

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 27, 2014

PROJECT ANALYST: Jane Rhoe-Jones

INTERIM SECTION CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: R-10264-14 / DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis / Develop a 10-station dialysis facility by relocating six stations from Elizabeth City Dialysis Center (Pasquotank) and four stations from Edenton Dialysis Center (Chowan) / Perquimans 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. (DVA) d/b/a Perquimans County Dialysis, whose parent company is DaVita HealthCare Partners, Inc., proposes to relocate six stations from Elizabeth City Dialysis Center (Pasquotank) and four stations from Edenton Dialysis Center (Chowan) to develop a new 10-station dialysis facility in Perquimans County. The primary site for the new dialysis facility is Harvey Point Road, Hertford, North Carolina 27944.

The proposed project requires up-fitting of a building shell (leased space), hiring and training of staff positions not filled by staff transfers from Elizabeth City Dialysis Center and Edenton Dialysis Center, as well as the purchase of equipment needed to operate an ESRD facility. Furthermore, the proposed facility will offer home training and support services for peritoneal dialysis patients.

Neither the county or facility need methodologies in the 2014 State Medical Facilities Plan (SMFP) are applicable to this review. Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a facility pursuant to a need determination in the

2014 SMFP. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable because the applicant is not proposing a capital expenditure greater than \$2 million.

However, Policy ESRD-2: Relocation of Dialysis Stations, on page 32, is applicable to this review. The policy states:

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

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

There is not a dialysis facility located in Perquimans County. Chowan and Pasquotank counties are contiguous to Perquimans County. According to the January 2014 Semiannual Dialysis Report (SDR), there is a surplus of 7 stations in Chowan County and a surplus of 11 stations in Pasquotank County. There is a deficit of 10 stations in Perquimans County.

The applicant proposes to relocate six existing dialysis stations from Pasquotank County and four existing stations from Chowan. The proposed project will not cause a deficit of dialysis stations in either Pasquotank or Chowan counties; nor will it cause a surplus of dialysis stations in Perquimans County. Therefore, the application is consistent with Policy ESRD-2 in the 2014 SMFP and is conforming to this criterion.

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

C

DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis proposes to relocate six stations from Elizabeth City Dialysis Center (Pasquotank) and four stations from Edenton Dialysis Center (Chowan) to develop a new 10-station dialysis facility to provide in-center dialysis and home training for peritoneal dialysis in Perquimans County. The January 2014 SMFP states that as of December 16, 2013, Elizabeth City Dialysis has 25 certified dialysis

stations and Edenton Dialysis Center has 17 certified dialysis stations. In Section III.3, page 20, the applicant states,

“The January 2014 Semiannual Dialysis Report indicated that there is a projected ten-station deficit of stations in Perquimans County. DVA Healthcare Renal Care, Inc. did an assessment of the patients living in Perquimans County that are receiving dialysis services at the Elizabeth City Dialysis Center in Pasquotank County and the Edenton Dialysis Center in Chowan County. The result of this assessment indicated that all of the identified patients indicated in the January 2014 Semiannual Dialysis Report and the document prepared by the Division of Health Service Regulation Planning Section are being served at the Elizabeth City Dialysis Center and the Edenton Dialysis Center. Therefore ... that those patients be given the opportunity to receive services at a facility located in their home county. Therefore, one area of justification for this project is providing improved geographic accessibility for ESRD services in Perquimans County.”

Population to be Served - Proposed Perquimans County Dialysis Center

In Section III.7, page 27, the applicant identifies the patient population to be served at the proposed dialysis facility during the first two years of operation following project completion, as illustrated below in the table:

PERQUIMANS COUNTY DIALYSIS Projected Dialysis Patient Origin						
COUNTY	OPERATING YEAR 1 2016		OPERATING YEAR 2 2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Perquimans	32	3	37	3	100.0%	100.0%
TOTAL	32	3	37	3	100.0%	100.0%

In Section II, pages 12-15, and in Section III.7, pages 27-28, the applicant provides the assumptions and methodology it uses to project the proposed in-center patient utilization of the new facility. Elizabeth City Dialysis had 112 in-center patients as of 6/30/2013. Edenton Dialysis Center had 54 in-center patients as of 6/30/2013.

