

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 2, 2013

PROJECT ANALYST: Kimberly Randolph

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: G-10104-13/ Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis/ Add two dialysis stations to the existing facility for a total of 12 certified dialysis stations upon project completion/ Alamance County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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The applicant, Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis, whose parent company is DaVita Healthcare Partners Inc., currently operates a 10-station dialysis facility located at 2019 North Church Street, Burlington. The applicant proposes to add two dialysis stations to the existing facility for a total of 12 certified dialysis stations upon project completion.

The 2013 State Medical Facilities Plan (2013 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Alamance County. However, the applicant is eligible to apply for additional stations in its existing facility, based on the facility need methodology. The utilization rate reported for North Burlington Dialysis in the January 2013 SDR shows 3.9 patients per station, which is greater than the required 3.2 patients per station. The utilization rate was calculated based on 39 in-center dialysis patients and 10 certified dialysis stations as of June 30, 2012 (39 patients / 10

stations = 3.9 patients per station. Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

**ESRD Facility Need Methodology
 2013 April Review – January 2013 SDR**

Required SDR Utilization		80.0%
Center Utilization Rate as of 06/30/12		97.5%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		10
In-Center Patients as of 06/30/12 (SDR2)		39
In-Center Patients as of 12/31/11 (SDR1)		39
Difference (SDR2 - SDR1)		0
Step	Description	Result
(i)	Multiply the difference by 2 for the projected net in-center change.	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/11	0
(ii)	Divide the result of Step (i) by 12	0
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the January [2013] SDR (06/30/12) until the end of calendar year 2012 (6 months)	0
(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	39
(v)	Divide the result of Step (iv) by 3.2 patients per station	12.1875
	and subtract the number of certified and pending stations as recorded in SDR2 [10] to determine the number of stations needed	2

* Source: Section III.2, page 19.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two stations. In the January 2013 SDR, Step (2)(C) of the facility need methodology states, *“The facility may apply to expand to meet the need established in (2)(B)(v), up to a maximum of 10 stations.”* The applicant proposes to add two new dialysis stations and, therefore, is consistent with the facility need determination of two dialysis stations.

Policy GEN-3: Basic Principles, pages 42-43, in the 2013 SMFP is also applicable to this review. Policy GEN-3 states:

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

projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

In Section II.3, pages 17-18, the applicant describes the methods used to insure and maintain quality care. On page 17, the applicant states its Quality Management Program includes the following Quality Programs:

- *“Quality Improvement Methodology - utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System - integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Staff and Patient Education Program - ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program - systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team - experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team - experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance).”*

In Section I.3, pages 7-8, the applicant describes the *“DaVita Quality Index, a unified measure of clinical performance for dialysis facilities.”* The applicant states it uses this quality index to evaluate overall clinical care and to identify needed improvements which will benefit dialysis patients.

On page 7, the applicant states *“DaVita consistently differentiates itself from other kidney care companies and surpasses national averages for clinical outcomes.”* See Exhibit 4 for supporting documentation. In Section I.3, page 8, the applicant discusses the staff and credits its quality service to quality staffing and staff training. The Medical Director for North Burlington Dialysis is Dr. Harmeet Singh. The applicant includes a copy of its Training Program Outline in Exhibit 17.

The applicant discusses its safety measures in Section XI.6(g), pages 54-55. On page 55, the applicant states *“North Burlington Dialysis has a Safety and Health program that includes teammate safety and health committees.”* In Exhibit 15, the applicant provides a copy of its isolation policies and procedures.

The applicant adequately demonstrates that the proposal will promote quality and safety in the provision of dialysis services in Alamance County.

Promote Equitable Access

In Section VI, pages 30-33, the applicant provides information about accessibility to its services. On page 30, the applicant states

“North Burlington Dialysis, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”

The applicant states dialysis services are available to all patients including low-income persons, racial and ethnic minorities, handicapped, elderly, and other underserved individuals. On page 30, the applicant indicates Medicare represents 73.5 percent of the payment source for treatment at North Burlington Dialysis and Medicaid represents an additional 7.8 percent. See Exhibit 14 for a copy of the applicant’s Business and Admissions/Transfer Policy.

In Section VI.2, pages 31-32, the applicant states North Burlington Dialysis meets all state and local building code requirements to allow equal access for handicapped patients. The applicant states *“Many of our patients are severely physically handicapped.”* On page 32, the applicant states the staff is trained to assist handicapped individuals into and out of the dialysis treatment stations.

