

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 23, 2015

Findings Date: January 23, 2015

Project Analyst: Kim Randolph

Team Leader: Lisa Pittman

Project ID #: G-10352-14

Facility: North Burlington Dialysis Center

FID #: 100785

County: Alamance

Applicant: Renal Treatment Centers Mid-Atlantic, Inc.

Project: Add 3 dialysis stations for a total of 14 stations upon completion of this project and Project ID # G-10265-14 (relocate 2 stations)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis Center (North Burlington Dialysis) proposes to add 3 dialysis stations for a total of 14 dialysis stations upon completion of this project and Project ID # G-10265-14 (relocate 2 stations). North Burlington Dialysis is located at 2019 N Church Street, Alamance County.

#### **Need Determination**

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to

the July 2014 SDR, the county need methodology indicates there is no need for additional stations in Alamance County. However, the applicant is eligible to apply for additional stations based on the facility need methodology, because the utilization rate reported for North Burlington Dialysis in the July 2014 SDR is 4.0 patients per station. This utilization rate was calculated based on 48 in-center dialysis patients and 12 certified dialysis stations as of December 31, 2013 (48 patients / 12 stations = 4.0 patients per station).

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

**October 1 Review - July 2014 SDR**

Required SDR Utilization		80.0%
Center Utilization Rate as of 12/31/13		100.0%
Certified Stations as of 12/31/13		12
Pending Stations (certified as of 06/18/14)		1
<b>Total Existing and Pending Stations</b>		<b>13</b>
In-Center Patients as of 12/31/13 (SDR2)		48
In-Center Patients as of 06/30/13 (SDR1)		46
Step	Description	
(i)	Difference (SDR2 - SDR1)	2
	Multiply the difference by 2 for the projected net in-center Change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/13	0.0869
(ii)	Divide the result of Step (i) by 12	0.0072
(iii)	Multiply the result of Step (ii) by the number of months from 12/31/13 until the end of the current calendar year.	0.0869
(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	52.1740
(v)	Divide the result of Step (iv) by 3.2 patients per station	16.3044
	and subtract the number of certified and pending stations as recorded in SDR2 [10] to determine the number of stations needed	3.3044 = 3 stations

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

### **Policies**

There is one policy in the 2014 SMFP that is applicable to this review, Policy GEN-3: Basic Principles. This policy 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 I, pages 7-9, Section II, pages 20-21, Section V, page 33, Section XI.6(g), pages 61-62, 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 III, pages 23-26, Section V, page 33, Section VI, pages 34-38, 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 II, pages 16-17, Section III, page 27, Section V, page 33, Section VIII, page 43, and referenced exhibits. 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. Therefore, 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 July 2014 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.

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North Burlington Dialysis proposes to add 3 dialysis stations for a total of 14 dialysis stations upon completion of this project and Project ID # G-10265-14 (relocate 2 stations).

**Population to be Served**

In Section IV.1, page 28, the applicant states the number of patients served at North Burlington Dialysis, as of December 31, 2013, is illustrated below.

<b>County of Residence</b>	<b>Number of ICH Patients*</b>	<b>Number of Home Patients</b>
Alamance	47	21
Guilford	0	1
Person	1	0
Rockingham	0	1
<b>Total</b>	<b>48</b>	<b>23</b>

\* In-Center Hemodialysis (ICH)

In Section III.7, page 24, the applicant identifies the projected patient origin for North Burlington Dialysis' in-center patients for the first two years of operation following completion of the project, as illustrated below.

County	Operating Year 1 (OY 1) (01/01/16 – 12/31/16)		Operating Year 2 (OY 2) (01/01/17 – 12/31/17)		County Patients as a Percent of Total	
	ICH	Home	ICH	Home	OY 1	OY 2
Alamance	44	0	48	0	97.8%	98.0%
Person	1	0	1	0	2.2%	2.0%
<b>Total</b>	<b>45 *</b>	<b>0 **</b>	<b>49</b>	<b>0 **</b>	<b>100.0%</b>	<b>100.0%</b>

\* North Burlington Dialysis will transfer 14 in-center patients and relocate 2 dialysis stations to Graham Dialysis, Project ID # G-10265-14, which is scheduled for completion and certification of stations on January 1, 2016.

\*\* North Burlington Dialysis' home training program will relocate to the new Graham Dialysis facility.

The applicant adequately identifies the population North Burlington Dialysis proposes to serve.

