

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 18, 2012

FINDINGS DATE: December 18, 2012

PROJECT ANALYST: Gloria C. Hale

CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: G-10028-12/ Triad Dialysis Center of Wake Forest University d/b/a Triad Dialysis Center/ Temporarily relocate 18 stations from High Point Kidney Center during renovation of High Point Kidney Center / Guilford County
FID # 980262

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

The applicant, Wake Forest University Health Sciences d/b/a Triad Dialysis Center of Wake Forest University, proposes to temporarily add 18 stations through an in-county transfer of stations from High Point Kidney Center (HPKC) in order to serve HPKC patients while HPKC is undergoing renovation. The 18 stations shall be returned to HPKC upon completion of the HPKC project which is concurrently under CON review [Project ID# G-10029-12]. Both Triad Dialysis Center (TDC) and HPKC are located in Guilford County. The applicant does not propose to establish new dialysis stations nor move stations from HPKC to contiguous counties. There will be no increase in the number of stations at TDC upon project completion. Therefore, neither of the need methodologies in the 2012 State Medical Facilities Plan are applicable to the review.

The North Carolina Semiannual Dialysis Report (SDR) July 2012, Table A, indicates that TDC is operating at 2.82 patients per station with a utilization rate of 70.45%. TDC has 22 certified dialysis stations. TDC's application proposes to temporarily add 18 stations from HPKC while HPKC is undergoing renovation. This would give them a total of 40 stations.

POLICY ESRD 2: RELOCATION OF DIALYSIS STATIONS applies and states the following:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

- 1. demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to temporarily add 18 dialysis stations from HPKC in Guilford County to Triad Dialysis Center, also located in Guilford County, while HPKC undergoes renovation. The 18 stations will be returned to HPKC once the project is completed. Consequently, there is no change in the inventory in the host county. Therefore, the applicant is conforming to this policy.

The total capital costs of the proposed project to temporarily add 18 dialysis stations while HPKC undergoes renovation is \$112,000, as stated in Section VIII, page 50. POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES of the SMFP 2012, page 40, does not apply because the capital expenditure for this project is under the capital cost threshold of \$2 million pursuant to G.S. 131E-178. Therefore, the application is conforming to this criterion.

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

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The July 2012 SDR indicates a total of 22 certified dialysis stations at TDC. In this application, TDC will temporarily add 18 stations that are being relocated from HPKC

while HPKC undergoes renovation. The 18 stations temporarily added to TDC will be returned to HPKC once the HPKC project is complete.

Population to be Served

In Section III.7, page 24, the applicant provides the current patient origin for services provided at TDC and the projected patient origin for the first two operating years. Operating year 1 projects utilization of TDC during the renovation of HPKC and operating year 2 projects utilization of TDC after HPKC's project has been completed, as illustrated in the following table:

TDC Projected Patient Utilization

County	5-Year AACR	Current 6/30/2012	<i>HPKC Reno./Constr. Ending 6/30/2014</i>	<i>HPKC Ending OY1 6/30/2015</i>	County Patients as a % of Total	
		ICH	ICH	ICH	OY1	OY2
Alamance	4.50%	1.00	1.09	1.14	0.54	1.54
Forsyth	1.20%	3.00	3.07	3.11	1.52	4.19
Rockingham	3.60%	1.00	1.07	1.11	0.53	1.50
Guilford	0.90%	67.00	68.21	68.83	33.76	92.77
<i>Guilford from HPKC</i>	0.90%		<i>106.90</i>	<i>107.86</i>	52.91	0
<i>Guilford to HPKC</i>	0.90%			<i>-107.86</i>		
<i>Randolph from HPKC</i>	9.80%		<i>21.70</i>	23.83	10.74	0
<i>Randolph to HPKC</i>	9.80%			<i>-23.83</i>		
Total		72.00	202.05	74.19	100	100
Projected Utilization of ICH Stations (3.2 Patients Per Station)		81.81%	126.28%	84.30%		
		22 Stations	40 Stations	22 Stations		

As the table above illustrates, TDC will serve additional patients from Guilford County and Randolph County in Operating Year One, 7/1/2013 – 6/30/2014, due to the relocation of these patients from HPKC during HPKC's renovation. At the end of Operating Year Two,

7/1/2014 – 6/30/2015, all of the additional Guilford County patients and all of the Randolph County patients that had relocated to TDC will transfer back to HPKC once HPKC's project is completed. The applicant states in Section III.3(d), page 22, that TDC is located within 10 minutes from HPKC and therefore, "*will have the ability to obtain care equally as convenient to home as is the HPKC facility.*" The applicant projects that it will serve 3.2 patients per station.

Therefore, the applicant has adequately identified the population it will serve.