In Section VI.7, page 33, the applicant states it has an open door policy and accepts all patients, including patients with hepatitis and/or AIDS. See Exhibit 15 for a copy of the applicant’s Isolation Procedures and Procedures.

The applicant adequately demonstrates that medically underserved groups will have equitable access to the proposed services.

Maximize Healthcare Value

In Section III.9, pages 22-23, the applicant states it promotes cost-effective approaches in the facility as listed below.

- North Burlington Dialysis purchases equipment through the DaVita Healthcare Partners Inc. centralized purchasing department, which can negotiate national contracts to obtain the best product for the best price;
- North Burlington Dialysis purchases all products utilized at the facility under a national contract;
- North Burlington Dialysis utilizes the reuse process for dialyzers, which contains cost and waste;
- North Burlington Dialysis utilizes computers for patient documentation and charting to reduce the need for paper;

- North Burlington Dialysis utilizes Bio-Technicians assigned to the facility to conduct preventative maintenance on the dialysis machines to extend the service life; and
- North Burlington Dialysis utilizes inventory control plans to eliminate overstocking and emergency ordering of supplies.

In Section IX, page 43, the applicant states it proposes to utilize existing space at North Burlington Dialysis for the addition of the two dialysis stations.

The applicant adequately demonstrates the proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. The application is consistent with the facility need determination in the January 2013 SDR and with 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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Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis currently operates a 10-station dialysis facility located in Burlington. The applicant proposes to add two dialysis stations to the existing North Burlington Dialysis facility for a total of 12 certified dialysis stations upon project completion. The January 2013 SDR indicates North Burlington Dialysis has a total of 10 certified dialysis stations as of June 30, 2012. Based on patient origin information provided in Section III.7, pages 21-22, the applicant also proposes 20 home-trained patients by December 31, 2013.

Population to be Served

In Section IV.1, page 24, the applicant identifies the population of in-center patients it serves as illustrated in the table below.

County of Residence	# of Patients Dialyzing In-Center
Alamance	39
Total	39

In Section III.7, pages 21-22, the applicant provides the projected patient origin for the first two years of operation following completion of the project, as illustrated in the following table.

County	Operating Year 1 01/01/14 - 12/31/14		Operating Year 2 01/01/15 – 12/31/15		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Alamance	41	21	44	22	100%	100%
Total	41	21	44	22	100%	100%

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III.7, pages 21-22, the applicant states its application is filed pursuant to the Facility Need Methodology utilizing data from the January 2013 SDR. The applicant proposes to add two dialysis stations to the existing North Burlington Dialysis facility for a total of 12 certified dialysis stations upon project completion.

On pages 21-22, the applicant provides the following assumptions for the proposed project.

- The project is scheduled for completion and certification of stations by January 1, 2014. Thus, Operating Year 1 (OY1) is the period from January 1, 2014 through December 31, 2014. Operating Year 2 (OY2) is the period from January 1, 2015 through December 31, 2015.
- The applicant identified a current patient population of 39 in-center patients, as of June 30, 2012.
- The applicant identified a current patient population of 20 home-trained patients, as of December 31, 2012, in Section IV.3, page 24.
- The applicant assumes the ESRD patient population of Alamance County will increase at the Five Year Average Annual Change Rate (AACR) published in the January 2013 SDR, for at least the period of project development, OY1, and OY2. The AACR for Alamance County is 4.5 percent.
- The applicant projects the North Burlington Dialysis Center and the home-trained program will grow at 4.5 percent, the five year AARC for Alamance County.

Therefore, on page 21, the applicant projects in-center utilization starting with the current total of 39 in-center patients, as shown below.

	North Burlington Dialysis Methodology for Projecting Utilization Using AACR's	Projected In-Center Patients
Alamance County Patient Growth through 12/31/13	$39 \times 1.045 =$	<i>40.755</i>
Alamance County Patient Growth through 12/31/14	$40.755 \times 1.045 =$	<i>41.588985</i>
Alamance County Patient Growth through 12/31/15	$41.588985 \times 1.045 =$	<i>44.50547887</i>

The applicant projects patient utilization at North Burlington Dialysis to be as follows for in-center patients:

Operating Year 1

41 patients dialyzing at 12 stations = 3.4 patients per station ($41 / 12 = 3.4166$)
 $[41 / (12 \times 4) = 0.8541]$ or 85 percent

Operating Year 2

44 patients dialyzing at 12 stations = 3.6 patients per station ($44 / 12 = 3.6666$)
 $[44 / (12 \times 4) = 0.9166]$ or 91 percent

On page 22, the applicant projects home-trained patient utilization starting with the current total of 20 patients, as shown below.