**Analysis of Need**

In Section III.7, page 24, the applicant states that as of December 31, 2013, North Burlington Dialysis had a 100% utilization rate ( $48 / 12 = 4.0$ ;  $4.0 / 4 = 1.00$ ). As of June 18, 2014 one additional dialysis station had been added (Project ID # G-10205-13), for a total of 13 dialysis stations and a 92% utilization rate ( $48 / 13 = 3.69$ ;  $3.69 / 4 = 0.92$ ).

In Section III.7, pages 24-26, the applicant provides the assumptions and methodology used to determine the need for additional stations and to project North Burlington Dialysis' patient utilization as summarized below.

1. The applicant identifies a beginning patient population of 48 in-center patients as of December 31, 2013, (47 patients from Alamance County and 1 patient from another county).
2. The five year average annual change rate for Alamance County was 2.8%, according to the July 2014 SDR.
3. In Section II, page 14, the applicant states North Burlington Dialysis experienced an annual growth rate of 11.3% since opening in 2011, as shown below.

	In-Center Patients			Annual Growth		Average Annual Change Rate
	12/31/11	12/31/12	12/31/13	2012	2013	
North Burlington Dialysis	39	40	48	2.6%	20.0%	11.3%

4. The applicant states instead of using the 11.3% annual growth rate, it used a more conservative growth rate of 8.6% to project patient utilization. The 8.6% growth rate

was derived by annualizing the facility growth rate from July 1, 2013 to December 31, 2013,  $(48-46 / 46 = 0.043; 0.043 \times 2 = 0.086)$ .

5. The applicant increases the beginning patient population of 47 Alamance patients by 8.6% per year through the end of OY 2.
6. The project is scheduled for completion and certification of stations on January 1, 2016. OY 1 is the period from January 1, 2016 through December 31, 2016, and OY 2 is the period from January 1, 2017 through December 31, 2017.
7. Based on the facility need methodology, the applicant states it is eligible for 3 additional dialysis stations for a total of 16 dialysis stations upon completion.
8. The applicant states on January 1, 2016, it will transfer 14 in-center patients and relocate 2 stations to Graham Dialysis (Project ID # G-10265-14), leaving a total of 14 stations and 42 patients at North Burlington Dialysis.

*Projected Utilization*

The following table demonstrates the calculations used to arrive at the projected in-center patient census for the first two operating years.

<b>North Burlington Dialysis</b>	<b>In-Center Patients</b>
The applicant begins with Alamance County patients dialyzing at North Burlington Dialysis as of December 31, 2013.	47
The applicant uses an 8.6% growth rate to project the census forward one year to December 31, 2014.	$47 \times 1.086 = 51.042$
The applicant uses an 8.6% growth rate to project the census forward one year to December 31, 2015.	$51 \times 1.086 = 55.386$
The applicant adds the 1 patient from outside Alamance County.	$55 + 1 = 56$
The applicant subtracts the 14 patients that will transfer to Graham Dialysis on January 1, 2016.	$56 - 14 = 42$
The applicant subtracts the 1 patient from outside Alamance County.	$42 - 1 = 41$
The applicant uses an 8.6% growth rate to project the ending Alamance County census for OY 1, December 31, 2016.	$41 \times 1.086 = 44.526$
The applicant adds the 1 patient from outside Alamance County to project the facility's ending census for OY 1, December 31, 2016.	$44 + 1 = 45$
The applicant uses an 8.6% growth rate to project the ending Alamance County census for OY 2, December 31, 2017.	$44.526 \times 1.086 = 48.355$
The applicant adds the 1 patient from outside Alamance County to project the facility's ending census for OY 2, December 31, 2017.	$48 + 1 = 49$

At the end of OY 1, North Burlington Dialysis is projecting an in-center patient census of 45 patients for a utilization rate of 80.36% or 3.21 patients per station  $(45 / 14 = 3.21; 3.21 / 4 =$

.8036). At the end of OY 2, Burlington Dialysis is projecting an in-center patient census of 49 patients for a utilization rate of 87.5% or 3.5 patients per station ( $49 / 14 = 3.5$ ;  $3.5 / 4 = .875$ ). Projected patient in-center utilization at the end of OY 1 is 3.21 in-center patients per station per week which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The applicant adequately demonstrates the need the population has for the proposed services.