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III, page 20, the applicant states that it conducted an assessment of Perquimans County dialysis patients and determined that they are receiving dialysis services at either Elizabeth City Dialysis Center or Edenton Dialysis Center. The applicant states those patients should be afforded the opportunity to receive services at a facility located in their home county; which would improve ESRD geographic accessibility for Perquimans County residents.

In-Center

On pages 20 and 21, the applicant projects that the 10 stations to be relocated to Perquimans County Dialysis will be utilized at 80% of capacity by the end of the first year of operation following the relocation of the 10 stations ($32 \text{ patients} / (4 \times 10) = .8$). In Section III.7, pages 27-28, the applicant provides the following information to support projected utilization:

- 29 in-center patients and three home-trained patients that receive dialysis services at Elizabeth City Dialysis and Edenton Dialysis Center live in Perquimans County.
- 28 of those 29 in-center patients have signed letters which indicate that they live closer to the proposed Perquimans County Dialysis facility and the facility would be more convenient for them.
- Exhibit 25 contains letters from 28 in-center patients and one home-trained patient indicating willingness to transfer to Perquimans County Dialysis for their dialysis treatments.
- Perquimans County Dialysis is expected to have 32 in-center patients by the end of the first operating year based on the assumption that growth will continue at the Perquimans County Average Annual Change Rate for the past five years (January 2014 Semiannual Dialysis Report (SDR), Table B) which is 13.1%.

Projected utilization is based on reasonable, credible and adequately supported assumptions.

Home Training - Proposed Perquimans County Dialysis Center

In Section III, page 28, the applicant states, “*The development of Perquimans County Dialysis will include the peritoneal dialysis and home hemodialysis modalities. As of June 30, 2013 [sic] and December 31, 2013 there were three home-trained patients being treated at Elizabeth City Dialysis. All of these patients are projected to transfer their care to Perquimans County Dialysis.*” The applicant states in clarifying information, “*We will be offering PD only at the Perquimans Dialysis facility.*”

The applicant further states on page 28,

“Home-training utilization projections using the average annual change rate for the past five years of 13.1% and starting out with 3 home-trained patients dialyzing at the Elizabeth City Dialysis Center who will relocate to Perquimans County Dialysis as of January 1, 2016:

January 1, 2016-December 31, 2016 – 3 home-trained patients X 1.131 = 3.393

January 1, 2017-December 31, 2017 – 3.393 home-trained patients X 1.131 = 3.837483

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

January 1, 2017-December 31, 2017 is the second operating year.” [Emphasis in original.]

“Based on the patients and stations above, Perquimans County Dialysis is projected to have at least 3 home-trained patients by the end of operating year 1 [sic] at least 3

home-trained patients by the end of operating year 2. The facility offers both home hemodialysis [sic] and peritoneal dialysis.”

In summary, the applicant is not proposing to add stations based on county or facility need, but rather to create a new facility through the relocation of existing stations from two existing dialysis facilities in contiguous counties.

The applicant adequately demonstrates the need the population proposed to be served has for the development of a new dialysis facility in Perquimans County which does not have any existing facilities.

Access to Services

In Section VI, page 38, the applicant states,

“Perquimans County Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

...

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

The applicant projects that 52.2% of its patients will be covered by Medicare and Medicaid; 7% by VA and another 33.1% 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, 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.

The applicant proposes to relocate six stations from Elizabeth City Dialysis Center (Pasquotank) and four stations from Edenton Dialysis Center (Chowan) to establish Perquimans County Dialysis - a new 10-station dialysis facility.

Elizabeth City Dialysis Center

Elizabeth City Dialysis Center is currently certified for 30 dialysis stations and will have 19 stations upon completion of this project (relocate six stations), Project ID# R-10202-13 (add nine stations), and Project ID# R-10176-13 (relocate 14 stations).

In Section III.6, pages 24-26, the applicant states:

“Elizabeth City Dialysis Center

The January 2014 Semiannual Dialysis Report indicates that there were 112 ESRD in-center dialysis patients receiving their treatments at the Elizabeth City Dialysis Center. The facility has 30 certified stations. The facility utilization rate identified in the SDR was 93.33% based on 30 certified stations as of June 30, 2013. DVA Healthcare Renal Care, Inc. submitted a CON application on August 15, 2013 to transfer fourteen stations from ... Elizabeth City Dialysis Center to develop a new facility in Elizabeth City to be known as ... Albemarle Dialysis. All of the patients projected to transfer to Albemarle Dialysis live in Pasquotank County. On September 15, 2013 ... Elizabeth City Dialysis Center submitted a Certificate of Need application to expand the Elizabeth City Dialysis Center by nine dialysis stations. That CON application was approved. The nine stations are projected to be certified when Albemarle Dialysis is certified.

