

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 9, 2017

Findings Date: May 9, 2017

Project Analyst: Bernetta Thorne-Williams

Team Leader: Lisa Pittman

Project ID #: G-11321-17

Facility: Burlington Dialysis

FID #: 956036

County: Alamance

Applicant: Renal Treatment Centers-Mid Atlantic, Inc.

Project: Add four stations for a total of 16 dialysis stations upon completion of this project, Project I.D. # G-11212-16 (relocate 8 stations) and Project I.D. # G-11289-17 (relocate 4 stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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

Renal Treatment Centers-Mid Atlantic, Inc. (RTC-Mid Atlantic) d/b/a Burlington Dialysis proposes to add four dialysis stations for a total of 16 dialysis stations upon completion of this project, Project I.D. # G-11212-16 (relocate eight stations) and Project I.D. # G-11289-17 (relocate four stations).

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 29 dialysis stations in Alamance County. Therefore, the January 2017 SDR does not indicate a need for additional stations in Alamance County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations. However, the 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 utilization rate reported for Burlington Dialysis in the January 2017 SDR is 3.9583 patients per station per week, or 98.96%. (3.9583 / 4 patients per station = 0.9895). This utilization rate was calculated based on 95 in-center dialysis patients and 24 certified dialysis stations (95 patients / 24 stations = 3.9583 patients per station per week).

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		98.96%
Certified Stations		24
Pending Stations		0
Total Existing and Pending Stations		24
In-Center Patients as of 6/30/16 (SDR2)		95
In-Center Patients as of 12/31/15 (SDR1)		101
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	-6
	Multiply the difference by 2 for the projected net in-center change	-12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	-0.1188
(ii)	Divide the result of step (i) by 12	-0.0099
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	-0.0594
(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	89.3564
(v)	Divide the result of step (iv) by 3.2 patients per station	27.9239
	and subtract the number of certified and pending stations to determine the number of stations needed	4

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

Policies

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

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

Promote Safety and Quality

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

Promote Equitable Access

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

Maximize Healthcare Value

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

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

Conclusion

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

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

C

Renal Treatment Centers-Mid Atlantic, Inc. (RTC-Mid Atlantic) d/b/a Burlington Dialysis proposes to add four dialysis stations for a total of 16 dialysis stations upon completion of this project, Project I.D. # G-11212-16 (relocate eight stations) and Project I.D. # G-11289-17 (relocate four stations).

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining 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 20, the applicant identifies the population served as of June 30, 2016, as illustrated below in the table:

Burlington Dialysis Patient Origin As of June 30, 2016		
County	# In-Center Dialysis Patients	Peritoneal Dialysis Patients
Alamance	79	11
Caswell	1	0
Guilford	8	2
Orange	1	0
Person	1	0
Randolph	3	1
Other States	2	0
Total	95	14

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

Burlington Dialysis Projected In-Center Patient Origin by County						
	OY1 CY2019		OY CY2020		Percent of Total OY1	Percent of Total OY2
County	IC	PD	IC	PD		
Alamance	63	15	65	16	80.4%	81.0%
Caswell	1	0	1	0	1.0%	1.0%
Guilford	8	2	8	2	10.3%	10.0%
Orange	1	0	1	0	1.0%	1.0%
Person	1	0	1	0	1.0%	1.0%
Randolph	3	1	3	1	4.1%	4.0%
Other States	2	0	2	0	2.1%	2.0%
Total	79	18	81	19	100.0%	100.0%

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

The applicant proposes to add four dialysis stations to the existing Burlington Dialysis facility for a total of 16 certified dialysis stations upon completion of this project, Project I.D. # G-11212-16 (relocate eight stations) and Project I.D. # G-11289-17 (relocate four stations). In Section B.2, page 7, the applicant states the application is filed pursuant to the

facility need methodology in the 2017 SMFP utilizing data from the January 2017 SDR. In Section C.1, pages 13-15, the applicant provides the assumptions used to demonstrate the need for the project. The facility's patients who reside in Alamance County have increased at a rate commensurate with the Five-Year Average Annual Change Rate (AACR) for Alamance County, which is 3.7%.

In Project I.D. # G-11212-16, the applicant was approved to relocate eight stations to develop a new dialysis facility, Elon Dialysis and in Project I.D. # G-11289-17, the applicant was approved to relocate four stations to develop another new facility, Mebane Dialysis. All of the facilities are located in Alamance County. Additionally, in Project I.D. # G-11212-16, the applicant indicated that 31 in-center patients would transfer their care from Burlington Dialysis to Elon Dialysis upon its certification which is projected to be January 1, 2018. In Project I.D. # G-11289-17, the applicant stated that 17 patients currently dialyzing at Burlington Dialysis indicated a willingness to transfer their care to Mebane Dialysis upon its certification which is projected to be January 1, 2019. The applicant does not project growth of any patients residing outside of Alamance County; those existing patients were added to the projected Alamance County patients at appropriate points in the methodology.

