

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 1, 2012
PROJECT ANALYST: Gregory F. Yakaboski
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: G-8806-12/ Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington Dialysis Center/ Add 3 dialysis stations to the existing facility for a total of 20 stations / 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.

C

Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington Dialysis Center (“Burlington Dialysis Center”) currently operates a 17-station dialysis facility located at 873 Heather Road in Burlington. The Burlington Dialysis Center had been a 27-station dialysis facility however Renal Treatment Centers Mid-Atlantic, Inc submitted and was approved to develop a 10-station in-center dialysis facility known as North Burlington Dialysis in Alamance County by transferring ten dialysis stations from the Burlington Dialysis Center. The North Burlington facility was certified on December 22, 2011. Burlington Dialysis Center has an agreement with North Burlington Dialysis to provide home training in peritoneal and home hemodialysis. In this application Burlington Dialysis Center proposes to add three dialysis stations to the existing facility for a total of 20 stations upon completion of this project.

The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2012 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 Burlington Dialysis Center in the January 2012 SDR is 3.33 patients per station, or 83.33%. This utilization rate was calculated based on 90 in-center dialysis

patients and 27 certified dialysis stations as of June 30, 2011 (90 patients / 27 stations = 3.33 patients per station; 3.33 patients per station / 4.00 patients per station = 83.33%). 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
 April Review**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/11		83.3%
Certified Stations		27
Pending Stations		0
Total Existing and Pending Stations		27
In-Center Patients as of 6/30/11 (SDR2)		90
In-Center Patients as of 12/31/10 (SDR1)		77
Difference (SDR2 - SDR1)		13
Step	Description	Result
(i)	Multiply the difference by 2 for the projected net in-center change	26
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/10	0.3377
(ii)	Divide the result of step (i) by 12	0.0281
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January [2012] SDR (6/30/11) until the end of calendar year 2011 (6 months)	0.1688
(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	105.1948
(v)	Divide the result of step (iv) by 3.2 patients per station	32.8734
	and subtract the number of certified and pending stations as recorded in SDR2 [27] to determine the number of stations needed	6

[NOTE: "Rounding" to the nearest whole number is allowed only in Step 1(C) and Step 2(B)(v). Fractions of 0.5000 or greater shall be rounded to the next highest whole number.]

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." As shown in the table above, based on the facility need methodology for dialysis stations, the number of stations needed is six stations, and the applicant proposes to add three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2012 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 15-16, the applicant states:

“DaVita Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN [sic] and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. These efforts receive the full support and guidance of the clinical executive leadership team of DaVita. Combined, this group brings hundreds of years of ESRD experience to the program. The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.

Our 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).*

DaVita's Quality Management Team works closely with each facility's Quality Improvement team to:

- *Improve patient outcomes*
- *Provide patient and staff training*
- *Develop Quality Improvement Programs*
- *Facilitate the Quality Improvement Process*
- *Continuously improve care delivered*
- *Assure facilities meet high quality standards*

Our goal is to have each facility serve as a quality improvement laboratory where successful outcomes can be disseminated throughout DaVita.

Burlington Dialysis Center will be attended by Dr. Munsoor Lateef, admitting Nephrologist who directly oversees the quality of care of the dialysis facility. In addition, Dr. Lateef serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the company's Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. This Quality Assurance Program addresses the Burlington Dialysis Center as a whole, then compares each sister unit to the whole and to industry standards. The Committee then makes recommendations to improve quality. Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes."

Burlington Dialysis Center adequately demonstrates how the proposal will promote safety and quality.

Promote Equitable Access

In Section VI.1(a), page 28, the applicant states:

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

The Burlington Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility will provide dialysis six days per week with two patient shifts per day to accommodate patient need.

The 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 under-served persons.”

In Section VI.2, page 30, the applicant states

“The Burlington Dialysis Center satisfies all state requirements and local building codes to allow equal access for handicapped patients. Many of our patients are severely physically handicapped. The facility will ensure access by these individuals by providing wheelchair ramps, handicapped bathrooms, wheelchair scales and ADA compliant doors at the facility. Additionally, our teammates are trained to assist handicapped persons into and out of their dialysis treatment stations.”

In Section VI.7, page 31, the applicant states

“The Burlington Dialysis Center has an open policy and accept all patients including those with hepatitis and/or AIDS. This facility has an established isolation area for the treatment of any patient with hepatitis and will accept patients with AIDS. See Exhibit 12 for a copy of the Interpretive Guidelines, Tag Number V266 and the DaVita Hemodialysis Policies, Procedures and Guidelines referencing Hepatitis Surveillance, Vaccination and Infection Control Measures. Renal Treatment Centers Mid-Atlantic complies with all federal and state requirements pertaining to isolation of patients with communicable diseases.”