...

With thirteen patients and six dialysis stations transferring from the Elizabeth City Dialysis Center to Perquimans County Dialysis, this will leave 99 in-center patients and 24 dialysis stations at the Elizabeth City Dialysis Center if we do not take into consideration any patient growth between June 30, 2013 and when Perquimans County Dialysis is projected to be certified (January 1, 2016).

... Taking into consideration that the Elizabeth City Dialysis Center had 112 in-center patients as of June 30, 2013 and that Pasquotank County had an Average Annual Change Rate for the Past Five Years of 7.2%, we have projected the growth in the patient population from July 1, 2013 to the date Perquimans County Dialysis is projected to be certified.

July 1, 2013-December 31, 2013 – 112 in-center patients X 1.036 = 116.032

January 1, 2014-December 31, 2014 – 116.032 in-center patients X 1.072 = 124.386304

January 1, 2015-December 31, 2015 – 124.386304 in-center patients X 1.072 = 133.3421178

Using the projections above, the Elizabeth City Dialysis Center would have 133 in-center patients ... when Perquimans County Dialysis is projected to be certified on January 1, 2016. With thirteen patients and six dialysis stations transferring from the Elizabeth City Dialysis Center to Perquimans County Dialysis, this will leave 120 in-center patients (133-13 = 120) and 24 dialysis stations at the Elizabeth City Dialysis Center. Once the transfer takes place, ... the ... utilization rate would be 125%. But the Elizabeth City Dialysis Center has been approved for an additional nine in-center stations. So the facility will have a utilization rate of 91% when Perquimans County Dialysis is projected to be certified.”

Note: the applicant’s analysis does not take into account the relocation of 14 stations to the new Albemarle Dialysis. If those stations are subtracted and the 45 patients expected to transfer, the utilization rate would be 98% [$30+9-14-6 = 19$; $133-45-13 = 75$; $75/19 = 3.95$; $3.95/4 = 0.987$].

Edenton Dialysis Center

In Section III.6, page 26, the applicant states,

“Edenton Dialysis Center

The January 2014 Semiannual Dialysis Report indicates that there were 54 ESRD in center dialysis patients receiving their treatments at the Edenton Dialysis Center. The facility has 17 certified stations. The facility utilization rate identified in the SDR was 79.41% based on 17 certified stations as of December 31, 2013. It is projected that four dialysis stations and fifteen current in-center patients from the Edenton Dialysis Center will transfer to Perquimans County Dialysis.

With fifteen patents and four dialysis stations transferring from the Edenton Dialysis Center to Perquimans County Dialysis, this will leave 39 in-center patients and 13 dialysis at Edenton Dialysis Center if we do not take into consideration any patient growth between June 30, 2013 and when the Perquimans County Dialysis is projected to be certified (January 1, 2016).

... Taking into consideration that the Edenton Dialysis Center had 54 in-center patients as of June 30, 2013 and that Chowan County had an Average Annual Change Rate for the Past Five Years of -018%, we have projected there will be no growth in the patient population from July 1, 2013 to the date Perquimans County Dialysis is projected to be certified.”

In Section III.6, page 24, the applicant states:

“The transfer of stations and patients from the Elizabeth City Dialysis Center and Edenton Dialysis Center will have no affect [sic] on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other under-served group [sic] and the elderly to obtain needed health care.”

The applicant demonstrates that the needs of the population presently served at Elizabeth City Dialysis Center and Edenton Dialysis Center will be adequately met following relocation of six stations and four stations, respectively, to Perquimans County Dialysis. Therefore, the application is conforming to this criterion.

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

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In Section III.9, page 29, the applicant states, “*DVA Healthcare Renal Care, Inc. studied appropriate alternatives to this application and concluded that developing a new facility in the herford [sic] area is the best option.*”

The applicant concludes that the proposed project would provide a more convenient option for the 29 Perquimans County patients currently dialyzing at either Elizabeth City Dialysis Center in Pasquotank County or Edenton Dialysis Center in Chowan County. Twenty eight of the 29 submitted letters of support for the proposed Perquimans County Dialysis facility expressing their willingness to transfer to that facility.