Operating Year 1 (OY1) = Calendar Year (CY) 2019
OY2 = CY2020

Projected Utilization

In Section C.1, page 15, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Begin with Alamance County patients dialyzing at Burlington Dialysis as of July 1, 2016 and project the population forward to December 31, 2016 using ½ of the Alamance County Five Year AACR 1.85%.	$79 \times 1.0185 = 80.4615$
Project the patient population forward one year to December 31, 2017 using Alamance County Five Year AACR of 3.7%.	$80.4615 \times 1.037 = 83.4385$
Subtract the 24 Alamance County patients projected to transfer their care to Elon Dialysis. The applicant projects the Alamance County patient population forward to December 31, 2018 using Alamance County Five Year AACR of 3.7%.	$83 - 24 = 59$ $59 \times 1.037 = 61.183$
The applicant also projects to have 16 in-center patients that reside outside of Alamance County. The applicant projects that seven of those patients will transfer their care to Elon Dialysis.	$16 - 7 = 9$
OY1: Subtract 15 Alamance County patients and one Orange County patient are projected to transfer their care to Mebane Dialysis and project the Alamance County patient population forward to December 31, 2019 using Alamance County Five Year AACR of 3.7%.	$61 - 16 = 45$ $45 \times 1.037 = 46.665$
Subtract one patient from those patients that reside outside of Alamance County and add in the patients from Alamance County.	$9 - 1 = 8$ $46.665 + 8 = 54.665$
This is the projected ending census for OY1.	
OY2: Project Alamance County patient population forward one year using Alamance County Five Year AACR of 3.7%. Add the eight patients from outside of Alamance County. This is the projected ending census for OY2.	$46.665 \times 1.037 = 48.3916$ $48.3916 + 8 = 56.3916$

The applicant states on page 15 that the number of projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2019) Burlington Dialysis is projected to serve 54 in-center patients for a utilization rate of 84.4% or 3.4 patients per station per week (54 patients / 16 stations = 3.375 / 4 = 0.84375). The projected utilization of 3.4 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Home hemodialysis and peritoneal dialysis

The applicant currently provides peritoneal dialysis (PD) training and proposes no change to this training program. The applicant does not provide home hemodialysis training nor does the applicant propose to provide those services as a part of this project. In Section C.1, pages 15-16, the applicant provides its assumptions for its PD patients.

Access to Services

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. We will serve patients regardless of ethnic or socioeconomic situation.”

In Section L.1, page 49, the applicant provides its historical payor mix for CY2016, as illustrated below.

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of PD Patients
Medicare	29.3%	30.7%	18.2%
Medicaid	4.0%	4.5%	0.0%
Commercial Insurance	10.1%	6.8%	36.3%
Medicare / Commercial	26.3%	25.1%	36.4%
Medicare / Medicaid	21.2%	22.7%	9.1%
VA	9.1%	10.2%	0.0%
Total	100.0%	100.0%	100.0%

On page 49, the applicant projects that 80.8% of all its patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, 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 dialysis services at Burlington Dialysis. 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.

- (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.

C

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

- Maintaining the status quo – the applicant concluded that maintaining the status quo did not meet the growing need for dialysis services at Burlington Dialysis. Therefore, this is not an effective alternative.
- Locating stations from another DaVita facility – the applicant states that the other operational DaVita facility in Alamance County (North Burlington Dialysis), also operated at a capacity greater than 80%. Thus, relocating stations from that facility would negatively impact the patients currently dialyzing at that facility. Therefore, this is not an effective alternative.

After considering the above alternatives, the applicant states that development of the project as proposed in the application will ensure that the facility addresses the issues of growth and access to dialysis services by its patients. Therefore, the applicant believes that adding four stations to the facility is the most effective alternative to meet the identified need.

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. Renal Treatment Centers-Mid Atlantic, Inc. d/b/a Burlington Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. Renal Treatment Centers-Mid Atlantic, Inc. d/b/a Burlington Dialysis shall add no more than four dialysis stations for a total of no more than 16 dialysis stations at Burlington Dialysis following completion of this project, Project I.D. # G-11212-16 and Project I.D. # 11289-17.**
- 3. Renal Treatment Centers-Mid Atlantic, Inc. d/b/a Burlington Dialysis shall install plumbing and electrical wiring through the walls for no more than**

four additional dialysis stations, which shall include any isolation or home hemodialysis stations.

4. Renal Treatment Centers-Mid Atlantic, Inc. d/b/a Burlington Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

Burlington Dialysis proposes to add four dialysis stations for a total of 16 dialysis stations upon completion of this project, Project I.D. # G-11212-16 (relocate eight stations) and Project I.D. # G-11289-17 (relocate four stations).

