

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 19, 2016

Findings Date: February 19, 2016

Project Analyst: Bernetta Thorne-Williams

Team Leader: Lisa Pittman

Project ID #: G-11089-15

Facility: North Burlington Dialysis Center

FID #: 100785

County: Alamance

Applicant(s): Total Renal Care, Inc.

Project: Add six dialysis stations for a total of 22 dialysis stations upon completion of this project, Project I.D. # G-10265-14 (relocate 2 existing stations to Graham Dialysis), Project G-10352-14 (add three stations) and Project I.D. # G-11015-15 (add 2 stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

Total Renal Care, Inc. (DVA) d/b/a North Burlington Dialysis Center (“the applicant”) proposes to add six dialysis stations for a total of 22 stations at North Burlington Dialysis Center upon completion of Project I.D. # G-10265-14 (relocate 2 stations to Graham Dialysis), Project I.D. # G-10352-14 (add three stations) and Project I.D. # G-11015-15 (add 2 stations for a total of 16 stations) and this project.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the

July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 18 dialysis stations in Alamance County, thus the applicant cannot apply to add additional stations based on the county need methodology. 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 in its existing facility based on the facility need methodology because the utilization rate reported for North Burlington Dialysis in the July 2015 SDR is 4.6923 patients per station, or 117.31% (4.6923 / 4 patients per station = 1.173075). This utilization rate was calculated based on 61 in-center dialysis patients and 13 certified dialysis stations (61 patients / 13 stations = 4.692 patients per station).

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

NORTH BURLINGTON DIALYSIS - OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/14		117.0%
Certified Stations		13
Pending Stations		5
Total Existing and Pending Stations		18
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR2)		61
In-Center Patients as of 6/30/14 (Jan 2015 SDR) (SDR1)		54
Step	Description	Result
	Difference (SDR2 - SDR1)	7
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.2593
(ii)	Divide the result of Step (i) by 12	0.0216
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/13 until 12/31/14)	0.2593
(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	76.8148
(v)	Divide the result of Step (iv) by 3.2 patients per station	24.0046
	and subtract the number of certified and pending stations to determine the number of stations needed	6.0046

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

Policies

There is one policy in the 2015 SMFP which is applicable to this review. POLICY GEN-3: BASIC PRINCIPLES on page 38 of the 2015 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 O, page 53, 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 L, pages 46-49 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 24-30, and Section N, page 52. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2015 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 six new stations at North Burlington Dialysis Center, an existing facility located at 2019 N. Church Street in Burlington. Upon completion of Project I.D. # G-10265-14 (relocate 2 stations to Graham Dialysis), Project I.D. # G-10352-14 (add 3 stations), Project I.D. # G-11015-15 (add 2 stations for a total of 16 stations) and this project, North Burlington Dialysis Center will be certified for 22 dialysis stations.

Population to be Served

On page 351, the 2015 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 Alamance County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 19, the applicant identifies the population served as of December 31, 2014, as illustrated below in the table:

NORTH BURLINGTON DIALYSIS Patient Origin December 31, 2014			
County	# of In-Center Patients	# of Home Dialysis Patients	# PD Patients
Alamance	59	0	8
Guilford	0	0	1
Other States	2	0	0
TOTAL	61	0	9

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 I.D. # G-10265-14, Project I.D. # G-10352-14, and Project I.D. # G-11015-15, as illustrated below in the table:

County	Operating Year 1 2017	Operating Year 2 2018	County Patients as Percent of Total	
	In-Center Patients	In-Center Patients	Year 1	Year 2
Alamance	69	78	97.2%	97.5%
Other States	2	2	2.8%	2.5%
TOTAL	71	80	100.0%	100.0%

The applicant does not project to serve any home hemodialysis or peritoneal dialysis patients at North Burlington Dialysis Center. The applicant provides the assumptions and methodology for the projections above on pages 13-16.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section B-2, page 7, the applicant provides the facility need methodology. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference.

Projected Utilization

The applicant projects to serve 71 in-center dialysis patients at the end of the first operating year, which is 3.22 patients per station per week or an 80.7% utilization rate.