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 the proposal is the least costly or most effective alternative to meet the need for a dialysis facility located in Perquimans County to serve Perquimans County dialysis patients. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis shall develop and operate no more than ten dialysis stations at Perquimans County Dialysis which shall include any home hemodialysis training or isolation stations.**
- 3. DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis shall install plumbing and electrical wiring through the walls for no more than ten dialysis stations which shall include any home hemodialysis training or isolation stations.**
- 4. After certification of the ten (10) relocated dialysis stations at Perquimans County Dialysis, DVA Healthcare Renal Care, Inc. d/b/a**

Elizabeth City Dialysis Center shall take steps to decertify six (6) dialysis stations for a total of no more than nineteen (19) certified stations at Elizabeth City Dialysis Center upon completion of this project (relocate 6 stations), Project ID# R-10202-13 (add 9 stations), and Project ID# R-10176-13 (relocate 14 stations).

5. After certification of the ten (10) relocated dialysis stations at Perquimans County Dialysis, DVA Healthcare Renal Care, Inc. d/b/a Edenton Dialysis Center shall take steps to decertify four (4) dialysis stations for a total of no more than thirteen (13) certified stations at Edenton Dialysis Center.

6. DVA Healthcare Renal Care, Inc. d/b/a Perquimans County 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 Section VIII.1, pages 46-47, the applicant states that the total capital cost of the project will be \$1,386,766 which includes \$780,500 - construction contract, \$131,700 - dialysis machines, \$90,000 - water treatment equipment, \$238,516 - equipment/furniture, \$90,000 - architect/engineering fees, \$10,890 - dialysis chairs, \$7,835 - scale, \$19,500 - television system, and \$17,825 - patient computer system.

In Section IX.3, page 50, the applicant projects that the total working capital (start-up and initial operating expenses) associated with the proposed project will be \$873,424, as follows:

▪ Start-up Expenses	\$145,610
▪ Initial Operating Expenses	<u>\$727,814</u>
Total Working Capital	\$873,424

In Section VIII.2-3, pages 47-48, the applicant states that the project will be funded from cash reserves of DaVita Healthcare Partners Inc., the parent company of DVA Healthcare Renal Care, Inc.

Exhibit 20 contains a letter dated April 12, 2013 from the Chief Accounting Officer of DaVita Healthcare Partners, which states in part:

“I am the Chief Accounting Officer of DaVita Healthcare Partners, Inc., the parent and 100% owner of DVA Healthcare Renal Care, Inc.

... I am writing this letter as Chief Accounting Officer of DaVita Healthcare Partners to confirm DaVita's commitment of \$1,386,766., for the capital expenditures associated with this project; a commitment of \$145,610, for its start up expenses; and a further commitment of \$727,814. [sic] in working capital. ...

DaVita Healthcare Partners has committed cash reserves in the total sum of \$2,260,190, for the capital costs, start-up costs and working capital for this project. ...

Exhibit 18 of the application contains the audited financial statements for DaVita Healthcare Partners, Inc. for the fiscal year ended December 31, 2013. As of December 31, 2013, DaVita Healthcare Partners, Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$4,605,541,000 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.

In Section X.1, page 52, the applicant provides the allowable charges per treatment for each payment source for Perquimans County Dialysis, as illustrated below in the table. The rates shown below are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.¹

PERQUIMANS COUNTY DIALYSIS	
Payor	Charge Per treatment
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,175.00
VA	\$193.00
Medicare/Commercial	\$240.00

The applicant projects revenues in Section X.2, page 53 and operating expenses in Section X.4, pages 56-57, of the application. In Section X.2-X.4, pages 53-57, the applicant reports projected revenues and expenses for Perquimans County Dialysis, as illustrated below in the table:

PERQUIMANS COUNTY DIALYSIS		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$1,414,616	\$1,583,417
Total Operating Costs	\$1,455,628	\$1,556,886
Net Profit	(\$41,012)	\$26,531

¹http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage_Renal_Disease_Pro Prospective_Payment_System_ICN905143.pdf

The applicant projects that revenues will exceed operating expenses in the second operating year. The assumptions used in preparation of the proformas, including the number of projected treatments are reasonable, credible and adequately supported. In Section VII.1, page 43 and Section X.5, page 58, the applicant provides projected staffing and salaries. The applicant states compliance with all staffing requirements in 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 42. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected. See Section X of the application for the applicant's assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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 Perquimans County Dialysis, whose parent company is DaVita HealthCare Partners, Inc., proposes to relocate six stations from Elizabeth City Dialysis Center (Pasquotank) and four stations from Edenton Dialysis Center (Chowan) to develop a new 10-station dialysis center in Hertford (Perquimans). DVA Healthcare Renal Care, Inc. is the only provider of ESRD services in Pasquotank and Chowan counties. Pasquotank County has one facility and one under development. Chowan County has one facility. There are no existing or approved dialysis facilities located in Perquimans County.