Capital and Working Capital Costs

In Section F.1, page 25 and Section F.10, page 27, the applicant states that there are no capital costs or working capital needs associated with the proposed project.

Availability of Funds

In Exhibit F-7, the applicant provides a copy of DaVita HealthCare Partners, Inc. (DaVita) United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2015. DaVita is RTC-Mid Atlantic's parent company. DaVita had \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets, and \$5,948,238,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for any capital and working capital needs that may arise for the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	Operating Year 1	Operating Year 2
Total Treatments	7,929	8,151
Total Gross Revenues (Charges)	\$3,913,983	\$4,069,572
Total Net Revenue	\$3,780,127	\$3,931,338
Total Operating Expenses (Costs)	\$2,945,245	\$3,046,278
Net Profit	\$834,882	\$885,060

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

In Section H.1, page 32, the applicant provides Burlington Dialysis' staffing and salaries. Form A in Section R, shows budgeted operating costs adequate to cover 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 (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add four dialysis stations to the existing Burlington Dialysis facility for a total of 16 certified dialysis stations upon completion of this project, Project I.D. # G-11212-16 (relocate eight stations) and Project I.D. # G-11289-17 (relocate four stations).

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining 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.

The January 2017 SDR indicates there are six dialysis facilities in Alamance County with one of those facilities still under development and one was certified on June 22, 2016, as follows:

**Alamance County Dialysis Facilities
 June 30, 2016**

Dialysis Facilities	Owner	# of Patients 6/30/16	Location	# of Certified Stations 12/2/16	# of Approved Stations	Percent Utilization 6/30/16
Alamance Dialysis	DaVita	0	Graham	10	0	0.0%
BMA Burlington	Fresenius	93	Burlington	45	0	51.67%
Burlington Dialysis	DaVita	95	Burlington	24	-12	98.96%
Carolina Dialysis-Mebane	Fresenius	56	Mebane	20	0	70.00%
Elon Dialysis	DaVita	Under development – New 10 station facility				
North Burlington Dialysis	DaVita	73	Burlington	16	4	114.06%

Source: January 2017 SDR

As illustrated above, there are five operational dialysis facilities located in Alamance County and one facility under development. Of those six facilities, four facilities are operated by DaVita and two facilities are operated by Fresenius. Two operational DaVita facilities had utilization rates over 80.0%. One facility operated by DaVita had no utilization to report as of June 30, 2016 because the stations were not certified until June 22, 2016 and another DaVita facility is still under development. Thus, all of the operational dialysis facilities in the county are reasonably well utilized.

In Section C.1, pages 13-15, the applicant demonstrates that Burlington Dialysis will serve a total of 54 in-center patients for a utilization rate of 84.4% or 3.4 patients per station per week ($54 \text{ patients} / 16 \text{ stations} = 3.375 / 4 = 0.84375$) at the end of OY1 (CY 2019). The projected utilization of 3.4 patients per station per week for OY1 exceeds the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates the need to add four additional stations at Burlington Dialysis based on the number of in-center patients it projects to serve.

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.1, page 32, the applicant provides current staffing in full time equivalents (FTEs) for Burlington Dialysis. The applicant does not propose any new staff as a result of the proposed project, as shown in the table below.

Position	Current Number of FTEs
Registered Nurse	3.0
Patient Care Technician (PCT)	9.0
Administrator	1.0
Dietitian	1.0
Social Worker	1.0
Home Training RN	1.0
Administrative Assistant	1.0
Biomedical Technician	0.5
Total	17.5

On page 32, the applicant states the Medical Director is an independent contractor, not an employee of the facility. In Section H.2, page 33, the applicant states that the Medical Director for Burlington Dialysis will be Dr. Munsoor Lateef, a board certified nephrologist. In Exhibit I-3, the applicant provides a letter signed by Dr. Lateef, dated February 15, 2017, confirming his commitment to continue to serve as the Medical Director. In Section H.3, pages 33-34, the applicant describes the methods used to recruit and fill vacant or new positions.

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, page 36, the applicant discusses the provision of necessary ancillary and support services. The applicant provides a list of those service providers on page 36. Exhibit I-3 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on page 38. Exhibits I-1 through I-2, respectively, contain copies of a facility administrator letter of support and an agreement from DaVita Laboratory Services, Inc. The facility administrator letter of support lists the following agreements: Alamance Regional Medical Center will provide acute, emergency, blood bank, diagnostic, X-ray, vascular and pediatric nephology services, UNC Health Care will provide transplant services, NC Division of Vocational Rehabilitation Services will provide vocational services and Alamance County DSS will provide transportation. The information in

Section I and Exhibits I-1 and I-2 is reasonable and adequately supports a finding of conformity with 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, page 49, the applicant reports that 80.8% of all the patients who received treatment at Burlington Dialysis had some or all of their services paid for by Medicare or Medicaid in CY 2016, as illustrated below.

