

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 12, 2017

Findings Date: June 12, 2017

Project Analyst: Mike McKillip

Team Leader: Lisa Pittman

Project ID #: G-11318-17

Facility: North Burlington Dialysis

FID #: 100785

County: Alamance

Applicant: Renal Treatment Centers - Mid-Atlantic, Inc.

Project: Add two dialysis stations for a total of 16 stations upon completion of this project, Project I.D. # G-11089-15 (Add six dialysis stations), Project I.D. # G-11212-16 (Relocate two stations from North Burlington Dialysis to Elon Dialysis), and Project I.D. # G-11289-17 (Relocate six stations from North Burlington Dialysis to Mebane Dialysis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Renal Treatment Centers - Mid-Atlantic, Inc. d/b/a North Burlington Dialysis [**North Burlington Dialysis**] proposes to add two dialysis stations for a total of 16 certified dialysis stations upon completion of this project, Project I.D. # G-11089-15 (Add six dialysis stations), Project I.D. # G-11212-16 (Relocate two stations from North Burlington Dialysis and eight stations from Burlington Dialysis for a total of ten stations at Elon Dialysis), and Project I.D. # G-11289-17 (Relocate six stations from North Burlington Dialysis and four stations from Burlington Dialysis for a total of ten stations at Mebane Dialysis).

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 no county need determination for Alamance County. However, 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 January 2017 SDR is 4.6 patients per station per week. This utilization rate was calculated based on 73 in-center dialysis patients and 16 certified dialysis stations as of June 30, 2016 (73 patients / 16 stations = 4.6 patients per station per week). Application of the facility need methodology indicates up to two additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		114.06%
Certified Stations		16
Pending Stations		6
Total Existing and Pending Stations		22
In-Center Patients as of 6/30/16 (SDR2)		73
In-Center Patients as of 12/31/15 (SDR1)		69
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.1159
(ii)	Divide the result of step (i) by 12	0.0097
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.0580
(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	77.2319
(v)	Divide the result of step (iv) by 3.2 patients per station	24.1350
	and subtract the number of certified and pending stations to determine the number of stations needed	2

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

Policies

There is one policy in the 2017 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. Policy GEN-3 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 51, 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 44-48, 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) and (d), page 11, and Section N, page 50. 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 application is consistent with the facility need determination in the January 2017 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, North Burlington Dialysis, proposes to add two dialysis stations for a total of 16 certified dialysis stations upon completion of this project, Project I.D. # G-11089-15 (Add six dialysis stations), Project I.D. # G-11212-16 (Relocate two stations from North Burlington Dialysis to Elon Dialysis), and Project I.D. # G-11289-17 (Relocate six stations from North Burlington Dialysis to Mebane Dialysis).

Patient Origin

On page 373 the 2017 SMFP defines the service area for dialysis stations 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 is Alamance County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 19, the applicant provides the historical patient origin for North Burlington Dialysis patients as of June 30, 2016, which is summarized in the following table:

North Burlington Dialysis Historical Patient Origin

County	In-Center	Home Hemodialysis	Peritoneal Dialysis
Alamance	73	0	2
TOTAL	73	0	2

Source: Table on page 19 of the application.

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

County	Operating Year 1 CY2019			Operating Year 2 CY2020			Percent of Total	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Alamance	63	0	6	65	0	7	100.0%	100.0%
Total	63	0	6	65	0	7	100.0%	100.0%

The applicant provides the assumptions and methodology used to project patient origin on pages 13-14. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.2, pages 6-7, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP utilizing data from the January 2017 SDR, and it proposes to add two dialysis stations to North Burlington Dialysis for a total of 16 stations at that facility. The applicant used the following assumptions:

1. The applicant projects the first two full operating years of the project will be January 1, 2019 – December 31, 2019 (CY2019) and January 1, 2020 – December 31, 2020 (CY2020).
2. On June 30, 2016, North Burlington Dialysis was providing dialysis treatment for 73 in-center patients, all of whom reside in Alamance County.
3. North Burlington Dialysis assumes the in-center patient population utilizing the facility who reside in Alamance County will increase at the rate of 3.7 percent per year. On page 14, the applicant states,

“The following are the in-center patient projections using the 3.7% Average Annual Change Rate for the Past Five Years as indicated in Table B of the January 2017 SDR for the 73 in-center patients living in Alamance County. The period of growth begins July 1, 2016 and is calculated forward to December 31, 2020.

