

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: January 30, 2013
PROJECT ANALYST: Bernetta Thorne-Williams
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: B-10053-12 / Total Renal Care of North Carolina, LLC d/b/a Biltmore Center / Develop a kidney disease treatment center to serve as a peritoneal dialysis home training facility / Buncombe 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.

NA

Total Renal Care of North Carolina, LLC (TRC) d/b/a Biltmore Center (BC), whose parent company is DaVita, Inc proposes to develop a kidney disease treatment center by establishing a freestanding facility for peritoneal dialysis (PD) home training program. Total Renal Care of North Carolina, LLC currently owns and operates Asheville Kidney Center (AKC) which operates 50 certified dialysis stations and the peritoneal dialysis home training program in Asheville, Buncombe County.

Neither the 2012 State Medical Facilities Plan (SMFP) nor the July 2012 Semiannual Dialysis Report (SDR) provides a need methodology for determining the need for PD home training programs. There are no policies in the SMFP applicable to this proposal. Therefore, this criterion is not applicable to this application.

- (2) Repealed effective July 1, 1987.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

Total Renal Care of North Carolina, LLC d/b/a Biltmore Center, whose parent company is DaVita, Inc, proposes to develop a kidney disease treatment center by establishing a freestanding facility for peritoneal dialysis home training program. Total Renal Care of North Carolina, LLC currently owns and operates Asheville Kidney Center which operates 50 certified dialysis stations and the peritoneal dialysis home training program in Asheville, Buncombe County. The applicant, Total Renal Care of North Carolina, LLC d/b/a Biltmore Center proposes to lease space for the proposed PD home training program in a medical building in which Mountain Kidney Associates operates its medical practice. The proposed site is located on property adjacent to Mission Hospital, located at 10 McDowell Street in Asheville. Biltmore Center does not propose to include any certified hemodialysis stations in the new facility.

Population to be served

In Section IV.1, page 27, the applicant identifies the PD home training population currently served by Asheville Kidney Center, as of December 31, 2011, as illustrated in the table below:

COUNTY	CURRENT	
	AKC HOME TRAINING PATIENTS	AKC PD HOME TRAINING PATIENTS % OF TOTAL*
Buncombe	25	44.6%
Transylvania	8	14.3%
Haywood	3	5.4%
Henderson	14	25.0%
Madison	1	1.8%
McDowell	5	8.9%
Total	56	100.0%

* Calculated by Project Analyst. percentages may not foot due to rounding.

In Section III.7, pages 23-25, the applicant provides the projected population for Biltmore Center in Year 1 and Year 2. The applicant assumes an 11% increase in its PD home training population, as discussed below.

- *“The project is scheduled for completion and certification on January 1, 2014. Operating year will be January 1, 2014-December 31, 2014. Operating year two will be January 1, 2014 [sic - 2015] –December 31, 2015.*
- *The Asheville Kidney Center currently provides home peritoneal training and support services for patients in the following counties: Buncombe, Haywood, Transylvania, Henderson, Polk, Madison, McDowell and Rutherford Counties.*
- *The Asheville Kidney Center PD program has grown by an average of 11% per year over the past three years.*
- *TRC assumes that the Biltmore PD program will grow at a rate of 11% each year during the first two years of operation.*

Based on the applicant’s projections, the proposed PD training program at Biltmore Center is projected to have 76 patients at the end of operating year one and 85 patients at the end of operating year two.

In Section VI.1(b), page 34, the applicant states the historical payor mix for patients receiving Medicare and Medicaid was 83.4%. The applicant does not expect any changes to its current payor mix as a result of the proposed project.

In Section VI.1(a), page 34, the applicant states how the residents of the service area will have access to the proposed services, including those residents that are low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. The applicant states:

“Biltmore Center, by policy, will make peritoneal dialysis services available to all residents in the service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”

The applicant adequately identified the population it proposes to serve.

Need Analysis

In Section III.7, pages 23-25 the applicant provides the projected utilization for the proposed freestanding PD training facility. The applicant states:

“TRC is proposing to develop a free standing home peritoneal dialysis training facility to be located at 10 McDowell Street in Asheville. The building also houses the Mountain Kidney Associates offices.

The Asheville Kidney Center is the current location for the home training for peritoneal dialysis in Buncombe County. ... This location [10 McDowell Street] is the former site of the Asheville Kidney Center.