Need Analysis

The applicant states in Section III.3, page 21, that its TDC CON application is being filed in conjunction with a CON application for the renovation of HPKC. Dialysis patients currently being served at HPKC will need to be temporarily relocated for dialysis services in other facilities. TDC proposes to serve approximately 123 of HPKC's 145 patients by temporarily adding 18 dialysis stations. The remaining 22 patients will be served at Thomasville Dialysis Center (TVDC) through a transfer of six dialysis stations from Lexington Dialysis Center (Project ID# G-10031-12). The HPKC renovation is needed since it was built over 20 years ago and does not provide enough space to accommodate the larger size of patients they are now serving. This impacts not only the patients, but the staff as well who necessarily need more space per station to be able to provide the care that is needed. The applicant explains this need further as follows,

"The obesity epidemic in America can be directly attributed to both an increase in diabetes, renal failure, and additional space requirements in renal disease treatment centers. Patients, themselves, are now two and three times the size of patients who required care when the facility was built. In order to accommodate the larger chairs, machine space, and circulation needed to transport patients in and out of treatment areas as well as continue to serve additional patients, HPKC has no choice but to expand its current patient treatment bays. The additional space will also allow staff a larger range of motion when caring for patients, allow for Hoyer lifts when needed, and prevent potential hazards that could arise from a "crowded" working environment."

Access

The applicant states in Section III.6, page 23, that it is the policy of Wake Forest University Health Sciences to "*accept patients based on medical necessity and not their ability to pay*". The applicant states that this policy is system-wide. Furthermore, patients will receive the "*same exemplary standards of care before, during, and after completion of this project.*" In addition, the facility's social work staff at all three facilities affected by the project, HPKC, TDC, and TVDC, are working "*in unison*" to prepare the patients for the changes planned and will "*continue to strive to assist all patients, including underserved groups, in obtaining the care they need.*" Furthermore, in Section VI.1, page 36, the applicant states that there is no discrimination in acceptance of patients based on race, sex, national origin nor disability. The facility also accepts the needy and

the homeless through its referral system. In supplemental information provided by the applicant, TDC projects that 80% of its patients receiving in-center hemodialysis will be covered by Medicare while 10% will be covered by Medicaid.

Therefore, the applicant demonstrates that there will be adequate access for the underserved.

In summary, the application adequately identified the population to be served and demonstrated need for temporary relocation of 18 dialysis stations to TDC to temporarily serve patients during the renovation of HPKC. In addition, the applicant demonstrated that the TDC facility will be in close proximity to the HPKC facility. 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.

C

The applicant proposes to temporarily add 18 dialysis stations to serve patients currently receiving services at HPKC while HPKC is undergoing renovation. The 18 stations would serve approximately 123 patients. In a separate CON application, Thomasville Dialysis Center (TVDC) is applying to receive six stations transferred from Lexington Dialysis Center to provide ICH services to the remaining 22 patients from HPKC. See Criterion (3) for discussion of access to services for all residents of the area, including underserved groups, which is incorporated hereby as if fully set forth herein. Therefore, the applicant is conforming to 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.

CA

The applicant states, in Section III.9, page 27, of the application, that “*The purpose of this project is to facilitate the proposed improvements for HPKC.*” Therefore the alternatives considered necessarily relate to the HPKC proposed project. The applicant describes the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – the applicant did not choose to continue to serve all of the patients at HPKC in its current facility since this alternative would not address the lack of patient treatment space and potential for overcrowding.

- 2) Transferring a portion of HPKC's stations to another area of Guilford County and creating a new facility – this alternative was not chosen by the applicant since temporary shelters would need to be brought in to house the facility's stations during construction which would prove to be much more costly than the proposed alternative, would disrupt patient travel patterns, and would still fail to address the identified per station space problem at HPKC.
- 3) Total relocation of entire facility to a new location within Guilford County – Similarly to alternative #2 above, this alternative was not chosen since it would be much more costly and would permanently disrupt patient travel patterns.

The applicant states that the proposed alternative would *“provide longevity of care to patients and a more comfortable working environment for staff. Patients will enjoy a new, updated facility in a familiar and convenient location. ...Renovation/ demolition/ reconstruction of HPKC and temporary transfer of 18 of its stations to TDC is the most effective alternative to resolving the issues faced at that facility.”*

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

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Wake Forest University Health Sciences d/b/a Triad Dialysis Center of Wake Forest University shall materially comply with all representations made in its certificate of need application and supplemental responses. In those instances where representations conflict, Wake Forest University Health Sciences d/b/a Triad Dialysis Center of Wake Forest University shall materially comply with the last made representation.**
2. **Wake Forest University Health Sciences d/b/a Triad Dialysis Center of Wake Forest University shall be certified for no more than 40 dialysis stations upon the temporary addition of 18 stations from Wake Forest University Health Sciences d/b/a High Point Kidney Center of Wake Forest University which shall include any home hemodialysis or isolation stations.**
3. **Wake Forest University Health Sciences d/b/a Triad Dialysis Center of Wake Forest University shall provide electrical wiring and plumbing through the walls to accommodate the temporary addition**

of 18 existing dialysis stations from High Point Kidney Center (G-10029-12) for a total of no more than 40 dialysis stations, which shall include any home hemodialysis or isolation stations.