Burlington Dialysis Center adequately demonstrates how the proposal will promote equitable access to the proposed services.

Maximize Healthcare Value

In Section III.9, pages 20-21, the applicant states:

“The Burlington Dialysis Center will promote cost-effective approaches in the facility in the following ways:

- The parent corporation, DaVita, operates over 1,800 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best products at the best price.*
- The Burlington Dialysis Center will purchase all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*
- The Burlington Dialysis Center will utilize the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers will be purchased under a national contract in order to get the best quality dialyzer for*

the best price.

- *The Burlington Dialysis Center will install an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility will also be done on computer which reduces the need for paper.*
- *The Burlington Dialysis Center Bio-medical Technician assigned to the facility will conduct preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule that reduces the need for repair maintenance and parts. This will extend the life of the dialysis machines.*
- *The Burlington Dialysis Center will have an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders will be done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly.”*

The applicant adequately demonstrates how its 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. See Criteria (3) and (13c). The application is consistent with Policy GEN-3.

In addition, Policy Gen-4: *Energy Efficiency and Sustainability for Health Service Facilities* in the 2011 SMFP states, “Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.” The capital costs of this project are less than \$2 million. Therefore, Policy Gen-4 is not applicable to this review.

The application is conforming to this criterion

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

C

Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington Dialysis Center (“Burlington Dialysis Center”) currently operates a 17-station dialysis facility located at 873 Heather Road in Burlington. The Burlington Dialysis Center had been a 27-station dialysis facility

however Renal Treatment Centers Mid-Atlantic, Inc submitted and was approved to develop a 10-station in-center dialysis facility known as North Burlington Dialysis in Alamance County by transferring ten dialysis stations from the Burlington Dialysis Center. The North Burlington facility was certified on December 22, 2011. Burlington Dialysis Center has an agreement with North Burlington Dialysis to provide home training in peritoneal and home hemodialysis. In this application Burlington Dialysis Center proposes to add three dialysis stations to the existing facility for a total of 20 stations upon completion of this project.

Population to be Served

In Section III.7, page 19, the applicant provides projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

Burlington Dialysis Center -Projected Patient Origin

COUNTY	YEAR ONE: 2013		YEAR TWO: 2014		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
Alamance	60	0	64	0	93.7%	94.1%
Guilford	3	0	3	0	4.7%	4.4%
Caswell	1	0	1	0	1.6%	1.5%
TOTAL	64	0	68	0	100%	100%

The applicant adequately identified the population proposed to be served.

Need Analysis

The assumptions and methodology used to project in-center utilization are provided in Section II, pages 11-13, and Section III.7, pages 18-20. On pages 19-20 the applicant states

“The Burlington Dialysis Center had 90 in-center patients as of June 30, 2011 based on the January 2012 Semiannual Dialysis Report on page 10. This is a station utilization rate of 83% based on the 27 certified stations in the facility. Of the 90 in-center patients cited in the SDR, 86 of the patients live in Alamance County.

On July 15, 2010 Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis submitted a Certificate of Need application to develop a 10-station in-center dialysis facility in Alamance County by transferring ten dialysis stations and thirty-two in-center patients from the Burlington Dialysis Center. That Certificate of Need was approved. The North Burlington facility was certified as of December 22, 2011 and the thirty-two in-center patients have transferred to North Burlington Dialysis. The home training in peritoneal dialysis program and patients have also transferred to North Burlington Dialysis. We are applying for a 3-station expansion of the Burlington Dialysis Center.

This leaves the Burlington facility with 58 in-center patients and 17 dialysis stations. Based on these numbers, Burlington Dialysis Center is projected to have at least 64 in-center patients by the end of operating year 1 for a utilization rate of 80% or 3.2 patients per station and at least 68 in-center patients by the end of operating year 2 for a utilization rate of 85% or 3.4 patients per station. This information is based on the calculations below. We have used a growth rate of 6.1% for the 54 in-center patients who live in Alamance County.

The period of the growth begins with January 1, 2012 forward to December 31, 2014. The following are the in-center patient projections using the 6.1% Average Annual Change Rate for the Past Five Years as indicated on page 19 of the January 2012 Semiannual Dialysis Report for the 86 in-center patients residing in Alamance County.

January 1, 2012-December 31, 2012—54 patients X 1.061 = 57.294

January 1, 2013-December 31, 2013 —57.294 patients X 1.061 = 60.788934

January 1, 2014-December 31, 2014— 60.788934 patients X 1.061 = 64.49705897

Operating Year One is projected to begin January 1, 2013 and end on December 31, 2013

Operating Year Two is projected to begin January 1, 2014 and end on December 31, 2014

The number of patients stated in the chart above was rounded down to the nearest whole number.