In Section C-1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Based on the July 2015 SDR, Alamance County Dialysis had 61 in-center patients and 13 stations for a station utilization rate of 117.31%, as of December 31, 2014. Fifty-nine of the 61 patients were residents of Alamance County.
- The applicant proposed in Project I.D. # G-10265-14 to relocate 2 stations from North Burlington Dialysis to develop Graham Dialysis. The applicant stated that 14 in-center patients who live in Alamance County would transfer their care to Graham Dialysis. Graham Dialysis was projected to be certified by January 1, 2016, and the patients would transfer at that time (67 Alamance County patients -14 transfers = 53 Alamance County patients).
- The applicant proposed in Project I.D. # G-11015-15 to add 2 stations to North Burlington Dialysis for a total of 16 dialysis stations, upon completion of that project and Project I.D. # G-10265-14.
- The applicant used a 14% annual growth rate to project future growth at North Burlington Dialysis from January 1, 2015 – December 31, 2018. The applicant states on page 14, that the calculated annual growth rate for North Burlington Dialysis is 27%. However, based on the actual growth rate from June 30, 2014 to December 31, 2014, the annualized growth rate

at that time was 26% $[(61-54)/54 = .1296$ or 13%, $13\% \times 2 = 26\%$]. It should be noted that the Five Year Average Annual Change Rate (AACR) for Alamance County is 3.3%, as reported in the July 2015 SDR.

- The applicant projects to continue to serve two patients who reside outside of Alamance County. The applicant did not project growth for those two patients.
- The applicant projects to have 71 in-center patients by the end of Operating Year 1 (OY1) with a utilization rate of 80.7% or 3.22 patients per station per week and 80 in-center patients by the end of OY2, for a projected utilization rate of 90.9% or 3.6 patients per station per week.
- OY1 is Calendar Year 2017
- OY2 is Calendar Year 2018

**NORTH BURLINGTON DIALYSIS CENTER
 IN-CENTER PATIENT GROWTH**

	Alamance County Patient Transfers to Graham Dialysis	# Alamance County Patients		Growth Rate		Year End Census		# Non-Alamance Patients		Total Year End Census
CY 2014		59								
CY 2015		59	x	1.14	=	67.2600	+	2	=	69.2600
CY 2016	-14	53.26	x	1.14	=	60.7164	+	2	=	62.7164
CY 2017 (OY1)		60.716	x	1.14	=	69.2166	+	2	=	71.2166
CY 2018 (OY 2)		69.216	x	1.14	=	78.9070	+	2	=	80.9070

As shown in the previous table, at the end of OY1 (2017), the applicant projects an in-center patient census of 71 patients, for a utilization rate of 80.7% or 3.22 patients per station per week at the end of OY1. At the end of OY2 (2018), the applicant projects an in-center patient census of 80 patients, which is a utilization rate of 90.9% or 3.64 patients per station per week. The projected utilization of 3.22 patients per station per week for OY1 satisfies the 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth in the dialysis patient population in Alamance County.

Access

In Section C-3, page 16, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap ... regardless of ethnic or socioeconomic situation.”

In Section L, page 50, the applicant provides its historical payor mix which indicates that Medicare and Medicaid represented 85.9% of all dialysis services in CY 2014. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by DVA and that the facility will conform to all federal, state and local codes and standards for handicapped access.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately 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 proposed services. 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 23, the applicant discusses the three 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 six stations – the applicant states the six station expansion would help to meet the growing demand for dialysis services at North Burlington Dialysis.
3. Operate a third shift - the applicants determined that a third shift would be inconvenient for patients and a facility operating at maximum capacity eliminates patient choice.

After considering the alternatives above, the applicant believes the most effective alternative is to add six stations to the existing facility to ensure adequate access for the dialysis patients of Alamance County.

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. Total Renal Care, Inc. d/b/a North Burlington Dialysis Center shall materially comply with all representations made in the certificate of need application.**
 - 2. Total Renal Care, Inc. d/b/a North Burlington Dialysis Center shall add no more than six dialysis stations for a total of no more than 22 certified dialysis stations upon completion of Project I.D. # G-10265-14 (relocate two stations), Project I.D. # G-10352-14 (add three stations), Project I.D. #G-11015-15 (add two stations) and this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care, Inc. d/b/a North Burlington Dialysis Center 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 six dialysis stations to North Burlington Dialysis Center for a total of 22 dialysis stations upon completion of this project, Project I.D. # G-10265-14, Project I.D. # G-10352-14 (add three stations) and Project I.D. # G-11015-15 (add 2 stations).