	North Burlington Dialysis Methodology for Projecting Utilization Using AACR's	Projected Home-Trained Patients
Alamance County Patient Growth through 12/31/13	$20 \times 1.045 =$	<i>20.9</i>
Alamance County Patient Growth through 12/31/14	$20.9 \times 1.045 =$	<i>21.8405</i>
Alamance County Patient Growth through 12/31/15	$21.8405 \times 1.045 =$	<i>22.8233225</i>

The applicant projects utilization at North Burlington Dialysis to be as follows for home-trained patients:

Operating Year 1

North Burlington Dialysis is projecting 21 home-trained patients.

Operating Year 2

North Burlington Dialysis is projecting 22 home-trained patients.

The applicant's projected in-center patient utilization at the end of Year 1 is equal to or greater than 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth. The applicant adequately demonstrates the need to add two additional dialysis stations to the existing North Burlington Dialysis facility.

Access to Services

In Section VI, page 30, the applicant states:

“North Burlington Dialysis, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”

The applicant projects 81.3 percent of its patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the service area, including the medically underserved, will have access to the proposed services.

In summary, the applicant adequately identifies the population to be served, demonstrates the need for two additional dialysis stations at North Burlington Dialysis, and demonstrates the extent to which all residents in the service area, in particular 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.

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In Section III.9, page 22, the applicant discusses two alternatives considered prior to the submission of this application, which include the following:

- 1) Maintain the Status Quo. The applicant states this alternative is not as effective because the utilization rate at North Burlington Dialysis Center was 97.5 percent as of June 30, 2012 and that utilization will continue to grow.
- 2) Add two dialysis stations at North Burlington Dialysis for a total of 12 dialysis stations. The applicant states that adding two additional stations to the existing

treatment space at North Burlington Dialysis is the most effective alternative to meet the increasing demand for dialysis services at the facility.

The applicant adequately demonstrates the need for two additional stations based on the continued growth of the ESRD patient population of Alamance County and the facility's projected utilization. See Criterion (3) for further discussion on need, which is incorporated hereby as if set forth fully herein. Furthermore, the application is conforming to all other statutory and regulatory review criteria. Therefore, the application is approvable.

In summary, the applicant adequately demonstrates that the 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 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 no more than two additional dialysis stations at North Burlington Dialysis for a total of no more than 12 stations upon completion of this project.**
 - 3. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis shall install plumbing and electrical wiring through the walls for no more than two additional dialysis stations, for a total of no more than 12 stations, which shall include any home hemodialysis or isolation stations.**
 - 4. 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 Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII, pages 38-40, the applicant projects a capital cost of \$28,961 for the proposed project. The applicant states it will fund the capital needs of the proposed project from the cash reserves of DaVita Healthcare Partners Inc. In Section IX.3, page 43, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 18 includes a letter dated March 15, 2013 from the Interim Chief Financial Officer of DaVita Healthcare Partners Inc., which states

“I am the Chief Accounting Officer of DaVita Healthcare Partners Inc., the parent of Renal Treatment Centers-Mid Atlantic, Inc.

We are submitting a Certificate of Need application to expand our North Burlington Dialysis Center by two ESRD dialysis stations. The project calls for a capital expenditure of \$28,961. This letter will confirm that DaVita Healthcare Partners Inc. has committed cash reserves in the total sum of \$28,961 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.”

In Exhibit 19, the applicant provides the audited financial statements for DaVita Healthcare Partners Inc. for the years ending December 31, 2012 and 2011. As of December 31, 2012, DaVita Health Care Partners Inc. had \$533,748,000 in cash and cash equivalents, \$16,018,596,000 in total assets and \$3,928,048,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

In Section X.1, page 45, the applicant projects the following charges per treatment for each payment source as shown below.

Payment Source	In-Center Charge
Medicare	\$240
Medicaid	\$143
Medicare/Medicaid	\$240
Commercial Insurance	\$1,442
VA	\$193
Medicare/Commercial	\$240

The applicant projects net revenue in Section X.2, page 45, and operating expenses in Section X.4, page 48, of the application. The applicant projects revenues will exceed expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	Operating Year 1 (OY1) 01/01/2014 - 12/31/2014	Operating Year 2 (OY2) 01/01/2015 - 12/31/2015
Total Projected Net Revenue	3,317,715	3,481,452
Total Projected Operating Costs	2,609,450	2,720,801
Projected Net Profit	708,265	760,651

Source: Application page 48.