### **Access**

In Section VI, page 34, the applicant states

*“The North Burlington Dialysis Center, by policy, makes dialysis services available to all residents in its service area without qualifications. We service patients without regard to race, sex, age or handicap. We serve patients regardless of ethnic or socioeconomic situation.*

...

*The North Burlington Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons.”*

The applicant projects 85.4% of its payments will be from Medicare or Medicaid. 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**

The applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the 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.

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In Section III.9, page 27, the applicant discusses the alternatives considered prior to submission of this application, which include:

- 1) Maintain the status quo – The applicant states this alternative is not as effective because the facility is growing, having experienced a three year average annual growth rate of 11.3% since the facility was certified in 2011. If the facility does not add additional stations, it will not meet the increasing demand for dialysis services at North Burlington Dialysis.
- 2) Apply for three additional stations - The applicant states that the chosen alternative, to apply to expand the existing North Burlington Dialysis facility by adding 3 stations for a total of 14 certified dialysis stations, is the most effective or least costly alternative for meeting the needs of the patients projected to receive treatment at North Burlington Dialysis.

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

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the 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 Center 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 Center shall develop and operate no more than 3 additional dialysis stations for a total of no more than 14 certified dialysis stations upon completion of this project and Project ID # G-10265-14 (relocate 2 stations), which shall include any isolation or home hemodialysis stations.**
3. **Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis Center shall install plumbing and electrical wiring through the walls for no more**



**than 3 additional dialysis stations for a total of no more than 14 dialysis stations, which shall include any isolation or home hemodialysis stations.**

**4. Renal Treatment Centers Mid-Atlantic, 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.

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In Section VIII, pages 43-44, the applicant projects a capital cost of \$17,398 for the project, which includes \$12,500 for dialysis machines, \$1,185 for additional equipment/furniture, \$1,135 for dialysis chairs, \$1,500 for TVs, and \$1,078 for chair side computers. In Section IX, page 48, the applicant indicates that start-up and initial operating expenses would not apply to this project because North Burlington Dialysis is not a new facility.

On page 45, the applicant indicates the project will be funded with accumulated reserves from DaVita Inc., the parent company of Renal Treatment Centers Mid-Atlantic, Inc. Exhibit 18 contains a letter dated September 10, 2014, from the Chief Accounting Officer of DaVita HealthCare Partners, Inc., which states:

*"This letter will confirm that DaVita HealthCare Partners Inc. has committed cash reserves in the total sum of \$17,398 for the project 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 Renal Treatment Centers-Mid Atlantic, Inc."*

Exhibit 19 contains the audited financial statements for DaVita HealthCare Partners Inc. for the years ending December 31, 2013 and 2012. As of December 31, 2013, DaVita HealthCare Partners Inc. had \$946,249,000 in cash and cash equivalents, \$3,472,278,000 in total current assets and \$4,605,541,000 in total equity. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 50, the applicant projects the allowable in-center charges per treatment for each source of payment, as shown below.

Sources of Payment	Allowable ICH Charge per Treatment*
Medicare	\$239.02
Medicaid	\$143.00
Medicare / Medicaid	\$239.02
Commercial Insurance	\$1,275.00
Medicare / Commercial	\$239.02
VA	\$193.00

\* North Burlington Dialysis currently has home dialysis patients but is not projecting revenue from home dialysis treatments during the first two operating years. The current home dialysis patients will transfer to the Graham Dialysis facility once it is complete and the stations are certified.

On pages 51-56, the applicant projects revenues and expenses for in-center treatments for the first two operating years, as shown below.

**North Burlington Dialysis ICH Treatments**

	OY 1 01/01/16 - 12/31/16	OY 2 01/01/17 - 12/31/17
Projected Gross Revenue	\$1,939,970	\$2,094,556
Projected Deduction*	\$83,848	\$90,589
Projected Net Revenue	\$1,856,122	\$2,003,967
Projected Operating Costs	\$1,804,639	\$1,910,064
Projected Net Profit	\$51,483	\$93,903

\* The applicant indicates the Projected Deduction is the Medicare adjustment, which is 20% of the Medicare line item on page 51 of the application.

As illustrated in the table above, the applicant projects revenues will exceed operating expenses in each of the first two operating years following completion of the project. 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. Operating costs and revenues are based on reasonable assumptions including projected utilization. See Section X.3, pages 52-54, for the applicant's treatment assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section VII.1, page 39, the applicant provides projected staffing and salaries. The financials in Section X.4-5, pages 55-56, budget operating costs adequate to cover the projected staffing.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of operating costs and charges. Therefore, the application is conforming with this criterion.