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of PD Patients
Medicare	29.3%	30.7%	18.2%
Medicaid	4.0%	4.5%	0.0%
Commercial Insurance	10.1%	6.8%	36.3%
Medicare / Commercial	26.3%	25.1%	36.4%
Medicare / Medicaid	21.2%	22.7%	9.1%
VA	9.1%	10.2%	0.0%
Total	100.0%	100.0%	100.0%

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Alamance	16%	52%	34%	18%	10%	20%
Statewide	15%	51%	36%	17%	10%	15%

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

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

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

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

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	36.1%
Other, inc. not specified	365	2.3%

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

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

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 applicants;

C

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

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

The application is conforming to this criterion.

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

C

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

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

In Section L.1(b), page 46, the applicant projects that 83% of in-center patients and 80.8% of all patients will have all or part of their services paid for by Medicare and or Medicaid.

Burlington Dialysis Projected Payor Mix OY2

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of PD Patients
Medicare	29.3%	30.7%	18.2%
Medicaid	4.0%	4.5%	0.0%
Commercial Insurance	10.1%	6.8%	36.3%
Medicare / Commercial	26.3%	25.1%	36.4%
Medicare / Medicaid	21.2%	22.7%	9.1%
VA	9.1%	10.2%	0.0%
Total	100.0%	100.0%	100.0%

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

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

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

C

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

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

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

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

C

In Section M.1, page 50, the applicant states that Burlington Dialysis offered the facility as a site for clinical rotations for University of North Carolina at Greensboro (UNC at Greensboro) nursing students. Exhibit M.I contains a copy of a training agreement between DaVita Dialysis Contracting, LLC and UNC at Greensboro. The information provided in Section M.1 and Exhibit M-1 is reasonable and credible and supports a finding of conformity to this criterion.

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

C

The applicant proposes to add four dialysis stations to the existing Burlington Dialysis facility for a total of 16 certified dialysis stations upon completion of this project, Project I.D. # G-11212-16 (relocate eight stations) and Project I.D. # G-11289-17 (relocate four stations).

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining 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.

The January 2017 SDR indicates there are six dialysis facilities in Alamance County with one of those facilities still under development, as follows:

**Alamance County Dialysis Facilities
 June 30, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Alamance Dialysis	DaVita	0	Graham	10	0	0.0%
BMA Burlington	Fresenius	93	Burlington	45	0	51.67%
Burlington Dialysis	DaVita	95	Burlington	24	-8	98.96%
Carolina Dialysis-Mebane	Fresenius	56	Mebane	20	0	70.00%
Elon Dialysis	DaVita	Under development – New 10 stations facility				
North Burlington Dialysis	DaVita	73	Burlington	16	4	114.06%

Source: January 2017 SDR

As illustrated above, there are five operational dialysis facilities located in Alamance County and one facility under development. Of those six facilities, four facilities are operated by DaVita and two facilities are operated by Fresenius. Two operational DaVita facilities had utilization rates over 80.0%. One facility operated by DaVita had no utilization to report as of June 30, 2016 because the stations were not certified until June 22, 2016 and another DaVita facility is still under development. Thus, all of the operational dialysis facilities in the county are reasonably well utilized.

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

“The expansion of Burlington Dialysis will have no effect on competition in Alamance County. Although the addition of stations at this facility could serve to provide more patient another option to select a provider ..., this project

primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Renal Treatment Centers-Mid-Atlantic, Inc.

The expansion of 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 other involved in the dialysis process to receive services.”

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

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

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

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section B, pages 9-10, the applicant discusses the methods it uses to insure and maintain quality. In Exhibit O-3, the applicant provides a listing of four dialysis facilities that were not in compliance with Medicare conditions of participation during the 18

months prior to submission of the application. However, each facility is back in compliance as of the date of this decision, as illustrated below.

DAVITA'S QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
Southeastern Dialysis Center - Kenansville	3/22/2016	Yes	6/10/2016
Durham Dialysis	3/22/2016	Yes	5/31/16
Marshville Dialysis	2/29/2016	Yes	4/15/2016
Durham West Dialysis	10/7/2015	Yes	9/30/2015

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

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Burlington Dialysis is an existing facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the

beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.1, pages 13-15, the applicant demonstrates that Burlington Dialysis will serve a total of 54 in-center patients at the end of OY1 (CY 2019) for a utilization rate of 84.4% or 3.4 patients per station per week (54 patients / 16 stations = 3.375 / 4 = 0.84375). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

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