certified in July 2016) and Project ID #R-10264-14 (relocate six stations to Perquimans Dialysis – projected certification is January 2019); which shall include any include any home hemodialysis training or isolation stations.**
  3. **DVA Renal Healthcare, Inc. d/b/a Elizabeth City Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

## C

The applicant proposes to add nine dialysis stations to Elizabeth City Dialysis, for a total of 28 dialysis stations at Elizabeth City Dialysis upon completion of this project, Project ID #R-10176-13 (relocate 14 stations – certified in July 2016), Project ID #R-10202-13 (add nine stations – certified in July 2016) and Project ID #R-10264-14 (relocate six stations to Perquimans Dialysis – projected certification is January 2019).

### **Capital and Working Capital Costs**

In the table in Section F-1, page 25, the applicant states that there are no capital costs associated with the proposed project. Additionally, in Section F-10, pages 27-28, the applicant states that there are no working capital needs as Elizabeth City Dialysis is an existing facility.

### **Availability of Funds**

Exhibit F-7 contains the 2015 Consolidated Financial Statements for DaVita Healthcare Partners, Inc. for year ending December 31, 2015; which states that DaVita Healthcare Partners, Inc. had \$1.5 billion in cash and cash equivalents, \$18.5 billion in total assets and \$4.5 billion in current assets. The applicant adequately demonstrates that sufficient funds would be available if capital needs were required for the project.

### **Financial Feasibility**

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

<b>ELIZABETH CITY DIALYSIS</b>		
<b>Revenue and Expenses</b>		
	<b>CY2019</b>	<b>CY2020</b>
Total Treatments*	14,672	14,894
Total Charges	\$6,081,669	\$6,197,122
Total Net Revenue	\$5,913,899	\$6,026,634
Total Operating Expenses	\$4,674,821	\$4,768,073
<b>Net Income</b>	<b>\$1,239,078</b>	<b>\$1,258,561</b>

\*Total treatments adjusted for missed treatments, Section F, Form C.

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used by the applicant in preparation of the pro forma financial statements including projected utilization, costs and charges are reasonable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal, and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

**C**

The applicant proposes to add nine stations to Elizabeth City Dialysis for a total of 28 certified dialysis stations at Elizabeth City Dialysis upon completion of this project, Project ID #R-10176-13 (relocate 14 stations – certified in July 2016), Project ID #R-10202-13 (add nine stations – certified in July 2016) and Project ID #R-10264-14 (relocate six stations to Perquimans Dialysis – projected certification is January 2019 in this application; in the original application projected certification date is January 2016).

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Pasquotank County. Facilities may also serve residents of counties not included in their service area.

The January 2017 SDR indicates there is one existing dialysis facility and one approved dialysis facility in Pasquotank County, as follows:

<b>PASQUOTANK COUNTY DIALYSIS FACILITIES            EXISTING &amp; APPROVED/CERTIFIED STATIONS &amp;            UTILIZATION as of June 30, 2016</b>						
<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
Elizabeth City Dialysis	DaVita	101	Elizabeth City	30	*-6	90.00%
Albemarle Dialysis	DaVita	NA	Elizabeth City	0	**0	00.00%

\*Six stations approved for transfer to Perquimans Dialysis. \*\*Not certified until July 2016; 14 stations approved.

As illustrated above, both the existing and approved facilities are owned and operated by the applicant, and the existing facility has a utilization rate of 90.0%. The new facility owned by the applicant has been approved and is projected to be certified by January 2019.

In Section G-2, page 31, the applicant states,

*“... Because this application utilizes the Facility Need Methodology and addresses the specific needs of patients who chose to receive service from DaVita, we will focus on the one operational facility for the purposes of examining possible duplication of services.*

*The one operational facility [sic] Pasquotank County was operating at 80% or greater utilization as reported in the January 2017 SDR. Therefore, this facility has the potential for adding stations, ... In Section B-2 and Section C of this application, we demonstrate the need that Elizabeth City Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Pasquotank County, it serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved serves in the service area.”*

In Section C-1, page 13, the applicant identifies the patient population it proposes to serve during the first two years of operation following completion of this project, Project ID #R-10176-13 (relocate 14 stations – certified in July 2016), Project ID #R-10202-13 (add nine stations – certified in July 2016) and Project ID #R-10264-14 (relocate six stations to Perquimans Dialysis – projected certification is January 2019, as illustrated below in the table:

<b>ELIZABETH CITY DIALYSIS PROJECTED IN-CENTER PATIENT ORIGIN by COUNTY</b>				
	<b>OY1 CY2019</b>	<b>OY2 CY2020</b>	<b>Percent of Total OY1</b>	<b>Percent of Total OY2</b>
<b>County</b>	<b>IC</b>	<b>IC</b>		
Pasquotank	75	76	59.6%	60.1%
Camden	9	9	7.7%	7.6%
Chowan	0	0	3.8%	3.8%
Currituck	6	6	5.8%	5.7%
Dare	1	1	3.2%	3.2%
Gates	2	2	1.9%	1.9%
Halifax	1	1	0.6%	0.6%
Hertford	0	0	0.6%	0.6%
Perquimans	15	15	13.5%	13.3%
Randolph	1	1	0.6%	0.6%
Tyrrell	0	0	0.6%	0.6%
Other States	2	2	1.3%	1.3%
<b>Total</b>	<b>113</b>	<b>114</b>	<b>100.0%</b>	<b>100.0%</b>