The applicant adequately demonstrates the need to develop a new 10-station dialysis center in Hertford based on the number of Perquimans County patients currently traveling to Elizabeth City or Edenton for dialysis services, the absence of any existing or approved dialysis facilities located in Perquimans County, and the projected number of in-center patients to be served. Exhibit 25 contains 38 letters from Perquimans County patients currently receiving services at either Elizabeth City Dialysis Center or Edenton Dialysis Center who express a willingness to transfer (29) or say they will transfer their care (9) to the proposed Perquimans County Dialysis facility.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved certified dialysis stations in Perquimans 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 VII.1, page 43, the applicant provides projected staffing for Perquimans County Dialysis, as illustrated in the following table:

PERQUIMANS COUNTY DIALYSIS	
Full-Time Equivalent (FTE) Positions	
RN	1.5
HTRN	0.5
PCT	4.5
Bio-Med Tech	0.3
Admin.	1.0
Dietician	0.3
Social Worker	0.3
Unit Secretary	1.0
Total FTEs	9.4

The applicant projects a total of 9.4 FTE positions and states on page 44 that some teammates will transfer from Elizabeth City Dialysis Center and Edenton Dialysis Center to Perquimans County Dialysis. The applicant also states it does not expect any difficulty in recruiting staff for the remaining positions. In Section V.4, page 35 and Section VII.2, page 44, the applicant identifies the Medical Director for Perquimans County Dialysis as Dr. Ravi Ramsamooj. In Exhibit 12 the applicant provides a letter from Dr. Ramsamooj indicating the doctor's willingness to serve as Medical Director of the facility. Additionally, in Section VII.10, page 45, the applicant states Perquimans County Dialysis will operate two shifts, six days a week from 6:00 a.m. to 4:00 p.m.

The applicant adequately documents the availability of resources, including health manpower and management personnel, for 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.

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In Section V.1, page 33, the applicant lists the providers of the necessary ancillary and support services. Exhibits 9-10 contain documentation on service agreements. Exhibit 25 contains letters of support from area healthcare providers and the local community. The applicant adequately demonstrates that necessary ancillary and support services will be 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 (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

C

In Section XI, pages 59-61, the applicant discusses the primary and secondary sites being considered for the proposed Perquimans County Dialysis facility. The applicant states that DVA plans to lease space for the proposed new facility. The applicant states the primary site is two acres and is located on Harvey Point Road in Hertford (Parcel ID#2-0061-0068) and is zoned for dialysis facility use. The secondary site is two acres located at US Highway 17, in Hertford (Parcel ID#2-0050-0001B) and is also zoned for dialysis facility use. See Exhibits 27 and 28 for maps of the proposed sites. The applicant further states on pages 60 and 61, that both sites are conveniently located for its patients.

In Section XI.6(h), page 65 and Exhibit 27, the applicant states the facility will be 7,600 square feet. In Section XI.6(a), page 62, the applicant states that each dialysis station will occupy 229 square feet. In Section VIII.1, page 47, the applicant projects the construction upfit cost will be \$780,500 and architect and engineering fees will be \$90,000, which is a total of \$870,500. Thus, per square feet cost is projected to be \$114.54 ($\$870,500/7,600 = \114.54). The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 65:

PERQUIMANS COUNTY DIALYSIS	
Facility Area	Estimated Total Sq. Ft.
Ancillary Areas:	
Administration/Offices/Reception/Elevator Lobby	325
Public Lobby	418
Mechanical Equipment	62
Biomedical	90
General Storage/Medical Records	444
Exam/Treatment & Medical Offices	688
Staff Lounge & Lockers	336
RO	559
Other: Handicap baths, dock and walkways	293
Sub-Total Support	3,215
Treatment Areas:	
Nurses Station	280
Dialysis Stations	2,295
Isolation Room(s)	150
Other: Walkways, Lab, Storage	109
Sub-Total Treatment	2,834
Corridors/Walls	1,551
Total Square Feet	7,600

In Section XI.6(d), page 63, the applicant states the facility will be constructed with energy-efficient glass, mechanically operated access doors and energy-efficient heating, ventilation and air conditioning (HVAC).