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

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North Burlington Dialysis proposes to add 3 dialysis stations for a total of 14 dialysis stations upon completion of this project and Project ID # G-10265-14 (relocate 2 stations). The following table identifies the existing and approved kidney disease treatment centers located in Alamance County as reported in the July 2014 SDR.

<b>Facility</b>	<b>Location</b>	<b>Utilization</b>
BMA Burlington	Burlington	58.33%
Burlington Dialysis	Burlington	106.25%
Carolina Dialysis – Mebane	Mebane	87.50%
Graham Dialysis*	Graham	0.00%
North Burlington Dialysis	Burlington	100.00%

\* Under development. The Graham Dialysis facility is scheduled for completion and certification of stations on January 1, 2016 (Project ID # G-10265-14).

In Section V.7, page 33, the applicant states Renal Treatment Centers Mid-Atlantic operates North Burlington Dialysis and Burlington Dialysis and is developing Graham Dialysis Center. The nephrologists from Central Carolina Kidney Associates are the only physicians who admit patients to its facilities. The applicant states the other two dialysis facilities located in Alamance County are owned by Fresenius Medical Care. Fresenius has a relationship with another nephrology practice and has its own referral source for patients.

The applicant is proposing to add three additional stations to its existing facility based on the facility need methodology. The applicant adequately demonstrates the need for three additional stations based on the number of in-center patients it proposes to serve. The discussions regarding analysis of need and competition found in Criteria (3) and (18a), respectively, are 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. 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.

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The following table illustrates the current and projected staffing for North Burlington Dialysis, as provided by the applicant in Section VII.1, page 39.

Position	Current Full-Time Equivalents (FTEs)	Projected Full-Time Equivalents (FTEs)
RN	2.0	2.0
HT RN	2.0	0.0
Patient Care Technician (PCT)	6.0	6.0
Biomedical Technician	0.5	0.5
Medical Director	Contract Position	Contract Position
Administration	1.0	1.0
Dietician	0.5	0.5
Social Worker	0.5	0.5
Unit Secretary	1.0	1.0
Reuse Technician	1.0	1.0
<b>Total FTEs</b>	<b>14.5</b>	<b>12.5</b>

As shown in the above table, the applicant proposes to employ a total of 12.5 FTE positions to staff North Burlington Dialysis upon completion of the proposed project.

In Section VII.10, page 42, the applicant provides the projected number of direct care PCTs for each shift offered at North Burlington Dialysis, after the addition of the three dialysis stations, as indicated in the table below.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6:00 am – 11:00 am	4	4	4	4	4	4
Afternoon	11:00 am – 4:00 pm	4	4	4	4	4	4
Evening	N/A	0	0	0	0	0	0

The applicant also indicates it will staff each shift, Monday through Saturday from 6:00 am to 4:00 pm, with two RNs. In Section V.4, page 32, the applicant states that Munsoor Lateef, M.D. will serve as medical director of the facility. However, Exhibit 13 contains a letter from Dr. Harmeet Singh stating that he is the medical director for North Burlington Dialysis.

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.

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In Section V, page 30, the applicant lists the providers of the necessary ancillary and support services at North Burlington Dialysis. Exhibits 9 contain a copy of a Patient Transfer Agreement with Alamance Regional Medical Center. Exhibit 10 contains a copy of Transplant Criteria Screen from University of North Carolina (UNC) and the Transplant Selection Criteria from Duke. The applicant discusses coordination with the existing health care system in Section V, pages 32-33. The applicant adequately demonstrates that the necessary ancillary and support services will continue to 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;

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In Section VI.1(b), page 34, the applicant indicates that 85.4% of the in-center patients and 80.0% of the home-trained patients who received treatment at North Burlington Dialysis had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical sources of payment for the facility.

**North Burlington Dialysis Payor Mix**

<b>Sources of Payment</b>	<b>ICH Percentage</b>	<b>Home-Trained Percentage</b>
Medicare	27.2%	15.0%
Medicaid	10.9%	0.0%
Medicare / Medicaid	30.9%	20.0%
Commercial Insurance	7.3%	20.0%
VA	7.3%	0.0%
Medicare / Commercial	16.4%	45.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

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

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Alamance County	16.4%	6.2%	21.0%
Statewide	16.5%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).<sup>1</sup>

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. However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services.