Capital and Working Capital Costs

In the table in Section F-1, page 25, the applicant provides the capital cost of the proposed project as summarized in the table below:

North Burlington Dialysis Proposed Project Capital Costs	
Construction Contract	\$ 557,000
Dialysis Machines	\$ 84,000
Water Treatment Equipment	\$ 95,000
Equipment/Furniture	\$ 65,000
Architect/Engineering Fees	\$ 50,000
Total Capital Cost	\$ 851,000

In Section F, pages 27-28, the applicant states that there are no working capital needs for the proposed project as North Burlington Dialysis Center is an existing facility.

Availability of Funds

In Section F, page 26, the applicant states that cash reserves/owner's equity is being used to finance the proposed project.

Exhibit F-5 contains a September 10, 2015 letter from the Vice President of Tax of DaVita HealthCare Partners, which states,

"We are submitting a Certificate of Need Application to expand our North Burlington Dialysis by six ESRD dialysis stations. The project calls for a capital expenditure of \$851,000. This letter will confirm that DaVita HealthCare Partners, Inc. has committed cash reserves in the total sum of \$851,000 for the project [sic] capital expenditure. DaVita HealthCare Partners, Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care, Inc."

In Section F, page 27, the applicant states:

"The financial strength of the company precludes any financial impact upon the operation and performance of the expansion that this application proposes. Therefore, there is no appreciable impact on either this application or from any that has been approved previously or is currently under review."

See Exhibit F-7 for a copy of the most recent audited financial statements for DaVita HealthCare Partners, Inc. for years ended December 31, 2013 and 2014. As of December 31, 2014, DaVita HealthCare Partners, Inc. had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets and \$5,360,311,000 in total equity. The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

The applicant projects revenues and expenses and provides assumptions in Section R, Form B, pages 1-2, as summarized below in the table:

NORTH BURLINGTON DIALYSIS Revenue and Expenses - Total Facility		
	OPERATING YEAR 1 CY 2017	OPERATING YEAR 2 CY 2018
Gross Patient Revenue	\$ 2,811,502	\$ 3,192,426
Deductions from Gross Patient Revenue	(\$126,467)	(\$143,610)
Total Revenue	\$ 2,685,035	\$ 3,048,816
Operating Expenses	\$ 2,372,077	\$ 2,605,474
Net Profit	\$ 312,958	\$ 443,342

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The applicant’s projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section H, page 32, the applicant provides projected staffing and salaries. Form A in Section R, page 1, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add six stations to North Burlington Dialysis Center for a total of 22 certified dialysis stations upon completion of Project I.D. # G-10265-14, Project I.D. # G-10352-14, Project G-11015-15 and this project.

On page 351, the 2015 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 Alamance County. Facilities may also serve residents of counties not included in their service area.

Table A in the July 2015 SDR indicates there are four operational facilities in Alamance County and one facility pending certification, as illustrated in the table below:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
BMA Burlington	45	114	2.53	63.33%
Burlington Dialysis (TRC)	26	90	3.46	86.54%
Carolina Dialysis – Mebane (BMA)	12	45	3.75	93.75%
North Burlington Dialysis (TRC)	13	61	4.69	117.31%
Graham Dialysis* (TRC)	10	0	0	0.0%
Data reported in the July 2015 SDR, as of 12/31/14. *Certification Pending. The 10 stations are coming from Burlington Dialysis (eight stations) and North Burlington Dialysis (two stations). North Burlington Dialysis has one station pending certification at Graham Dialysis.				

Of those facilities listed above, Fresenius Medical Care owns two and the applicant owns three. As reported in the July 2015 SDR, three of the four operational facilities operated above 80% utilization. BMA Burlington had 63.33% utilization. According to the July 2015 SDR, there is a surplus of 18 dialysis stations in Alamance County. However, the applicant is applying to add six additional stations based on the facility need methodology.