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

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

In Section VI.1(a), page 38, the applicant states Perquimans County Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), page 38, the applicant reports that 85.3% and 92.6% of the patients who received treatments at Elizabeth City Dialysis Center and Edenton Dialysis Center, respectively, had some or all of their services paid for by Medicare or Medicaid in the past year. The tables below illustrate the historical payment source for the existing facilities:

ELIZABETH CITY DIALYSIS CENTER PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	16.9%
Medicaid	4.2%
Medicare/Medicaid	31.1%
Commercial Insurance	7.7%
VA	7.0%
Medicare/Commercial	33.1%
Total	100.0%

EDENTON DIALYSIS CENTER PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	16.7%
Medicaid	11.1%
Medicare/Medicaid	37.0%
Commercial Insurance	3.7%
VA	3.7%
Medicare/Commercial	27.8%
Total	100.0%

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

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Perquimans County	18.6%	8.6%	21.1%
Statewide	17%	6.71%	19.7%

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

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

In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/31/2012*, page 74).

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

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*² (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.” (p. 216)

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%

² www.usrds.org/adr.aspx

45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6. Table includes North Carolina statistics only.³

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
TOTAL	\$49.2	100.0%

*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 332.

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

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

C

In Section VI.1(f), page 40, the applicant states,

“Perquimans County Dialysis will have 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. Graham Dialysis [sic Perquimans County Dialysis] will have no obligation under the Hill Burton Act.”

In Section VI.6(a), page 42, the applicant states, *“There have been no civil rights access complaints filed within the last five years.”*

³ www.esrdnetwork6.org/publications/reports.html

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 39, the applicant provides the projected payor mix for the proposed services at the new facility as follows:

PERQUIMANS COUNTY DIALYSIS PROJECTED PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	16.8%
Medicaid	6.1%
Medicare/Medicaid	32.8%
Commercial Insurance	6.6%
VA	6.1%
Medicare/Commercial	31.6%
Total	100.0%

The applicant projects the payor mix at Perquimans County Dialysis will be similar to the current payor mix for Elizabeth City Dialysis and Edenton Dialysis Center.

In Section VI.1(a), page 38, the applicant states,

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

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

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

C

In Section VI.5, page 41, the applicant states that:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Perquimans County Dialysis. Perquimans County Dialysis will grant privileges to all qualified nephrologists. Referrals to nephrologists most commonly come from primary care physicians or specialty physicians in Perquimans and surrounding counties or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the facility directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if it were found to be medically necessary. Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies which comprise **Exhibit 13**. [Emphasis in original.] The patient, again, will be referred to a qualified Nephrologist for final evaluation and then admission based on the doctor’s orders.”*

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

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

C

In Section V.3, page 35, the applicant states,

“Pasquotank [sic] will be offered as a clinical learning site for nursing students at the local community colleges and nursing programs. ... Pasquotank [sic] County Dialysis will be open to developing relationships with any program that offers clinical training programs.”

Exhibit 11 contains a letter from the facility administrator at Elizabeth City Dialysis indicating the interest of Perquimans County Dialysis in establishing a relationship with College of the Albemarle in Elizabeth City. 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

DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis, whose parent company is DaVita HealthCare Partners, Inc., proposes to relocate six stations from Elizabeth City Dialysis Center (Pasquotank) and four stations from Edenton Dialysis Center (Chowan) to develop a new 10-station dialysis center in Hertford (Perquimans). DVA Healthcare Renal Care, Inc. is the only provider of ESRD services located in Pasquotank and Chowan counties. Pasquotank County has one dialysis facility and one under development. Chowan County has one dialysis facility. There are currently no dialysis facilities located in Perquimans County.

In Section V.7, pages 36-37, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“There are no dialysis facilities located in Perquimans County. The development of DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis will have no effect on any dialysis facilities located in the counties contiguous to Perquimans County. ...