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

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

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

<sup>1</sup> <http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

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

The 2013 USRDS Annual Data Report provides 2011 ESRD spending by payor, as follows:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:



<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.<sup>3</sup>

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

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

C

In Section VI.1, page 36, the applicant states

*“The North Burlington Dialysis Center has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons... .”*

In Section VI.6, page 38, 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.

<sup>3</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

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

C

In Section VI.1, page 35, the applicant provides the projected payor mix for the proposed services at North Burlington Dialysis, which is shown below.

**Projected North Burlington Dialysis ICH Payor Mix**

Sources of Payment	Percentage*
Medicare	27.2%
Medicaid	10.9%
Medicare / Medicaid	30.9%
Commercial Insurance	7.3%
VA	7.3%
Medicare / Commercial	16.4%
<b>Total</b>	<b>100.0%</b>

\* North Burlington Dialysis does not project to serve any home dialysis patients upon completion of this project.

The applicant projects no change from the current payor mix for in-center dialysis services, which is 85.4% Medicare and Medicaid. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, pages 37-38, and Exhibit 14, the applicant describes the range of means by which patients will have access to the proposed services. The applicant adequately demonstrates that North Burlington Dialysis will offer a range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3, page 32, the applicant states North Burlington Dialysis has an agreement with Education Corporation of America d/b/a Virginia College to provide clinical training and observation experiences for students. See Exhibit 12 for a copy of the Student Training Agreement with Education Corporation of America d/b/a Virginia College. The information provided in Section V.3 and the referenced exhibit is reasonable and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

North Burlington Dialysis proposes to add 3 dialysis stations for a total of 14 dialysis stations upon completion of this project and Project ID # G-10265-14 (relocate 2 stations). The following table identifies the existing and approved kidney disease treatment centers located in Alamance County as reported in the July 2014 SDR.

Facility	Location	Utilization
BMA Burlington	Burlington	58.33%
Burlington Dialysis	Burlington	106.25%
Carolina Dialysis – Mebane	Mebane	87.50%
Graham Dialysis *	Graham	0.00%
North Burlington Dialysis	Burlington	100.00%

\* Under development. The Graham Dialysis facility is scheduled for completion and certification of stations on January 1, 2016 (Project ID # G-10265-14).

In Section V.7, page 33, the applicant discusses how any enhanced competition in the service area will promote the cost effectiveness, quality and access to the proposed services. The applicant states it does not expect this proposal to have an effect on competition in Alamance County. The applicant states Renal Treatment Centers Mid-Atlantic operates Burlington Dialysis and North Burlington Dialysis and is developing Graham Dialysis. The nephrologists from Central Carolina Kidney Associates are the only physicians who admit patients to its facilities. The applicant states the other two dialysis facilities located in Alamance County are owned by Fresenius Medical Care. Fresenius has a relationship with another nephrology practice and has its own referral source for patients. The applicant states its goal is not to compete with the other provider but to *“provide improved access to dialysis patients with the three-station expansion... .”* See also Sections II, III, V, VI, and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and credible 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 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 that it will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

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.

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, North Burlington Dialysis operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

## C

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

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

#### **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- As of December 31, 2013, the July 2014 SDR indicates North Burlington Dialysis had a utilization rate of 100% with 48 in-center patients dialyzing on 12 stations ( $48 / 12 = 4.0$ ;  $4.0 / 4 = 1.0$ ).

*.2202(a)(2) Mortality rates;*

- C- In Section IV.2, page 28, the applicant reports North Burlington Dialysis' 2012 and 2013 facility mortality rates, as 11.1%, and 10.8% respectively.

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

-C- In Section IV.3, page 28, the applicant states that North Burlington Dialysis has 23 home-trained and home dialysis patients as of December 31, 2013.

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

-C- In Section IV.4, page 29, the applicant indicates that North Burlington Dialysis had zero patient with a transplant performed and eight patients referred for a transplant evaluation in 2013.

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

-C- In Section IV.5, page 29, the applicant states that North Burlington Dialysis has six 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 IV.6, page 29, the applicant reports that North Burlington Dialysis had a total of 64 hospital admissions from January 1, 2013 – December 31, 2013; 11 (17.2%) were dialysis related admissions and 53 (82.8%) were non-dialysis related admissions.