It is projected that at least 2 current in-center patients from North Burlington Dialysis will transfer to Elon Dialysis upon its certification. After the period of growth ending in 2017, there will be 77 in-center patients, all from Alamance County (see line (c) below). When we deduct the 2 Alamance County patients projected to transfer to Elon Dialysis upon its certification, North Burlington Dialysis will have 75 Alamance County patients at the beginning of 2018 (see line (d) below).

It is projected that at least 16 current in-center patients from North Burlington Dialysis will transfer to Mebane Dialysis upon its certification. After the period of growth ending in 2018, there will be 77 in-center patients, all from Alamance County (see line (d) below). When we deduct the 16 Alamance County patients projected to transfer to Mebane Dialysis upon its certification, North Burlington Dialysis will have 61 Alamance County patients at the beginning of 2019 (see line (e) below).”

Projected Utilization

The applicant’s methodology is illustrated in the following table.

	In-Center
The applicant begins with the facility census of Alamance County in-center patients as of June 30, 2016.	73
The census of Alamance County in-center patients is increased by 1.85% to project the census forward six months to December 31, 2016.	$[73 \times (0.037/12 \times 6)] + 73 = 74.3505$
The census of Alamance County in-center patients is increased by 3.7% to project the census forward one year to December 31, 2017.	$(74.3505 \times 0.037) + 74.3505 = 77.10147$
The applicant subtracts two patients who are projected to transfer to Elon Dialysis.	$77 - 2 = 75$
The census of Alamance County in-center patients is increased by 3.7% to project the census forward one year to December 31, 2018.	$(75 \times 0.037) + 75 = 77.775$
The applicant subtracts 16 patients who projected to transfer to Mebane Dialysis.	$77 - 16 = 61$
The census of Alamance in-center patients is increased by 3.7% to project the census forward one year to December 31, 2019. This is the projected ending census for Operating Year 1.	$(61 \times 0.037) + 61 = 63.257$
The census of Alamance in-center patients is increased by 3.7% to project the census forward one year to December 31, 2020. This is the projected ending census for Operating Year 2.	$(63.257 \times 0.037) + 63.257 = 65.59751$

The applicant projects to serve 63 in-center patients or 3.9 patients per station per week ($63/16 = 3.9$) by the end of Operating Year 1 and 65 in-center patients or 4.1 patients per station per week ($65/16 = 4.1$) by the end of Operating Year 2 for the proposed 16-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The January 2017 SDR indicates that North Burlington Dialysis operated at a utilization rate of 114 percent (4.6 patients per station) as of June 30, 2016. Based on data reported in the SDR, during the period from June 30, 2015 to June 30, 2016, the in-center census at North Burlington Dialysis increased from 71 to 73 patients, which is an annual rate of growth of 2.8 percent. In this application, the applicant assumes a projected annual rate of growth of 3.7 percent for the in-center patient census (Alamance County residents only) at North Burlington Dialysis, which is equal to the Alamance County Five Year Average Annual Change Rate (2011-2015). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Peritoneal Dialysis

On page 15, the applicant provides the following table showing its projections of peritoneal dialysis (PD) patients through the first two operating years of the project.

PD Patient Projections	Start Date	# of Patients Start of Year	# of Patients End of Year	Average # of Patients in Year
Interim Period 1	7/1/2016	2	3	2.5
Current Year	1/1/2017	3	4	3.5
Interim Period 2	1/1/2017	4	5	4.5
Operating Year 1	1/1/2018	5	6	5.5
Operating Year 2	1/1/2019	6	7	6.5

Source: Table on page 15 of the application.

On page 15, the applicant describes its assumptions as follows:

“North Burlington Dialysis had 2 PD patients as of June 30, 2016 based on information included in Table A of the January 2017 SDR. ... The period of growth begins July 1, 2016 and is calculated forward to December 31, 2020. It is reasonable to assume that the North Burlington Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth.”