The proposed Perquimans County Dialysis will not have an adverse effect on competition since the patients already being served by DVA Healthcare Renal Care [sic] be transferring their care from one DVA facility to another DVA facility, which will be more convenient for the patients who have indicated this in the letters they signed. There are no other dialysis facilities in the proposed service area; therefore, there can be no effect on the competition. The Elizabeth City Dialysis Center and the Edenton Dialysis Center are providing dialysis services to all of the patients who live in Perquimans County.

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

See also Sections II, III, V, VI and VII in which the applicant discusses the cost-effectiveness, quality and access to the proposed services.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive

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

- The applicant adequately demonstrates the need for the proposed project and that the proposed project is a cost-effective alternative;
- The applicant adequately demonstrates that it will provide quality services;
- The applicant adequately demonstrates that it will provide adequate access to medically underserved populations.

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

The applicant currently provides dialysis services at Elizabeth City Dialysis Center and Edenton Dialysis Center and is proposing to relocate dialysis stations from each center to develop Perquimans County Dialysis. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Elizabeth City Dialysis Center and Edenton Dialysis Center operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

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

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

.2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-C- In Section II.1, page 10, the applicant states the utilization rates at Elizabeth City Dialysis and Edenton Dialysis Center are reported in Table A of the January 2014 SDR provided in Exhibit 7. For Elizabeth City Dialysis, the January 2014 SDR utilization rate of 93.3% was calculated based on 112 in-center dialysis patients and 30 certified dialysis stations as of June 30, 2013 (112 patients / 30 stations = 3.73 patients per station; 3.73 patients per station / 4.00 patients per station = 93.33%). For Edenton Dialysis Center, the January 2014 SDR utilization rate of 79.4% was calculated based on 54 in-center dialysis patients and 17 certified dialysis stations as of June 30, 2013 (54 patients / 17 stations = 3.176 patients per station; 3.176 patients per station / 4.00 patients per station = 79.41%).

(2) *Mortality rates;*

-C- In Section IV.2, page 31, the applicant reports: Elizabeth City Dialysis - 2011, 2012 and 2013 facility mortality rates as 16.5%, 19.6% and 20.5%, respectively; and Edenton Dialysis Center - 2011, 2012 and 2013 facility mortality rates as 15.2%, 13.7% and 13.7%, respectively.

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

-C- In Section IV.3, page 31, the applicant states, “Elizabeth City Dialysis Center had 37 home-trained patients as of June 30, 2013. Edenton Dialysis Center has a home training agreement with the Elizabeth City Dialysis Center for the provision of home training services.”

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

-C- In Section IV.4, page 31, the applicant states, “Elizabeth City Dialysis Center had four patients receive a transplant in 2013. Twenty-five patients were referred for transplant evaluation in 2013. Edenton Dialysis Center had no patients receive a transplant in 2013. Eight patients were referred for transplant evaluation in 2013.”

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

- C- In Section IV.5, page 32, the applicant states, “*Elizabeth City Dialysis Center has eleven patients on the transplant waiting list. Edenton Dialysis Center has four 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 32, the applicant states that for Elizabeth City Dialysis Center there were 112 hospital admissions in 2013, 14 (12.5%) of which were dialysis related and 98 (87.5%) non-dialysis related. Also for Edenton Dialysis Center, there were 63 hospital admissions in 2013, 13 (20.6%) of which were dialysis related and 50 (79.4%) 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 32, the applicant states that there were no patients dialyzing at Elizabeth City Dialysis Center with AIDS or Hepatitis B, as of December 31, 2013. Also there were no patients treated with infectious disease who have converted to infectious status within the last year. The applicant further states as of December 31, 2013, for Edenton Dialysis Center there were no patients dialyzing with Hepatitis B, but there was one patient with AIDS. And there were no patients treated with infectious disease who have converted to infectious status within the last year. (For Edenton Dialysis Center, the applicant states December 31, 2012; however, the project analyst assumes that the applicant means December 31, 2013.)
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
- C- Exhibit 9 contains a signed letter of intent from Albemarle Hospital agreeing to enter into a Patient Transfer Agreement with Perquimans County Dialysis and to provide the following services to patients receiving their dialysis treatments at Perquimans County Dialysis:
- Acute Dialysis
 - Emergency Room Care
 - Diagnostic Evaluation Services
 - X-ray Services

- Special, Immunological and Routine Laboratory Services
- Blood Banking Services
- Surgical Services including Vascular Surgery

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-C- Exhibit 10 contains a letter from Carolinas Medical Center agreeing to enter into a Transplant Agreement with Perquimans County Dialysis including the components identified above.