.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 IV.7, page 29, the applicant reports that in 2013, North Burlington Dialysis had zero patients with infectious disease and zero patients converted to infectious status.

*(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- The applicant does not propose a new facility. North Burlington Dialysis is an existing 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- The applicant does not propose a new facility. North Burlington Dialysis is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- The applicant does not propose a new or replacement facility. North Burlington Dialysis is an existing 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 8 which contains copies of DaVita's written policies and procedures, including back up procedures for 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- The applicant does not propose a new facility. North Burlington Dialysis is an existing 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- See Sections II.1, page 11; VII.2, page 40; and XI.6, pages 60-62.

.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- The applicant provides the following projected patient origin in Section III.7, page 24, as shown below.

County	Operating Year 1 (01/01/16 – 12/31/16)		Operating Year 2 (01/01/17 – 12/31/17)		County Patients as a Percent of Total	
	ICH	Home	ICH	Home	OY 1	OY 2
Alamance	44	0	48	0	97.8%	98.0%
Person	1	0	1	0	2.2%	2.0%
<b>Total</b>	<b>45</b>	<b>0</b>	<b>49</b>	<b>0</b>	<b>100.0%</b>	<b>100.0%</b>

In Section III.7, pages 24-26, the applicant provides the assumptions and methodology used to project patient origin. The discussion regarding patient origin 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- The applicant does not propose a new facility. North Burlington Dialysis is an existing 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 II.1, page 13, the applicant states, “Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis Center admits and provides dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

**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- The applicant does not propose a new facility. 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 II, pages 16-17 and Section III.7, page 24, the applicant projects that it will serve 45 patients on 14 stations at the end of the first operating year, based on the methodology and assumptions found on pages 24-26 of the application ( $45 / 14 = 3.21$  patients per station per week). 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 III.7, pages 24-26, the applicant provides the assumptions and methodology used to project patient utilization. The discussion regarding projected utilization 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- See Section V.1, page 30. The applicant indicates Alamance Regional Medical Center will provide diagnostic and evaluation services.

.2204(2) *Maintenance dialysis;*

- C- See Section V.1, page 30. The applicant indicates it will provide maintenance dialysis.

.2204(3) *Accessible self-care training;*

- C- See Section II.2, pages 19-20 and Section V.1, pages 30-32. The applicant states it will provide self-care training until Graham Dialysis is certified, then the home training program will move from North Burlington Dialysis to Graham Dialysis.

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

- C- See Section V.2, page 31. The applicant states “*North Burlington Dialysis is certified to provide patient training for all of the home training modalities. The facility will provide protocols and routines for patient follow-up.*” The applicant states it will provide self-care training until Graham Dialysis is certified, then the home training program will move from North Burlington Dialysis to Graham Dialysis.

.2204(5) *X-ray services;*

- C- See Section V.1, page 30. The applicant indicates Alamance Regional Medical Center

will provide X-ray services.

.2204(6) *Laboratory services;*

-C- See Section V.1, page 30. The applicant indicates Dialysis Laboratories will provide laboratory services.

.2204(7) *Blood bank services;*

-C- See Section V.1, page 30. The applicant indicates Alamance Regional Medical Center will provide blood bank services.

.2204(8) *Emergency care;*

-C- See Section V.1, page 30. The applicant indicates Alamance Regional Medical Center will provide emergency care.

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

-C- See Section V.1, page 30. The applicant indicates Alamance Regional Medical Center will provide acute dialysis in an acute care setting.

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

-C- See Section V.1, page 30. The applicant indicates Alamance Regional Medical Center will provide vascular surgery for dialysis treatment patients.

.2204(11) *Transplantation services;*

-C- See Section V.1, page 30. The applicant indicates UNC Hospitals will provide transplantation services.

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

-C- See Section V.1, page 30. The applicant indicates Vocational Rehabilitation will provide vocational rehabilitation counseling and services.

.2204(13) *Transportation;*

-C- See Section V.1, page 30. The applicant indicates Alamance County Transportation Services will provide transportation services.

## **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 C.F.R. Part 494).*

-C- In Section VII, pages 39-40, the applicant provides the proposed staffing and states it will comply with all staffing requirements set forth in 42 C.F.R. Part 494 (formerly 42

C.F.R., Section 405.2100). The discussion regarding 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- See Section VII.5, page 41, and Exhibit 17.