At the end of OY1 (2017), the applicant projects an in-center patient census of 71 patients, for a utilization rate of 80.7% or 3.22 patients per station per week. At the end of OY2 (2018), the applicant projects an in-center patient census of 80 patients, which is a utilization rate of 90.9% or 3.64 patients per station per week. 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 six stations to North Burlington Dialysis Center 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 discussion of competition found in Criterion (18a) 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 Alamance 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, page 32, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for North Burlington Dialysis Center. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	3.0	-	3.0
Technician (Patient Care)	8.0	1.0	9.0
Administrator	1.0	-	1.0
Dietician	0.5	-	0.5
Social Worker	0.5	-	0.5
Home Training RN	0.5	-	0.0
Administrative Assistant	1.0	-	1.0
Biomed Tech	0.5	-	0.5
Total	15.0	1.0	15.5

As illustrated in the table above, the applicant projects an increase in the total number of FTE positions at North Burlington Dialysis Center by .5 positions. The applicant proposes to increase the number of Patient Care Technicians (PCT) by one FTE and eliminate the Home Training RN position. The applicant does not propose to offer home training services at North Burlington Dialysis as those services are being relocated to Graham Dialysis.

In Section H-7, page 35, the applicant provides the projected direct care staff for North Burlington Dialysis in Operating Year 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	3.0	2,080	6,240	3,120	2.0
PCT	9.0	2,080	18,720	3,120	6.0
Total	12.0	2,080	24,960	3,120	8.0

In Section I-3(a), page 38, the applicant identifies Dr. Harmett Singh, as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of an August 2015 letter signed by Dr. Singh of Central Carolina Kidney Associates, P.A., supporting the project and confirming his 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 list the providers of the necessary ancillary and support services to be 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 DaVita Laboratory Services, Inc., and Dr. Singh (Medical Director), respectively, documenting availability of the necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. 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 46-47, the applicant states, “*North Burlington Dialysis, by policy, makes dialysis services available to all residents in its service area. ... North Burlington 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 addition, on pages 47-49, the applicant discusses its financial policies. In Section L-7, page 50, the applicant states that Medicare/Medicaid represented 85.9% of all dialysis services provided at North Burlington Dialysis Center in calendar year 2014. The following table illustrates the historical payor sources for North Burlington Dialysis:

PAYOR TYPE	% IN-CENTER PATIENTS	% OF PD PATIENTS	TOTAL PERCENT PATIENTS
Commercial Insurance	6.5%	0.0%	5.6%
Medicare	25.8%	33.3%	26.8%
Medicaid	9.7%	0.0%	8.5%
Medicare/Medicaid	32.2%	22.2%	30.9%
VA	9.7%	0.0%	8.5%
Medicare/ Commercial*	16.1%	44.5%	19.7%
Total	100.0%	100.0%	100.0%

*The applicant clarified that “other” as listed on page 50 of the application, is Medicare/commercial

On page 19, the applicant reports having served no HH patients in CY2014. Regardless, the applicant adequately demonstrates that it has historically served the medically underserved population.

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Alamance County and statewide.

County	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Alamance	16.0%	6.2%	21.0%
Statewide	17.0%	6.7%	19.7%
*More current data, particularly with regard to the estimated uninsured percentages, was not available.			

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those persons who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*, provides prevalence data on North Carolina dialysis patients by age, race and gender, and is summarized as follows, on page 59:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	35.1%
Other, not specified	355	2.3%
Source: Southeastern Kidney Council Network6 Inc. 2014 Annual Report. ²		

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 L-3(d), page 49, the applicant states:

“North Burlington 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 50, the applicant states, *“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 C-3, page 16, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. ...

Payment will not be required upon admission. 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-3(c), page 50, the applicant states:

“North Burlington Dialysis makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.”

In Section L-1(b), page 47, the applicant reports that it expects 85.9% of the in-center patients who receive treatments at North Burlington Dialysis Center to have all or part of their services paid for by Medicare and Medicaid, as indicated below in the table.

PAYOR TYPE	% IN-CENTER PATIENTS	% OF PD PATIENTS	TOTAL PERCENT PATIENTS
Commercial Insurance	6.5%	0.0%	5.6%
Medicare	25.8%	33.3%	26.8%
Medicaid	9.7%	0.0%	8.5%
Medicare/Medicaid	32.2%	22.2%	30.9%
VA	9.7%	0.0%	8.5%
Medicare/ Commercial	16.1%	44.5%	19.7%
Total	100.0%	100.0%	100.0%

On page 47, the applicant states it assumes the payor mix for North Burlington Dialysis will remain the same as its historical payor mix. The applicant indicates on page 13 of the application that it did not provide support and training for any PD patients in 2014. Regardless, the applicant adequately projects to serve the medically underserved population.