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

-C- Exhibit 27 provides site specific documentation of the availability of power and water from the Town of Hertford, Oman-Gibson Associates and Piedmont Natural Gas.

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

-C- See Exhibit 22, in which the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.

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

-C- The applicant provides written documentation of availability and commitment to pursue acquiring the proposed primary and/or secondary site in Exhibits 27-28.

(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 63, the applicant states, “*Perquimans County Dialysis will operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health safety requirements.*” The applicant states that Perquimans County Dialysis will obtain and maintain Medicare Certification. See Exhibit 22 for excerpts from the Health and Safety Policy and Procedure Manual and Exhibit 23 for the In-Service Calendar with mandatory training classes.

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

-C- The applicant provides projected patient origin in Section III.7, page 27, as follows:

PERQUIMANS COUNTY DIALYSIS Projected Dialysis Patient Origin						
COUNTY	OPERATING YEAR 1 2016		OPERATING YEAR 2 2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
	Perquimans	32	3	37	3	100.0%
TOTAL	32	3	37	3	100.0%	100.0%

See Section III.7, pages 27–28 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

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

-C- In Section III.8, page 28, the applicant states, “*100% of the patients that [sic] will travel less than 30 miles one way for dialysis treatments.*”

(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(8), page 12, the applicant states,

“Renal Treatments Mid-Atlantic, Inc. d/b/a Graham 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.”

In clarifying information, the applicant states, “*The reference to RTC Mid-Atlantic d/b/a Graham Dialysis was an error on my part.*”

.2203 PERFORMANCE STANDARDS

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

-C- The applicant proposes to establish Perquimans County Dialysis, a new ESRD facility, by relocating 10 stations. In Section II, page 13, the applicant states that it anticipates 32 in-center patients and 3.2 patients per station per week at the end of operating year one, based on the methodology and assumptions found on pages 14-15 of the application. See Criterion (3) for discussion of projected utilization which is incorporated hereby as if set forth fully herein.

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

-NA- Perquimans County Dialysis is not an existing facility.

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

(2) *maintenance dialysis;*

-C- The table in Section V.1, page 33, states the applicant will provide in-center maintenance dialysis.

(3) *accessible self-care training;*

-C- The table in Section V.1, page 33, states the applicant will provide in-center hemodialysis self-care training, intermittent peritoneal dialysis, CAPD and

CCPD. In clarifying information, the applicant states that, *“The project will also include home training and support for peritoneal dialysis patients. The Elizabeth City Dialysis Center will provide home hemodialysis training and support. ... Home hemodialysis patients will be referred to the Elizabeth City Dialysis Center. We will be offering PD only at the Perquimans Dialysis Facility.”*

(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, Question 2(d), page 34, stating,

“Perquimans County Dialysis will provide 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.”

In clarifying information the applicant states, *“Home hemodialysis patients will be referred to the Elizabeth City Dialysis Center.”*

(5) *x-ray services;*

-C- The table in Section V.1, page 33, states patients will be referred to Albemarle Hospital for x-ray services.

(6) *laboratory services;*

-C- The table in Section V.1, page 33, 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 33, states patients will be referred to Albemarle Hospital for blood bank services.

(8) *emergency care;*

-C- The table in Section V.1, page 33, 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 33, states patients will be referred to Albemarle Hospital for acute dialysis in an acute care setting. See Exhibit 9 for a copy of the hospital's letter of intent to enter into a patient transfer agreement with Perquimans County Dialysis.

(10) *vascular surgery for dialysis treatment patients;*

-C- The table in Section V.1, page 33, states dialysis patients will be referred to Albemarle Hospital for vascular surgery.

(11) *transplantation services;*

-C- The table in Section V.1, page 33, states patients will be referred to Sentara Norfolk General Hospital for transplantation services. See Exhibit 10 for documentation from Sentara Norfolk General Hospital and Carolinas HealthCare System.

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

-C- The table in Section V.1, page 33, states patients will be referred to Vocational Rehabilitation for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1, page 33, states patients will be referred to various transportation agencies.

.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 43, the applicant provides the proposed staffing for Perquimans County Dialysis. The applicant states, "*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 ...*"

(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 45, 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 23 contains the Perquimans County Dialysis Annual In-Service Calendar.