Access

In Section L.1(a), pages 44-45, the applicant states that North Burlington Dialysis makes its services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.7, page 48, the applicant reports that 88% of the in-center patients who received treatments at North Burlington Dialysis had some or all of their services paid for by Medicare or Medicaid in CY2016. In Section L.1, page 45, the applicant projects 88% of 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, demonstrates the need the population has for two additional stations at North Burlington Dialysis, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect

of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

In Section E.1, page 23, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative due to the fact that utilization of the North Burlington Dialysis facility is growing.
- Relocate Stations from an Existing DaVita Facility – The applicant states it considered relocating stations from an existing DaVita facility but rejected that alternative because the other DaVita facilities in Alamance County are currently well-utilized.

After considering those alternatives, the applicant states the alternative represented in the application 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 the 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 North 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 North Burlington Dialysis shall develop and operate no more than two additional dialysis stations for a total of no more than 16 certified stations upon completion of this project, Project I.D. # G-11089-15 (Add six dialysis stations), Project I.D. # G-11212-16 (Relocate two stations from North Burlington Dialysis to Elon Dialysis), and Project I.D. # G-11289-17 (Relocate six stations from North Burlington Dialysis to Mebane Dialysis), which shall include any isolation or home hemodialysis stations.**

3. Renal Treatment Centers - Mid-Atlantic, Inc. d/b/a North Burlington Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.

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

C

In Section F.1, page 24, the applicant states that it will not incur any capital costs to develop this project. In Sections F.10-F.12, pages 26-28, the applicant states there will be no start-up expenses or initial operating expenses incurred for this 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.

	CY2019 Operating Year 1	CY2020 Operating Year 2
Total Treatments	10,003	10,448
Total Gross Revenues (Charges)	\$2,667,793	\$2,799,188
Total Net Revenue	\$2,526,656	\$2,653,490
Total Operating Expenses (Costs)	\$2,363,085	\$2,455,866
Net Income	\$163,571	\$197,624

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section 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 the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

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

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

C

The applicant, North Burlington Dialysis, proposes to add two dialysis stations for a total of 16 certified dialysis stations upon completion of this project, Project I.D. # G-11089-15 (Add six dialysis stations), Project I.D. # G-11212-16 (Relocate two stations from North Burlington Dialysis to Elon Dialysis), and Project I.D. # G-11289-17 (Relocate six stations from North Burlington Dialysis to Mebane Dialysis).

On page 373 the 2017 SMFP defines the service area for dialysis stations 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 is Alamance County. Facilities may serve residents of counties not included in their service area.

The January 2017 SDR indicates there are six dialysis facilities in Alamance County, including four operational facilities, and two approved but not yet operational facilities, as of June 30, 2016. Of those six facilities, four facilities are operated by DaVita and two facilities are operated by Bio-Medical Applications of North Carolina (BMA).

Alamance County Dialysis Facilities

Dialysis Facilities	Certified Stations 6/30/2016	CON Issued Not Certified	Percent Utilization	Patients Per Station
Alamance Dialysis (DaVita)	10	0	NA	NA
BMA Burlington	45	0	51.67%	2.1
Burlington Dialysis (DaVita)	24	-8	98.96%	4.0
Carolina Dialysis-Mebane (BMA)	20	0	70.00%	2.8
Elon Dialysis (DaVita)	0	10	NA	NA
North Burlington Dialysis (DaVita)	16	4	114.06%	4.6

Source: January 2017 SDR

As shown in the table above, one facility operated by DaVita, Alamance County Dialysis, had no utilization to report as of June 30, 2016 because the stations were not certified until June 22, 2016. Another DaVita facility, Elon Dialysis, is still under development. However, both of the operational DaVita facilities operated with a utilization rate over 98%.

North Burlington Dialysis proposes to add two in-center dialysis stations for a total of 16 dialysis stations upon project completion. North Burlington Dialysis was serving 73 patients weekly on 16 stations, which is 4.6 patients per station or 114% of capacity, as of June 30, 2016. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 13-15 of the application. The growth projections are based on a projected 3.7% average annual growth rate in the number of in-center dialysis patients

(Alamance County residents only) at the North Burlington Dialysis facility. At the end of Operating Year Two, North Burlington Dialysis projects utilization will be 4.1 in-center patients per station (65 patients / 16 dialysis stations = 4.1), which is 102% of capacity. The applicant adequately demonstrates the need to develop two additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities in Alamance County. Therefore, 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 31, the applicant provides the current staffing for the facility, which includes 13.0 full-time equivalent (FTE) employees. The applicant states that no additional staffing is projected to be added to the facility following completion of the project. In Section H.3, pages 32-33, the applicant describes its experience and process for recruiting and retaining staff. Exhibit I-3 contains a copy of a letter from Harmeet Singh, M.D., expressing his interest in continuing to serve as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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 35, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-3 contains a letter from the medical director of the facility expressing his support for the proposed project. 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. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