... The home patient population in Buncombe and surrounding counties continues to increase. The Asheville Kidney Center is a 50-station facility that offers home hemodialysis training and support services as well as home training in peritoneal dialysis and support. These two modalities are located in the same wing of the Asheville Kidney Center. With both the home hemodialysis and the peritoneal dialysis modalities experiencing a rapid growth in patient population, the facility has run out of room. The relocation of the home peritoneal dialysis program will resolve the physical space issues at the Asheville Kidney Center.

...

We have calculated the number of patients that the Biltmore Center proposes to serve at the end of operating year 1 and operating year 2 after the relocation of the peritoneal dialysis training and support program that is currently located at the Asheville Kidney Center.

...

Utilization Projection: TRC is using an annual change rate of 11% which is the experience the peritoneal dialysis home training and support program has averaged over the past three years. The program had 56 peritoneal dialysis patients at the end of December 2011.

January 1, 2012-December 31, 2012- 56 PD patients X 1.11 = 62.16

January 1, 2013-December 31, 2013- 62.16 in-center patients X 1.11 = 68.9976

January 1, 2014-December 31, 2014- 68.9976 in-center patients X 1.11 = 76.587336

January 1, 2015-December 31, 2015- 76.587336 in-center patients X 1.11 = 85.01194296

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

Operating Year 1 [sic - 2] is projected to begin January 1, 2015 and end December 31, 2015

Based on the information above the Biltmore Center will have 76 PD patients at the end of operating year one and 8 [sic - 85] PD patients at the end of operating year two.”

Projected utilization is based on reasonable and supported assumptions regarding continued growth. The applicant also adequately demonstrates the need for the proposed freestanding facility for peritoneal dialysis home training and support program.

In summary, the applicant adequately identified the population to be served and demonstrated the need the population has for the freestanding facility for peritoneal dialysis home training program. 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.

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In this application, the applicant proposes to relocate its existing PD home training program from the Asheville Kidney Center to a new facility, Biltmore Center. In Section III.6, page 23, the applicant states:

“To the extent that this is a reduction of services at the Asheville Kidney Center, TRC has demonstrated that this relocation will not adversely affect the Asheville Kidney Center or the home hemodialysis patients.

The applicant states that the relocation is necessary to prevent congestion at its current location and to better meet the growing needs of its peritoneal dialysis patients. In Section III.3(a), page 22, the applicant states:

“TRC is proposing to develop a new free standing home training facility exclusively for peritoneal dialysis training and support. TRC does not [sic] that the home patient population at the Asheville Kidney Center is rapidly increasing. The Asheville Kidney Center cannot be physically expanded. Relocation of the peritoneal dialysis training and support program to a new facility will allow the home hemodialysis training and support program to continue to expand. Failure to relocate the home peritoneal dialysis program will lead to patient congestion during training days and especially on clinic days. During home clinic days the home patients are scheduled for their monthly or bi-weekly visits to the facility for physician and nursing assessment of dialysis adequacy, lab draws, any prescription changes with the clinical team.”

According to maps.google.com, the distance from Asheville Kidney Center, located at 1600 Centre Park Drive to the proposed PD home training site at 10 McDowell Street is 3 miles, about 11 minutes. This relocation will not affect access by the medically underserved.

Although the PD home training service is being relocated, the applicant demonstrates that the needs of the population presently served at Asheville Kidney Center will continue to be adequately met after the project is completed. Therefore, the application is conforming with this criterion.

- (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 25, the applicant describes the two alternatives considered which include the following:

- 1) Continuing at its current site – the applicant concluded that continuing to provide home peritoneal dialysis at the Asheville Kidney Center, which has increased at an average of 11% over the past three years, would not address the congestion concerns currently facing the facility.
- 2) Relocation of the peritoneal dialysis program – the applicant concluded that the relocation of the peritoneal dialysis training and support program from the Asheville Kidney Center was the most efficient method of meeting the needs of the ESRD patient population.