We did not provide a growth rate for the three patients living in Guilford County and the one patient living in Caswell County. Therefore, the Burlington Dialysis Center is projected to have 64 in-center patients at the end of operating year one (60 Alamance County patients and 3 Guilford County patients and one Caswell County patient = 64 patients). The facility is projected to have 68 in-center patients at the end of operating year two (64 Alamance County patients and 3 Guilford County patients and one Caswell County patient = 68 patients).

NOTE: The patient numbers for operating year 1 and 2 will be used to determine the number of treatments, operating revenue and operating expenses in Section X of this application.”

The applicant projects the facility will serve 64 in-center patients or 3.2 in-center patients per station per week ($64/20 = 3.2$) by the end of Year One, which exceeds the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions. Therefore, the applicant adequately demonstrates the need for the proposed stations.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for three additional dialysis stations. 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, pages 20-21, the applicant describes the alternatives considered prior to the submission of its application, which were to either maintain the status quo or increase the number of dialysis stations at the facility. The application is conforming or conditionally conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (12), (13), (14), (18a), (20) and the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Consequently, the application is conforming to this criterion subject to the following conditions:

- 1) **Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington Dialysis Center shall materially comply with all representations made in its certificate of need application.**
- 2) **Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington Dialysis Center shall develop and operate no more than three additional dialysis stations for a total of 20 certified stations which shall include any home hemodialysis training and isolation stations.**
- 3) **Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington Dialysis Center shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
- 4) **Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington Dialysis Center 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.1, pages 36-37, the applicant states the capital cost is projected to be \$41,387. In Section IX, page 41, the applicant states that no working capital will be needed.

In Section VIII, page 38, the applicant states it will fund the capital needs of the proposed project from the cash reserves of DaVita Inc., the parent company of Renal Treatment Centers Mid-Atlantic, Inc. Exhibit 15 contains a letter, dated March 12, 2012, from the Chief Accounting Officer of DaVita, Inc. which states:

“I am the Chief Accounting Officer of DaVita, Inc., the parent and 100% owner of Renal Treatment Centers Mid-Atlantic, Inc.

We are submitting a Certificate of Need Application to expand our Burlington Dialysis Center ESRD facility by three dialysis stations. The project calls for a capital expenditure of \$41,387. This letter will confirm that DaVita, Inc. has committed cash reserves in the total sum of \$41,387 for the project capital expenditure. DaVita 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 16, the applicant provides audited financial statements for DaVita, Inc. which document that DaVita, Inc. had \$393,752,000 in cash and cash equivalents as of December 31, 2011. The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

In Section X, pages 43-47, the applicant projects revenues will exceed expenses in the first three years of operation after completion of the project. The rates in Section X.1, page 43, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services. The applicant adequately demonstrates that projected revenues and expenses are based on reasonable and supported assumptions.

Therefore, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Consequently, 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.

C

Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington Dialysis Center proposed to add 3 dialysis stations to an existing 17 station dialysis facility. The facility is currently projected to serve 58 in-center patients factoring in the 32 in-center patients transferring to the North Burlington facility. Based on the Alamance County's Average Annual Change Rate for the past five years the facility is projected to have 64 in-center patients at the end of project Year One. With no increase in dialysis stations projected utilization would be 3.76 patients per week per station ($64/17 = 3.76$). Projected utilization would be 4.0 patients per week per station ($64/17 = 4.0$) if just four additional patients came to the facility and there was no increase in the number of dialysis stations. Projected growth is reasonable as it based on the Average Annual Change Rate for the past five years The facility need methodology indicates that six additional stations are needed. The applicant adequately demonstrates the need to add three dialysis stations to the existing facility for a total of 20 stations upon completion of this project. The applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing services and 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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The following table illustrates current and projected staffing for Burlington Dialysis Center, as provided by the applicant in Section VII.1, page 34:

POSITION	CURRENT FTEs	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
RN	3	0	3
PCT	8	0	8
Bio-Med Tech	.5	0	.5
MD			
Admin	1	0	1
Dietician	.5	0	.5
Social Worker	.5	0	.5
Unit Secretary	1	0	1
Reuse	1	0	1
Total	15.5	0	15.5

As shown in the above table, the applicant proposes to employ a total of 15.5 full-time equivalent (FTE) positions to staff the Burlington Dialysis Center upon completion of the proposed project. The applicant does not project adding any FTE staff as a result of the proposed project. In Section V.4, page 26, the applicant states that Dr. Munsoor Lateef serves as the medical director of the facility. Exhibit 10 contains a letter signed by Dr. Lateef, which states that he is the medical director for the Burlington Dialysis Center and

supports the proposed project. In Section VII.2, page 33, the applicant states Dr. Lateef is a Board-Certified in Nephrology.