As shown in the previous table, at the end of OY1 (2019), the applicant is projecting an in-center patient census of 100 patients (13 patients are projected to transfer to Perquimans Dialysis), for a utilization rate of 89.2% or 3.57 patients per station per week (100 patients / 28 stations = 3.57 / 4 = 0.892 or 89.2%). At the end of OY2 (2020), the applicant is projecting an in-center patient census of 86 patients for a utilization rate of 90.1% or 3.60 patients per station per week (101 patients / 28 stations = 3.60/4 = 0.901 or 90.1%). The projected utilization of 3.2 patients per station per week for OY1 meets the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates that projected utilization is based on growth of in-center patients at the facility.

The applicant adequately demonstrates the need to add nine stations to the Elizabeth City Dialysis facility based on the number of in-center patients it proposes to serve. The discussion of analysis of need found in Criterion (3) is incorporated herein by reference.

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

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

C

In Section H-1, page 32, the applicant provides a table as illustrated below, with the current staff in full time equivalents (FTEs) for Elizabeth City Dialysis. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart. The applicant does not propose any new staff as a result of the proposed project, as shown below in the table.

<b>ELIZABETH CITY DIALYSIS CURRENT AND PROJECTED STAFFING</b>	
<b>Position</b>	<b>Current Number of FTEs</b>
Registered Nurse	4.0
Patient Care Technician (PCT)	12.0
Administrator	1.0
Dietitian	1.0
Social Worker	1.0
Home Training RN	2.0
Administrative Assistant	1.0
Biomedical Technician	0.5
<b>Total</b>	<b>22.5</b>

In Section H-2, page 33 and Section I-3, page 37, the applicant identifies Dr. Karl Brandspigel, as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of a February 15, 2017 letter signed by Dr. Brandspigel of Albemarle Nephrology (board certified in nephrology and internal medicine) supporting the project to add dialysis stations and confirming his continued commitment to serve as Medical Director. In Section H-3, pages 33-34, the applicant states that vacant staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program.

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

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

C

In Section I-1, page 36, the applicant lists the providers of the necessary ancillary and support services provided at the existing facility. The applicant discusses coordination with the existing health care system on pages 37-38. Exhibits I-1 and I-3 contain documents from the facility administrator at Elizabeth City Dialysis, DaVita, DaVita Laboratory Services, Inc., and local physicians, respectively, documenting availability of the necessary ancillary and support services. The facility administrator's letter of support lists the following agreements: Sentara Albemarle Medical Center provides acute, emergency, blood bank, diagnostic, X-ray, surgical, vascular and pediatric nephology services, Vidant Medical Center provides transplantation services, NC Division of Vocational Rehabilitation Services provides vocational services and Inter-County

Public Transportation Authority (ICPTA) provides transportation. The information in Section I and corresponding exhibits is reasonable and supports a finding of conformity to this criterion.

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

NA

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

NA

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

NA

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

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

C

In Section L-1, pages 45-46, the applicant states, “*Elizabeth City Dialysis, by policy, makes dialysis services available to all residents in its service area without qualifications. ... Elizabeth City Dialysis helps uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.*”

In Section L-7, page 49, the applicant reports that 87.6% of all the patients and 88.1% of all in-center patients who received treatment at Elizabeth City Dialysis had some or all of their services paid for by Medicare or Medicaid in CY 2016, as below illustrated.

<b>Payment Source</b>	<b>Percent of Total Patients</b>	<b>Percent of IC Patients</b>	<b>Percent of PD Patients</b>
Medicare	20.0%	21.7%	7.7%
Medicaid	2.9%	3.3%	0.0%
Commercial Insurance	4.8%	3.3%	15.4%
Medicare / Commercial	33.3%	27.2%	76.9%
Medicare / Medicaid	31.4%	35.9%	0.0%
VA	7.6%	8.7%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Pasquotank	16%	51%	45%	19%	11%	17%
Camden	15%	50%	20%	10%	10%	16%
Chowan	22%	52%	39%	23%	10%	18%
Currituck	15%	50%	13%	11%	8%	18%
Dare	19%	51%	12%	11%	10%	20%
Gates	18%	51%	38%	16%	11%	17%
Halifax	18%	52%	61%	24%	17%	17%
Hertford	18%	51%	66%	26%	16%	17%
Perquimans	24%	52%	29%	17%	14%	17%
Randolph	16%	51%	20%	17%	10%	21%
Tyrrell	19%	46%	47%	28%	12%	25%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*\*This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*<sup>1</sup> percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28<sup>2</sup>. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The applicant adequately demonstrates that it currently provides 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;

<sup>1</sup><http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

<sup>2</sup><http://esrd.ipro.org/wp-content/uploads/2016/11/2015-NW-6-Annual-Report-Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf>

C

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

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

In Section L-6, page 48, the applicant states, in reference to any facilities owned by DaVita in the state, that there have been no civil rights equal access complaints filed within the last five years.