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.7, page 48, the applicant reports that 88% of the patients who received treatments at North Burlington Dialysis had some or all of their services paid for by Medicare or Medicaid in CY2016. The table below shows the historical (CY2016) payment source for the facility:

Payment Source	Total Patients by Percent of Total
Medicare	29.9%
Medicaid	6.0%
Commercial Insurance	4.5%
Medicare/Commercial	17.9%
Medicare/Medicaid	34.3%
VA	7.5%
Total	100.00%

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
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 IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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

²http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

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

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section L.3, page 47, 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.”

In Section L.6, page 47, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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(b), page 45, the applicant projects that 88% of the patients who will receive treatments at North Burlington Dialysis in the second operating year (CY2020) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected Year 2 payment source for the facility for in-center patients:

Payment Source	Total Patients by Percent of Total
Medicare	29.9%
Medicaid	6.0%
Commercial Insurance	4.5%
Medicare/Commercial	17.9%
Medicare/Medicaid	34.3%
VA	7.5%
Total	100.00%

In Section L.1, page 45, the applicant provides the assumptions used to project payer mix. The applicant's projected payment sources are consistent with the facility's historical (CY2016) payment sources as reported by the applicant in Section L.7, page 48. The applicant adequately demonstrated that medically underserved groups will have access to the services offered at North Burlington Dialysis. 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 47, the applicant describes the range of means by which a person will have access to the dialysis services at North Burlington Dialysis, including referrals from nephrologists. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis 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 49, the applicant states that North Burlington Dialysis has established relationships with local community training programs, including Virginia College, and the applicant will continue to offer the same opportunities to local health professional training programs. Exhibit M-2 contains a copy of the applicant's training agreement with Virginia College. The information provided is reasonable and adequately supports a determination that the application is conforming 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, North Burlington Dialysis, proposes to add two dialysis stations for a total of 16 certified dialysis stations upon completion of this project, Project I.D. # G-11089-15 (Add six dialysis stations), Project I.D. # G-11212-16 (Relocate two stations from North Burlington Dialysis to Elon Dialysis), and Project I.D. # G-11289-17 (Relocate six stations from North Burlington Dialysis to Mebane Dialysis).

On page 373 the 2017 SMFP defines the service area for dialysis stations 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 is Alamance County. Facilities may serve residents of counties not included in their service area.

The January 2017 SDR indicates there are six dialysis facilities in Alamance County, including four operational facilities, and two approved but not yet operational facilities, as of June 30, 2016. Of those six facilities, four facilities are operated by DaVita and two facilities are operated by Bio-Medical Applications of North Carolina (BMA).

Alamance County Dialysis Facilities

Dialysis Facilities	Certified Stations 6/30/2016	CON Issued Not Certified	Percent Utilization	Patients Per Station
Alamance Dialysis (DaVita)	10	0	NA	NA
BMA Burlington	45	0	51.67%	2.1
Burlington Dialysis (DaVita)	24	-8	98.96%	4.0
Carolina Dialysis-Mebane (BMA)	20	0	70.00%	2.8
Elon Dialysis (DaVita)	0	10	NA	NA
North Burlington Dialysis (DaVita)	16	4	114.06%	4.6

Source: January 2017 SDR

As shown in the table above, one facility operated by DaVita, Alamance County Dialysis, had no utilization to report as of June 30, 2016 because the stations were not certified until June 22, 2016. Another DaVita facility, Elon Dialysis, is still under development. However, both of the operational DaVita facilities operated with a utilization rate over 98%.

In Section N.1, page 50, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The expansion of the North Burlington Dialysis will have no effect on competition in Alamance County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, 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 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 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 B, C, E, F, G, H and L where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

Therefore, the application is conforming to this criterion.

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

C

In Section B.4(a), 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. The applicant states that the facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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- North 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, page 13, the applicant projects to serve 63 in-center patients by the end of Operating Year 1, which is 3.9 patients per station ($63 / 16 = 3.9$). The discussion regarding projected utilization 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 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.