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 49, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a nephrologist with privileges at North Burlington Dialysis. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies, found at Exhibit L-3. ...”

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 North Burlington Dialysis has been offered as a clinical training site for student nurses attending Education Cooperation of America d/b/a Virginia College.

Exhibit M-2 contains a copy of the student training agreement with Education Cooperation of America d/b/a Virginia College. The information provided in Section M and referenced exhibits is reasonable 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 six dialysis stations for a total of 22 stations at North Burlington Dialysis Center upon completion of Project I.D. # G-10265-14 (relocate 2 stations), Project I.D. # G-10352-14 (add three stations), Project G-11015-15 (add 2 stations for a total of 16 stations) and this project.

On page 351, the 2015 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 Alamance County. Facilities may also serve residents of counties not included in their service area.

Table A in the July 2015 SDR indicates there are four operational facilities in Alamance County and one facility pending certification, as illustrated in the table below:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
BMA Burlington	45	114	2.53	63.33%
Burlington Dialysis (TRC)	26	90	3.46	86.54%
Carolina Dialysis – Mebane (BMA)	12	45	3.75	93.75%
North Burlington Dialysis (TRC)	13	61	4.69	117.31%
Graham Dialysis* (TRC)	10	0	0	0.0%
Data reported in the July 2015 SDR, as of 12/31/14. *Certification Pending. The 10 stations are coming from Burlington Dialysis (eight stations) and North Burlington Dialysis (two stations). North Burlington Dialysis has one station pending certification at Graham Dialysis.				

Of those facilities listed above, Fresenius Medical Care owns two and the applicant owns three. As reported in the July 2015 SDR, three of the four operational facilities operated above 80% utilization. BMA Burlington had 63.33% utilization.

In Section N-1, page 52, 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 North Burlington Dialysis will have no effect on competition in Alamance County. The addition of six stations at this facility serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care, Inc. and not any other providers in the service area.

The expansion of North Burlington 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 others 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 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 an 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 North Burlington Dialysis Center will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that North Burlington Dialysis Center 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

See Section B-4(a), for its discussion regarding the methods DVA uses to ensure and maintain quality. The discussion is found on pages 9-12. In Section O-3, page 53, the applicant states:

“Exhibit O-3 lists facilities located in NC owned by the parent company DaVita HealthCare Partners Inc. that did not operate in compliance with the Medicare conditions of participation during the 18 month look back period. Each facility is currently in compliance.”

In Exhibit O-3, the applicant states that three facilities were cited for deficiencies that resulted in a finding of Immediate Jeopardy, during the 18 months immediately preceding submittal of the application, as shown in the table below:

DVA Quality Care			
Facility	Survey Date	Back in Compliance	
Burlington Dialysis	6/16/2014	Yes	7/29/2014
Dialysis Care of Edgecombe County	7/1/2014	Yes	7/30/2014
Dialysis Care of Rowan County	9/17/2014	Yes	10/22/2014

Based on a review of the information in the application and publicly available information, 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.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

- C- In Section G-1, page 31, the applicant provides the utilization rate for North Burlington Dialysis. The December 31, 2014 utilization rate was reported as 117.31% with 61 in-center patients dialyzing on 13 stations.

.2202(a)(2) Mortality rates;

- C- In Section C-9, page 20, the applicant provides the mortality rates for North Burlington Dialysis, as follows:

North Burlington Dialysis	Beginning In-center Patients	Ending In-center Patients	Average	Deaths	% Gross Mortality
2014	48	61	54.5	1	1.8%
2013	40	48	44.0	6	13.6%
2012	39	40	39.5	5	12.7%

.2202(a)(3) *The number of patients that are home-trained and the number of patients on home dialysis;*

-C- In Section C-7, page 19, the applicant states North Burlington Dialysis reports having served nine home trained patients.

.2202(a)(4) *The number of transplants performed or referred;*

-C- In Section C-10, page 20, the applicant states the number of transplants performed or referred by North Burlington Dialysis Center in 2014 was 7.