In Section X.3, pages 46-47, the applicant used the following assumptions to project revenue for OY1 and OY2:

Assumptions

1. Average number of patients for the current year is increased by the county AACR through the first two operating years;
2. The total number of treatments includes the in-center and home-trained patients at an average of three treatments per week, per patient, for 52 weeks;
3. The total number of treatments is reduced by five percent to allow for missed treatments; and
4. Average reimbursement per treatment is based on the applicant's historical experience and expected future reimbursement.

In Section X, pages 48-49, the applicant provides projected staffing and salaries. In Section VII, page 34, the applicant states the facility is in compliance with the requirements of 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 36. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

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Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis proposes to add two dialysis stations to the existing North Burlington Dialysis facility for a total of 12 certified dialysis stations upon project completion.

The applicant adequately demonstrates the need for two additional stations based on the number of in-center patients it proposes to serve. According to the January 2013 SDR, as of June 30, 2012, the 10-station North Burlington Dialysis facility was operating at 97.5 percent of capacity ($39 / 10 = 3.9$; $3.9 / 4 = 97.5$ percent). The target utilization rate is 80 percent or 3.2 patients per station, per week, at the end of the first operating year. Therefore, the applicant is eligible to expand its facility and may apply for additional stations. In Section III.7, page 21, the applicant states that upon completion of this project, the facility will have 12 stations serving 41 patients (end of OP1), which is a utilization rate of 85 percent ($41 / 12 = 3.4166$; $3.41 / 4 = 85$ percent). The application is conforming to the performance standard promulgated in 10A NCAC 14C .2203.

In Section V.7, page 29, the applicant states Renal Treatment Centers Mid-Atlantic, Inc. operates two kidney disease treatment centers in Alamance County; Burlington Dialysis Center and North Burlington Dialysis Center. According to the 2013 SDR, the utilization rate as of June 30, 2012 at these facilities was 89.71 percent and 97.5 percent respectively. Fresenius Medical Center operates one kidney disease treatment center in Burlington, BMA of Burlington which had a utilization rate of 72.96 percent as of June 30, 2012 and has another facility under construction in Mebane.

On page 29, the applicant states:

“This project will have no impact on the other outpatient dialysis facilities in Alamance County.

...

Renal Treatment Centers Mid-Atlantic is not trying to compete with the other provider with the expansion of dialysis stations at North Burlington Dialysis. Our goal is to provide improved access to dialysis patients with the two-station expansion of North Burlington Dialysis.”

The applicant demonstrates a need for two more stations at North Burlington Dialysis Center based on the number of in-center patients currently utilizing the facility. Assuming the target utilization rate is 80 percent, with 39 in-center patients, the facility needs 12 stations to operate at 80 percent of capacity [$39 / 4 = 9.75$; $9.75 / 0.8 = 12.1875$].

The applicant adequately demonstrates the proposed project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. 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.

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In Section VII.1, page 34, the applicant provides the current and projected number of full-time equivalent (FTE) positions as shown in the table below.

POSITION	CURRENT # OF FTES	PROJECTED # OF NEW FTES	TOTAL # OF FTES
RN	2.0	0.0	2.0
HTRN	1.5	0.0	1.5
Patient Care Tech (PCT)	5.0	1.0	6.0
Bio-Med Tech	0.5	0.0	0.5
Admin.	1.0	0.0	1.0
Dietician	0.8	0.0	0.8
Social Worker	0.8	0.0	0.8
Unit Secretary	1.0	0.0	1.0
Other – Reuse	0.5	0.0	0.5
Total	13.1	0.0	14.1

Note: The Medical Director is a contract position, not an FTE of the facility.

As shown in the table above, the applicant proposes to employ a total of 14.1 full-time equivalent (FTE) positions to staff North Burlington Dialysis upon completion of the proposed project. In Section V.4, page 28, the applicant states that Dr. Harmeet Singh will continue to serve as medical director of the facility and is a board-certified nephrologist. Exhibit 13 contains a letter of support from Dr. Singh.

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.

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In Sections V.1-2, pages 26-27, the applicant lists the providers of the necessary ancillary and support services. Alamance Regional Medical Center provides emergency services, acute hemodialysis services, diagnostic and evaluation services, X-ray services, blood bank services, and vascular surgery services. The other services are provided by the individual providers listed on page 26. See supporting documentation in Exhibits 10 and 11. The applicant discusses coordination with the existing health care system in Sections V.2 – V.6, pages 27-29. The applicant provides supporting documentation in Exhibits 12 and 13. The information provided in those sections and exhibits is reasonable and credible and supports a finding of conformity with this criterion.