The applicant has documented the availability of adequate health manpower and management personnel, including the medical director, for the provision of 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.1-2, pages 24-26, the applicant lists the providers of the necessary ancillary and support services. The information provided in Section V is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

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

NA

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

services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

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In Section VI.1(b), page 28, the applicant reports that 79.7% of the patients who received treatments at Burlington Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source of the facility:

DIALYSIS CARE OF HOKE COUNTY	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	28.3%
Medicaid	6.8%
Medicare/Medicaid	23.0%
Commercial Insurance	8.1%
VA	12.2%
Medicare/Commercial	21.6%
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 as of June 2010 and CY2008-CY 2009, respectively. The data in the table were obtained on May 17, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligible as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Alamance	16%	6.2%	21.0%

Statewide	17%	6.7%	19.7%
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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 Burlington Dialysis Center.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

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 applicants' 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.

The applicant demonstrates that medically underserved populations currently have adequate access to the dialysis services provided at Burlington Dialysis Center. 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.6 (a), page 31, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 29, 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. 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.

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In Section VI.5, pages 30-31, 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.

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In Section V.3(c), page 26, the applicant states that it has an existing agreement with Central Carolina Community College. Exhibit 9 contains a copy of the agreement which provides for the applicant to “*accept faculty and dialysis students for clinical practice and learning experiences.*” The information provided in Section V.3 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.

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See Sections II, III, V, VI and VII. In particular, see Section V.7, page 27, in which Burlington Dialysis Center discusses the impact of the proposed project on competition in the service area as it relates to promoting 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 include a positive impact on cost-effectiveness, quality and access to dialysis services in Alamance County. This determination is based on the information in the application, and the following:

- ◆ The applicant adequately demonstrates the need to develop three additional dialysis stations at Burlington Dialysis Center and that it is a cost-effective alternative;
- ◆ The applicant has and will continue to provide quality services; and
- ◆ The applicant has and will continue to provide adequate access to medically underserved populations.

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 Burlington Dialysis Center in Burlington, NC. 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- See Section IV.1, page 22, and Exhibit 7 (copy of the January 2012 SDR).

.2202(a)(2) Mortality rates;

-C- In Section IV.2, page 22, the applicant reports the 2009, 2010, and 2011 facility mortality rates.

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

-NA- In Section IV.3, page 22, the applicant states “*The Burlington Dialysis Center does not serve home-trained patients since North Burlington Dialysis was certified.*”

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

-C- In Section IV.4, page 23, the applicant states that 21 patients were referred for transplant evaluation and that 2 patients received at transplant in 2011.

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

-C- In Section IV.5, page 23, the applicant states there are 13 patients on the transplant waiting list.

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

-C- See Section IV.6, page 23.

.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 23.

(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

- NA- Burlington Dialysis Center 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- Burlington Dialysis Center 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- Burlington Dialysis Center 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- Exhibit 8 contains a copy of written policies and procedures for back up 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- Burlington Dialysis Center 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 32 and, XI.6(e) and (g), page 52.
.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.3, pages 18-20.
.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- Burlington Dialysis Center 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 11, the applicant states, “Renal Treatment Centers Mid-Atlantic, Inc. d/b/a 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- Burlington Dialysis Center 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 III.7, page 20, the applicant projects to serve 64 in-center patients by the end of Year 1, which is 3.2 patients per station ($64 / 20 = 3.2$).
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II, pages 12-13 and Section III.7, pages 18-20, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

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 24.
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1, page 24.
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1, page 24 and Section IV.3, page 22.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.1, page 24.
- .2204(5) *X-ray services;*
 - C- See Section V.1, page 24.
- .2204(6) *Laboratory services;*
 - C- See Section V.1, page 24.
- .2204(7) *Blood bank services;*
 - C- See Section V.1, page 24.
- .2204(8) *Emergency care;*
 - C- See Section V.1, page 24.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1, page 24.
- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- See Section V.1, page 24.
- .2204(11) *Transplantation services;*
 - C- See Section V.1, page 24.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
 - C- See Section V.1, page 24.
- .2204(13) *Transportation*
 - C- See Section V.1, page 24.

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.*
 - C- In Section VII.1, page 32, the applicant provides the proposed staffing. In Section VII.2, pages 32-33, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.
- .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 34, and Exhibits 14, 20 and 21.