The applicant concluded that option number 2, relocation of the PD training and support program was its most effective and least costly alternative. The applicant states, *“it will allow the Asheville Kidney Center to utilize the existing home training space exclusively for home hemodialysis. Providing home hemodialysis training and support at the Asheville Center will be more convenient for all involved and allow the facility and teammates to focus on the home hemodialysis program. The program is also experiencing a rapid growth and needs the space for expansion of the program.”*

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative. The application is conforming to all other applicable statutory and regulatory review criteria. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Total Renal Care of North Carolina, LLC d/b/a Biltmore Center shall materially comply with all representations made in the certificate of need application.**
 2. **Total Renal Care of North Carolina, LLC d/b/a Biltmore Center shall establish a freestanding home dialysis training and support program exclusively for peritoneal dialysis patients, with no hemodialysis stations.**
 3. **Prior to the insurance of the Certificate of Need, Total Renal Care of North Carolina, LLC d/b/a Biltmore Center shall provide documentation of the acute care facility in which the Biltmore Center intends to enter into a transfer agreement with.**
 4. **Total Renal Care of North Carolina, LLC d/b/a Biltmore Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the 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, page 43, the applicant states that the proposed capital cost of the project is \$953,919, including \$732,500 for construction contract costs, \$129,724 for equipment and furniture costs, \$57,000 for architect/engineering costs, \$21,550 for other costs (dialysis chairs), and \$13,145 for televisions costs. In Section IX.1, page 47, the applicant states there will be no start-up expenses associated with the proposed project. On page 47, the applicant states the applicant projects an initial operating expense of \$847,438. The initial operating expenses are projected to cover the first four months of operation of the Biltmore Center including the “*up-fit of the facility*”. In Section VIII.2, page 44 and Section IX, page 48, the applicant states that the project will be funded by the cash reserves of DaVita, Inc, the parent company of Total Renal Care of North Carolina, LLC. Exhibit 21 of the application contains the audited financial statements for DaVita, Inc., the parent company of Total Renal Care, Inc and Total Renal Care of North Carolina, Inc for the years ending December 31, 2011 and December 31, 2010. As of December 31, 2011, DaVita had \$393,752 in cash and cash equivalents. Exhibit 20 contains a letter dated September 10, 2012 from the Chief Accounting Officer of DaVita, Inc. The letter states in part:

“I am the Chief Accounting Officer of DaVita, Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care, Inc. which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC (“TRC”).

We are submitting a Certificate of Need application to develop a standalone peritoneal dialysis End Stage Renal Disease dialysis facility in Asheville in Buncombe County. The project calls for a capital expenditure of \$953,919 and a working capital of \$847,438.

DaVita and Total Renal Care of North Carolina, LLC have committed cash reserves in the amount of \$1,801,357 for this project. We will ensure that these funds are made available for the development and operation of this project. ...”

The applicant adequately demonstrated the availability of sufficient funds for the capital and initial operating expense needs of the proposed project.

In Section X.3, page 50, the applicant states:

“For each source of revenue the assumption used was ... total # of treatments times 5% for missed treatments times payor percentage times payor reimbursement rate for the projected in-center treatments. ...”

In Section X.3, page 50, the applicant provides the projected rates and payor mix for the proposed freestanding PD facility, as shown in the tables below.

PD home training	Patient payment % by Source of Revenue	# Treatments	Reimbursement per Treatment
Revenue Source Year 1			
Medicare	20.4%	2,177	\$192.00
Medicare/Medicaid	20.4%	2,177	\$240.00
Commercial	11.1%	1,184	\$800.29
VA	5.5%	587	\$240.00
Medicare/ Commercial	42.6%	4,545	\$240.00
Revenue Source Year 2			
Medicare	20.4%	2,434	\$192.00
Medicare/Medicaid	20.4%	2,434	\$240.00
Commercial	11.1%	1,324	\$800.29
VA	5.5%	656	\$240.00
Medicare/ Commercial	42.6%	5,082	\$240.00

This information is consistent with the payor mix reported by the applicant in Section VI.1(c), page 35 of the application: Additionally, the rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

In Sections X.2-X.4, pages 49-51, the applicant reports projected revenues and expenses, as illustrated in the table below:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$3,149,344	\$3,487,808
Total Operating Costs	\$2,485,303	\$2,774,248
Net Profit	\$664,041	\$713,560

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming with this criterion.