.2202(a)(5) *The number of patients currently on the transplant waiting list;*

-C- In Section C-10, page 20, the applicant states North Burlington Dialysis had four patients on the transplant waiting list.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section C-11, page 20, the applicant states the hospital admission rates as: Dialysis related 20.6% or 22 patients; Non-dialysis related 79.4% or 85 patients.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- In Section C-10, page 20, the applicant states that North Burlington Dialysis Center had zero persons with infectious disease and zero patients converted to an infectious status during the last calendar year.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(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 (Replaced with 42 CFR Part 494).*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
 - (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Exhibit K-1(f) for copies of written policies and procedures for back up electrical service in the event of a power outage.

- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- This application is to add stations and does not propose a new facility.

- .2202(b)(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 K-1(g), page 42, the applicant states: “North Burlington Dialysis will provide service in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply and other relevant health and safety requirements” See also Section H-2, page 33.

.2202(b)(7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.

-C- In Section C-1, page 13, the applicant provides projected patient origin by county for North Burlington Dialysis Center, based on the patients who currently dialyze there. The applicant's assumptions and methodology for its projections are provided on pages 13-16 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

.2202(b)(8) For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.

-NA- This application is to add stations and does not propose a new facility.

.2202(b)(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 for such services.

-C- In Section L-3(c), page 47, the applicant states, "North Burlington Dialysis makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status."

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- This application is to add stations and does not propose a new 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 13-14, the applicant documents the need for the project and demonstrates that it will serve a total of 71 in-center patients on 22 stations at the end of the first operating year, which is 3.22 patients per station per week, or a utilization rate of 80.7%. 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. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) Diagnostic and evaluation services;

- C- In Section I-1, page 37, the applicant states that diagnostic and evaluation services will be referred to Alamance Regional Medical Center (Alamance RMC).

.2204(2) Maintenance dialysis;

- C- In Section I-1, page 37, the applicant states that in-center maintenance dialysis is provided at North Burlington Dialysis.

.2204(3) Accessible self-care training;

- C- In Section I-1, page 37, the applicant states that self-care training is provided at North Burlington Dialysis.

.2204(4) Accessible follow-up program for support of patients dialyzing at home;

- C- In Section I-1, page 37, the applicant states that an accessible follow-up program for support of patients dialyzing at home is provided at North Burlington Dialysis. However, the applicant states on page 15, that once Graham Dialysis receives its certification (certification was projected for January 1, 2016), the home training program located at North Burlington Dialysis will be relocated to Graham Dialysis.

.2204(5) X-ray services;

- C- In Section I-1, page 37, the applicant states that patients in need of x-ray services will be referred to Alamance RMC.

.2204(6) Laboratory services;

- C- In Section I-1, page 37, the applicant states that laboratory services will be provided by DaVita Laboratory Services, Inc.

.2204(7) *Blood bank services;*

- C- In Section I-1, page 37, the applicant states that patients in need of blood bank services will be referred to Alamance RMC.

.2204(8) *Emergency care;*

- C- In Section I-1, page 37, the applicant states that patients in need of emergency care will be referred to Alamance RMC.

.2204(9) *Acute dialysis in an acute care setting;*

- C- In Section I-1, page 37, the applicant states that patients in need of acute dialysis services will be referred to Alamance RMC.

.2204(10) *Vascular surgery for dialysis treatment patients;*

- C- In Section I-1, page 37, the applicant states that patients in need of vascular surgery services will be referred to Alamance Vein and Vascular.

.2204(11) *Transplantation services;*

- C- In Section I-1, page 37, the applicant states that patients in need of transplantation services will be referred to University of North Carolina Health Care. Exhibit I-3 contains a copy of the August 2015 letter from Dr. Singh the medical director at North Burlington Dialysis which documents the provision of transplantation services to the proposed facility.

.2204(12) *Vocational rehabilitation counseling and services; and*

- C- In Section I-1, page 37, the applicant states that vocational rehabilitation counseling services are provided by the North Carolina Division of Vocational Rehabilitation Services.

.2204(13) *Transportation*

- C- In Section I-1, page 37, the applicant states that transportation services will be provided by the Alamance County Department of Social Services (DSS).

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(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 (Replaced with 42 CFR Part 494).*
- C- In Section H-2, page 33, the applicant states that it will comply with *42 C.F.R. Section 405.2100* (Replaced with 42 CFR Part 494). In Section H-1, page 32, the applicant provides a staffing chart. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.
- .2205(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 H-4, page 34, the applicant discusses its training at DVA facilities.