The application is conforming to this criterion.

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

C

In Section L-1(a), page 45, the applicant states:

*“Elizabeth City Dialysis, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.”*

In Section L-1(b), page 46, the applicant projects that 88.1% of in-center patients and 87.6% of all patients will have all or part of their services paid for by Medicare and or Medicaid.

<b>ELIZABETH CITY DIALYSIS PROJECTED PAYOR MIX PY2 (2020)</b>			
<b>Payment Source</b>	<b>Percent of Total Patients</b>	<b>Percent of IC Patients</b>	<b>Percent of PD Patients</b>
Medicare	20.0%	21.7%	7.7%
Medicaid	2.9%	3.3%	0.0%
Commercial Insurance	4.8%	3.3%	15.4%
Medicare / Commercial	33.3%	27.2%	76.9%
Medicare / Medicaid	31.4%	35.9%	0.0%
VA	7.6%	8.7%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

As illustrated above, the applicant does not project a change in its projected payor mix from that of its current payor mix.

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

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

C

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

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Elizabeth City Dialysis. Patients, families and friends can obtain access by contacting a nephrologist with privileges at the facility. Should a patient contact the facility either directly or indirectly, the patient will be referred to a qualified nephrologist for evaluation and subsequent admission if it were found to be medically necessary. Patients from outside the facility [sic] catchment area requesting transfer to this facility will be processed in accordance with the facility [sic] transfer and transient policies ...”*

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

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

C

In Section M-1, page 50, the applicant states that Elizabeth City Dialysis offered the facility as a site for clinical rotations at the College of The Albemarle. Exhibit M-2 contains a copy the letter sent to the College of The Albemarle regarding clinical training for its student nurses. The information provided in Section M-1 and Exhibit M-2 is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case

of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add nine stations to Elizabeth City Dialysis for a total of 28 certified dialysis stations at Elizabeth City Dialysis upon completion of this project, Project ID #R-10176-13 (relocate 14 stations – certified in July 2016), Project ID #R-10202-13 (add nine stations – certified in July 2016) and Project ID #R-10264-14 (relocate six stations to Perquimans Dialysis – projected certification is January 2019 in this application. However, in clarifying information received June 30, 2017, the applicant states October 2018).

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Pasquotank County. Facilities may also serve residents of counties not included in their service area.

The January 2017 SDR indicates there is one existing dialysis facility and one approved dialysis facility in Pasquotank County, as follows:

<b>PASQUOTANK COUNTY DIALYSIS FACILITIES EXISTING &amp; APPROVED CERTIFIED STATIONS &amp; UTILIZATION as of June 30, 2016</b>						
<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
Elizabeth City Dialysis	DaVita	101	Elizabeth City	30	*-6	90.00%
Albemarle Dialysis	DaVita	NA	Elizabeth City	0	**0	00.00%

\*Six stations approved for transfer to Perquimans Dialysis. \*\*Not certified until July 2016; 14 stations approved.

As illustrated above, both the existing and approved facilities are owned and operated by the applicant, and the existing facility has a utilization rate of 90.0%. The new facility owned by the applicant has been approved and is projected to be certified by January 2019.

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

*“The expansion of Elizabeth City Dialysis will have no effect on competition in Pasquotank County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider ..., this project primarily*

*serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DVA Healthcare Renal Care, Inc.*

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

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

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

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

Therefore, the application is conforming to this criterion.

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

## C

In Section B-4, pages 9-10, the applicant discusses the methods it uses to insure and maintain quality. In Exhibit O-3, the applicant provides a listing of four dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. However, each facility is back in compliance as of the date of this decision, as below illustrated.

<b>DVA QUALITY CARE</b>			
<b>Facility</b>	<b>Survey Date</b>	<b>Back in Compliance</b>	
Southeastern Dialysis Center-Kenansville	3/22/2016	Yes	6/10/2016
Durham Dialysis	3/22/2016	Yes	5/31/2016
Marshville Dialysis	2/29/2016	Yes	4/15/2016
Durham West Dialysis	10/7/2015*	Yes	9/30/2015

\*Back in compliance prior to survey on 10/7/2015

Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

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

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

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

-NA- Elizabeth City Dialysis is an existing facility.

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

-C- In Section C-1, pages 13-15, the applicant demonstrates that Elizabeth City Dialysis will serve a total of 100 in-center patients at the end of OY1 (CY 2019) for a utilization rate of 89.3% or 3.57 patients per station per week ( $100 \text{ patients} / 28 \text{ stations} = 3.571 / 4 = 0.8928$ ). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C-1, pages 13-16, the applicant provides the assumptions and methodology used to project utilization of the facility including PD utilization. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.