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

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According to the July 2012 North Carolina Semiannual Dialysis Report, Asheville Kidney Center in Asheville is one of three providers of End Stage Renal Disease in Buncombe County and the only provider of those services in Asheville. The other two ESRD facilities in Buncombe County are also operated by Total Renal Care of North Carolina, LLC. Those facilities are, Swannanoa Dialysis Center and Weaverville Dialysis, which according to Google Maps are located 9.3 miles and 9.6 miles, respectively from Asheville Kidney Center. In this application, Total Renal Care of North Carolina, LLC proposes to relocate its existing PD home dialysis training and support services currently operating at the Asheville Kidney Center. See Criterion (3) for the discussion regarding the need to relocate the existing PD home dialysis training and support services which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates the relocation of the existing PD home dialysis training and support services at Asheville Kidney Center will not result in the unnecessary duplication of existing or approved peritoneal dialysis services. Consequently, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

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In Section VII.1, pages 39, the applicant provides the proposed staffing during the first two operating years following completion of the project, as illustrated in the table below.

POSITION	PROJECTED FULL TIME EQUIVALENT POSITIONS (FTES) YEARS 1 AND 2
PD HTRN	6.0
Bio-Med Tech	0.2
Admin.	.75
Dietitian	.60
Social Worker	.60
Unit Secretary	1.0
Total	9.15

As shown in the above table, the applicant proposes to employ a total of 9.15 FTE positions to staff the PD home training facility during the first two operating years following completion of the project. The current staffing for the PD home training and support services at Asheville Kidney Center totals 6.55 FTEs, the proposed project includes the addition of 2 PD HRTN FTEs and the addition of .3 FTEs in its dietitian and social worker departments. In Section VII, page 39, the applicant states, “*The current teammates who provide the training and support for the peritoneal dialysis program will transfer to the relocated site.*” In Section V.4(c), page 31, the applicant states that Dr. Bryson Fleming, the Medical Director for Asheville Kidney Center, has agreed to serve as the Medical Director for the Biltmore Center. See Exhibit 14 for a letter dated September 14, 2012, from Dr. Fleming, expressing his willingness to serve as the Medical Director for Biltmore Center. In Section VII.10, page 41, the applicant states that the Biltmore Center will operate Monday-Friday, from 7 am to 5 pm with a qualified home training registered nurse on call 24 hours a day / 7 days a week.

The applicant adequately demonstrates the availability of adequate health manpower and management personnel, including a medical director, for the provision of PD home training and support services. Therefore, the application is conforming with 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.

CA

In Section V.1, pages 29-30, the applicant provides a list of providers of the necessary ancillary and support services. Exhibit 8 contains a copy of the transplant agreement with Carolinas Medical Center. Exhibit 7 contains an intent letter to provide transfer services, however, the letter failed to state the acute care facility in which the Biltmore Center will have a transfer agreement with to provide the following services:

- Acute Dialysis
- Emergency Room Care;
- Diagnostic Evaluation;
- X-ray Services;
- Special Immunological and Routine Laboratory Services; and
- Surgical Services including Vascular Surgery

In Sections II.2, pages 18-19, the applicant further states that Biltmore Center will provide the following services: (1) social services, (2) dietary services, (3) patient education, (4) emergency care, (5) diagnostic services, (6) pharmaceutical support, (7) home training assessment and, (8) transplant evaluation.

The information regarding coordination of services in Section V, pages 29-30 of the application and referenced exhibits are reasonable and credible and support a finding of conformity with this criterion subject to Condition # 3 in Criterion 4.

The applicant adequately demonstrates that the necessary ancillary and support services will be provided and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion subject to the condition. See Criterion 4 and 10A NCAC 14C .2202(b)(1) in these findings for conditions.

- (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

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;

C

In Section VI.1(b), page 34, the applicant reports that 83.4% of the patients who received treatments at Asheville Kidney Center had some or all of their services paid by Medicare or Medicaid in the past year. The table below illustrates the historical payment source of the facility:

SOURCE OF PAYMENT	AS A PERCENT OF TOTAL
Medicare	20.4%
Medicare/Medicaid	20.4%
Commercial Insurance	11.1%
VA	5.5%
Other	
Medicare Commercial	42.6%

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 Buncombe County and statewide.

	CY 2009 Total # of Medicaid Eligibles as % of Total Population *	CY 2009 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	CY 2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Buncombe County	36%	16.1%	18.3%
Statewide	17%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by the Asheville Kidney Center facility. In fact, only 5.8% of all 2011 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 and 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 Centers for Medicare & Medicaid Services (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.”^[1]

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010:

“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”¹

The report validates the statistical constancy reported by CMS above. 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%

¹ (www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf)

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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 demonstrating the following:

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6. Includes North Carolina, South Carolina and Georgia

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

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

In Section VI.1(f), page 35, the applicant states:

“Biltmore Center will have no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.”