- (9) An applicant proposes 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

NA

(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, page 30, the applicant states

“North Burlington Dialysis, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”

The applicant’s dialysis policies, procedures, and guidelines are located in Exhibit 14.

In Section VI.1, page 30, the applicant reports that 81.3 percent of the patients who received treatments at North Burlington Dialysis had some or all of the services paid for by Medicare or Medicaid in the past year. The table below illustrates the current historical payor source for the facility.

North Burlington Dialysis Historical Payor Source	
Payor Source	Percentage
Medicare	26.6%
Medicaid	7.8%
Medicare/Medicaid	21.9%
Commercial Insurance	12.5%
VA	6.2%
Medicare/Commercial	25.0%
Total	100.0%

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

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Alamance County	16%	6.20%	21.0%
Statewide	17%	6.71%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by North Burlington Dialysis. In fact, in 2011 only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010: *“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”* Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”

The report provides 2010 ESRD spending by payor, as follows:

ESRD Spending by Payor*		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

* Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender, as shown below.

Number and Percent of Dialysis Patients by Age, Race, and Gender*		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
Total	9,342	100.0%

* Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.

The applicant demonstrates that medically underserved populations currently have adequate access to services available at North Burlington Dialysis. 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 31, 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...” In Section VI.6, page 33, the applicant states *“There have been no civil rights equal access complaints filed within the last five years.”* The application is conforming to this criterion.

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

C

In Section VI.1(c), page 31, the applicant provides the projected payor mix for the proposed services at the facility. The applicant projects no change from the current payor mix for dialysis visits as stated in Criterion (13a) above for OY1 and OY2. The applicant projects 81.3 percent of all in-center patients will have some or all of the services paid for by Medicare and Medicaid, with VA covering another 6.2 percent.

In Section VI.2, pages 31-32, the applicant states the facility is designed and constructed to accommodate handicapped persons.

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

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

C

In Section VI.5, pages 32-33, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with 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

Exhibit 12 contains a copy of the applicant's letter, addressed to the President of Alamance Community College, offering North Burlington Dialysis as a clinical training site for nursing students. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed

service area. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

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

C

The applicant proposes to add two dialysis stations to the existing North Burlington Dialysis facility for a total of 12 certified dialysis stations upon completion of the proposed project. The January 2013 SDR shows there is a surplus of nine dialysis stations in Alamance County; however, the applicant qualifies for additional dialysis stations based on the facility need methodology. According to the January 2013 SDR, North Burlington Dialysis is one of three existing dialysis facilities in Alamance County with utilization rates ranging from 72.96 percent to 97.5 percent.

In Section V.7, page 29, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality, and access. The applicant states

“This project will have no impact on the other outpatient dialysis facilities in Alamance County.

...

Renal Treatment Centers Mid-Atlantic is not trying to compete with the other provider with the expansion of dialysis stations at North Burlington Dialysis. Our goal is to provide improved access to dialysis patients with the two-station expansion of North Burlington Dialysis.

We view this project as having no impact, positive or negative, on the cost effectiveness or quality of our services. Our costs are low and our quality superior. However, we do feel that accessibility to our services by the patients living in the service area identified will be enhanced.”

The applicant demonstrates a need for two more stations at North Burlington Dialysis Center based on the number of in-center patients currently utilizing the facility. Assuming the target utilization rate is 80 percent, with 39 in-center patients, the facility needs 12 stations to operate at 80 percent of capacity [$39 / 4 = 9.75$; $9.75 / 0.8 = 12.1875$].

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 provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include 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 based on “Facility Need”, to add two dialysis stations for a total of 12 certified dialysis stations following completion of the proposed project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to North Burlington Dialysis patients;
- The applicant will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information in Section V of the application, regarding ancillary and support services and coordination of services with the existing health care system, is reasonable and credible and demonstrates the provision of quality care; and
- The applicant will continue to provide adequate access to medically underserved populations. In Section VI.1, page 30, the applicant states “*North Burlington Dialysis, by policy, has always made dialysis services available to all residents in its service area without qualification.*” The applicant states it does not discriminate based on race, sex, age, handicap, or ethnic or socioeconomic groups of patients.

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

The applicant currently provides dialysis services as Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis in Burlington. According to the Acute and

Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

- C- In Section IV.1, page 24, the applicant provides the utilization rate as reported in the January 2013 SDR of 97.5 percent with 3.9 ($39 / 10 = 3.9$) patients per station.