In Section VI.6 (a), page 37, 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

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In Section VI.1(c), page 35, the applicant provides the projected payor mix for the proposed services at Biltmore Center. The applicant projects no change from the current payor mix for dialysis visits as stated in Criterion (13a) and illustrated in the table below.

BILTMORE CENTER PROJECTED PAYOR MIX	
SOURCE OF PAYMENT	AS A PERCENT OF TOTAL
Medicare	20.4%
Medicare/Medicaid	20.4%
Commercial Insurance	11.1%
VA	5.5%
Other	
Medicare Commercial	42.6%

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

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

C

In Section VI.5(a), page 36, the applicant states:

*“Patients with End Stage Renal Disease will have access to peritoneal dialysis services upon referral to a Nephrologist with privileges at Biltmore Center. These referrals will come from primary care physicians or specialty physicians in the [sic] Buncombe County or other counties in the area or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends may obtain access by contacting a Nephrologist with privileges at Biltmore Center. Should a patient contact Biltmore Center either directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside Biltmore Center service area requesting transfer to this facility will be processed in accordance with the facility transient policies that comprise **Exhibit 16** [emphasis in original] ...”*

The applicant adequately demonstrated it offers a range of means by which patients will have access to the proposed services. Therefore, the application is conforming 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

In Section V.3, page 31, the applicant states:

“Biltmore Center will employ registered nurses, a social worker and dietician. The local community colleges are engaged in the training of nursing students and Certified Nursing Assistant students. Biltmore Center will be offered as a clinical learning site for nursing and CNA students at area high schools, community college and four-year universities.”

Further on page 31, the applicant states, *“The Asheville Kidney Center has had long-term agreements with Asheville-Buncombe Technical Community College and Western Carolina University for health professional students. These programs and students will have access to the Biltmore Center.”*

See Exhibit 13 for a letter dated September 10, 2012 to the President of Asheville-Buncombe Technical Community College offering the use of the Biltmore Center as a clinical training site.

The information provided in Sections V.3, page 31, and Exhibit 13 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, Total Renal Care of North Carolina, LLC currently provides PD home training and support at its Asheville Kidney Center in Asheville, Buncombe County. In fact, Total Renal Care of North Carolina, LLC, is the only provider of end stage renal disease services in Buncombe County. The Asheville Kidney Center is the only provider of end stage renal disease treatment in Asheville. In this application, the applicant proposes to establish a freestanding PD home training and support facility to better accommodate the growing need for home dialysis training. Biltmore Center adequately demonstrates it will foster competition by promoting cost effectiveness, quality, and access to services in the proposed service area. See Sections II, III, VI and VII of the application for additional discussion by the applicant about the impact of its proposal on cost effectiveness, quality and access to PD home training and support services.

The applicant adequately demonstrates that its proposal would enhance competition by promoting cost effectiveness, quality and access to the proposed services based on the information in the application and the following analysis:

- 1) Projected utilization of the PD home training patients is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding historical and projected utilization which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges. See the Criterion (5) for discussion regarding financial feasibility which is incorporated hereby as if fully set forth herein. Therefore, the applicant adequately demonstrates the cost effectiveness of its proposal.
- 2) The applicant projects to provide adequate access to medically underserved groups, including VA / commercial patients, Medicare / Medicaid and Medicare and Medicaid recipients. See Section VI of the application and Criterion (13c) for discussion regarding projected access by these groups which is incorporated hereby as if fully set forth herein.

- 3) The applicant adequately documents that it will provide quality care. See Sections II and VII of the application.

Therefore, the applicant adequately demonstrates that its proposal 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 at two other Total Renal Care of North Carolina, LLC facilities in Buncombe County, in addition to the services provided at the Asheville Kidney Center. Those facilities are Swannanoa Dialysis Center, located in Swannanoa and Weaverville Dialysis, located in Weaverville. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, these facilities 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 with this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183(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.

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, as conditioned, and required by 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANTS

(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;*
- .2202(a)(2) *Mortality rates;*
- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*
- .2202(a)(4) *The number of transplants performed or referred;*
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- .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.*

-NA- The applicant does not propose to develop a facility with hemodialysis stations.

(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*

-CA- Exhibit 7 contains a proposed letter of intent, however the applicant did not specify which acute care hospital the Biltmore Center plans to enter into a transfer agreement with. Therefore, the applicant is conforming with this rule subject to the following condition.

Prior to the insurance of the Certificate of Need, Total Renal Care of North Carolina, LLC d/b/a Biltmore Center shall document the acute care facility in which the Biltmore Center intends to enter into a transfer agreement with.

- .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.*
- C- Exhibit 8 contains a written letter dated September 10, 2012 which outlines the details of a proposed transplantation agreement between the Biltmore Center and Carolinas Medical Center.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- Exhibits 9 and 10 contain documentation that power and water will be available at the proposed facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- In Section II.1, page 11, the applicant states that Asheville Kidney Center and Weaverville Dialysis Center will serve as back-up facilities in the event of a power outage. Also see Exhibit 10 for a copy of segments of DaVita's Emergency Disaster 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.*
- C- In Section XI., page 53, the applicant states the Asheville Kidney Center operated at the proposed location for several years. On page 54, the applicant states, "*The owner [Trimedco] has indicated verbally that the site is available for lease.*" See Exhibit 11 for a copy of a letter stating the intent to locate the Biltmore Center at the property located at 10 McDowell Street, in Asheville and Exhibit 23 for a standard copy of a lease agreement.

- .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- In Sections II.1, page 12 and XI.6(g), pages 57-58 the applicant states that services will be provided in conformity with applicable laws and regulations. See Exhibit 12 for a copy of the facility's Health and Safety Policy.
- .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 II.1, pages 12-14.
- .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.*
- C- In Section II.1, page 14 the applicant provides documentation that at least 80 percent of the projected patient population resides within 30 miles of the proposed PD home training and support 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 24, the applicant states the Biltmore Center will provide PD home training and support 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.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

- NA- The applicant does not propose to establish any dialysis stations.

.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.*

-NA- The applicant does not propose to establish any dialysis stations.

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

-C- In Sections II.1, pages 15-16 and III.7, pages 23-25, the applicant provides the assumptions and methodology used to project utilization of the proposed PD home training facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicants must demonstrate that the following services will be available:

.2204(1) *Diagnostic and evaluation services;*

-C- In Section V.1(e), page 29, the applicant states that diagnostic and evaluation services will be provided by Mission Hospitals.

.2204(2) *Maintenance dialysis;*

-C- In Section V.1(c), page 29, the applicant states that dialysis maintenance will be provided by Asheville Kidney Center.

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

-C- See Section V.1(d), page 29, the applicant states that accessible self-care training will be provide by the applicant at Biltmore Center.

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

-C- See Section V.2(d), page 29. Accessible follow-up and support of patients dialyzing at home will be provided at the Biltmore Center.

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

-C- In Section V.1(g), page 29, the applicant states that x-ray services will be provided at Mission Hospitals.

.2204(6) *Laboratory services;*

- C- In Section V.1(h), page 29, the applicant states that laboratory services will be provided by Dialysis Laboratories. However, in Exhibit 7, the applicant indicates that laboratory services will be provided by the hospital. The applicant provides a generic letter from an unnamed hospital stating it will provide laboratory services. See Condition 3 in Criterion 4.

.2204(7) *Blood bank services;*

- C- In Section V.1(i), page 29, the applicant states blood bank services will be provided by Mission Hospitals.

.2204(8) *Emergency care;*

- C- In Section V.1(b), page 29, the applicant states emergency care will be provided by Mission Hospitals.

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

- C- In Section V.1(a), page 29, the applicant states acute dialysis care will be provided at Mission Hospitals.

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

- C- In Section V.1(p), page 29, the applicant states vascular surgery will be provided at Mission Hospitals.

.2204(11) *Transplantation services;*

- C- See Section V.1(f), page 29. In Exhibit 8, the applicant provides a letter for the Assistant Vice President of Carolinas Medical Center (CMC) which states CMC will enter into a transplant agreement with the proposed Biltmore Center facility.

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

- C- In Section V.1(o), page 29, the applicant states that vocational rehabilitation counseling and services will be provided by N.C. Department of Vocational Rehabilitation.

.2204(13) *Transportation*

- C- In Section V.1(q), page 30, the applicant states that transportation will be provided by DSS and various private providers.

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 Sections VII.2, pages 39-40, the applicant provides the proposed staffing. The applicant states on page 39 that the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 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 40 and Exhibit 19.