.2202(a)(2) Mortality rates;

- C- In Section IV.2, page 24, the applicant reports the 2012 facility mortality rates as 10.9 percent. The facility mortality rate for 2010 and 2011 was marked N/A by the applicant.

.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 24, the applicant states that North Burlington Dialysis had a census of 20 home-trained hemodialysis patients on December 31, 2012.

- .2202(a)(4) *The number of transplants performed or referred;*
-C- In Section IV.4, page 24, the applicant states nine patients were referred for transplant evaluation in 2012 and one patient received a transplant in 2012.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
-C- In Section IV.5, page 25, the applicant states that the 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 25, the applicant reports a total of 69 hospital admissions; 8 were dialysis-related admissions and 61 were non-dialysis related admissions. *“The applicant states the majority of the dialysis related admissions were due to the inability of the patient’s vascular access to provide adequate blood flow for the dialysis treatment.”*
- .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 25, the applicant reports that as of December 31, 2012, there were two patients with AIDS. There were no patients with Hepatitis B. No patients converted to infectious status in 2012.

(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- Renal Treatment Centers Mid-Atlantic, Inc. d/b/a 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- Renal Treatment Centers Mid-Atlantic, Inc. d/b/a 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- Renal Treatment Centers Mid-Atlantic, Inc. d/b/a 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 for a copy of North Burlington Dialysis' Hemodialysis Policies, Procedures, and Guidelines for Termination of Dialysis in an Emergency, which includes written policies and procedures for back up of 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- Renal Treatment Centers Mid-Atlantic, Inc. d/b/a 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 XI.6(g), page 54, for documentation that North Burlington Dialysis' services will be provided in conformity with applicable laws and regulations.
- .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- See Section III.7, pages 21-22, for the assumptions and methodology the applicant uses to project patient origin. See also discussion in Criterion (3), which is incorporated hereby as if set forth fully herein.
- .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- Renal Treatment Centers Mid-Atlantic, Inc. d/b/a 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, page 12, the applicant states, "Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis will admit and provide dialysis services to

patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.“

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- Renal Treatment Centers Mid-Atlantic, Inc. d/b/a 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.1, page 13, the applicant projects to serve 41 in-center patients by the end of OY1, which is 3.4 patients per station ($41 / 12 = 3.4166$).

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

-C- In Section II.1, pages 14-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The applicant projects an annual increase in its current Alamance County patient utilization by applying the county five year AACR.

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 26 and Exhibit 10. The applicant states Alamance Regional Medical Center will provide diagnostic and evaluation services.

.2204(2) Maintenance dialysis;

-C- See Section V.1, page 26. The applicant states it will provide maintenance dialysis.

.2204(3) Accessible self-care training;

-C- See Section V.1, page 26. The applicant states it will provide hemodialysis self-care training.

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

-C- See Section V.1, page 27. The applicant states it provides follow-up programs for

support of patients dialyzing at home. The applicant states home-trained patients are monitored by its Quality Management team.

- .2204(5) *X-ray services;*
 - C- See Section V.1, page 26 and Exhibit 10. The applicant states Alamance Regional Medical Center will provide X-ray services.

- .2204(6) *Laboratory services;*
 - C- See Section V.1, page 26. The applicant states Dialysis Laboratories will provide laboratory services.

- .2204(7) *Blood bank services;*
 - C- See Section V.1, page 26. The applicant states Alamance Regional Medical Center will provide blood bank services.

- .2204(8) *Emergency care;*
 - C- See Section V.1, page 26. The applicant states Alamance Regional Medical Center will provide emergency care.

- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1, page 26. The applicant states 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 26. The applicant states Alamance Regional Medical Center will provide vascular surgery for dialysis treatment patient services.

- .2204(11) *Transplantation services;*
 - C- See Section V.1, page 26. The applicant states UNC Hospital will provide transplantation services.

- .2204(12) *Vocational rehabilitation counseling and services; and*
 - C- See Section V.1, page 26. The applicant states Vocational Rehabilitation will provide vocational rehabilitation counseling and services.

- .2204(13) *Transportation*
 - C- See Section V.1, page 26. The applicant states Alamance County Transportation Service will provide transportation.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).*
 - C- In Section VII, page 34, the applicant states North Burlington Dialysis will continue to comply with all staffing requirements set forth in 42 C.F.R., Part 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated

hereby as if set forth fully herein.

.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 Exhibit 17 for a copy of the applicant's training program outlines.