4. Wake Forest University Health Sciences d/b/a Triad Dialysis Center of Wake Forest University shall be certified for no more than 22 stations at the completion of this project.
 5. Wake Forest University Health Sciences d/b/a Triad Dialysis Center of Wake Forest University, prior to issuance of the certificate of need, shall acknowledge in writing to the Certificate of Need Section acceptance of and agree to comply with all conditions stated herein.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 51, the applicant projects that the total capital cost of the project will be \$112,000. A breakdown of the capital cost is provided in the following table:

**Triad Dialysis Center of Wake Forest
University
Temporary Addition of 18 Dialysis Stations
Capital Costs**

Project Costs	Additional Stations
Construction Contract	\$ 20,000
(RO) Water Treatment Equipment	\$ 65,500
Equipment/Furniture	\$ 26,500
Total	\$112,000

In Sections IX.1, page 54, the applicant indicates that there are no start-up or initial operating expenses. In Section VIII.2, page 51, the applicant states that funding for the project will be provided from accumulated reserves. A letter, dated September 10, 2012 from the Chief Financial Officer and Executive Vice President of Wake Forest Baptist Medical Center, was provided as supplemental information which indicates the availability of funds for the project. The letter states:

“The project has been budgeted to cost approximately \$112,000. Triad Dialysis Center is a subsidiary of Wake Forest University Health Sciences. Wake Forest University Health Sciences commits to provide monies to its subsidiaries in order to fund these costs.”

Attachment D contains the audited financial statements for Wake Forest University Health Sciences and subsidiaries as of June 30, 2011 and 2010. Wake Forest University Health Sciences and subsidiaries had \$669,880,000 and \$559,199,000 in net assets as of June 30, 2011 and 2010, respectively. Cash and cash equivalents for June 30, 2011 and 2010 were \$36,418,000 and \$9,877,000, respectively. Therefore, the applicant adequately demonstrates the availability of sufficient funds for the proposed project.

In Section X.1, pages 57, the applicant provides projected allowable charges per treatment for each payment source for ICH services. This is illustrated in the following table:

**TDC In-Center Hemodialysis
 Allowable Charges by Payor Source
 July 1, 2013 – June 30, 2014**

SOURCE OF PAYMENT	CHARGE PER TREATMENT
Private Pay	\$1019.70
Medicare	\$235.00
Medicaid	\$195.00
Medicare/Medicaid	\$235.00
Commercial Insurance	\$1019.70
Medicare/Commercial	\$235.00
VA	\$252.00
State Kidney Program	0
Medicare Advantage Plans	\$235.00

In regard to the charges displayed in the tables above, the applicant states in Section X.1, page 56, that revenue is based on a bundled rate and that allowable charges per payor are variable based on contract terms. In Section X.2, page 57, and Section X.4, page 61, the applicant projects net revenues and operating expenses, respectively, as follows:

**TDC Projected Net Revenues, Operating Expenses and Net Profit
 Operating Years 1 and 2**

	OPERATING YEAR 1 (7/1/2014 –6/30/2015)	OPERATING YEAR 2 (7/1/2015 –6/30/2016)
Net Revenue	\$6,986,128	\$2,767,960
Total Operating Expenses	\$6,694,049	\$2,574,702
Net Profit	\$292,079	\$193,258

TDC projects that revenue will exceed operating expenses in each of the first two operating years of the proposed project. The assumptions used in preparation of the *pro formas*, included in Section X, pages 58-60, are reasonable.

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

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

C

The applicant proposes to temporarily add 18 dialysis stations for a total of 40 stations to serve patients currently receiving services at HPKC while HPKC is undergoing renovation. TDC would transfer back 18 dialysis stations to HPKC once the renovation and expansion is completed. Both TDC and HPKC are located in Guilford County and the applicant states that the TDC facility is within 10 minutes from HPKC. The applicant projects that during operating year 1 it will have an occupancy rate of 126.28% and a utilization rate of 5.05 patients per station and will operate a third patient shift.

The applicant demonstrated the need to temporarily add 18 dialysis stations to serve patients currently receiving services at HPKC during that facility's renovation and considered alternatives. The applicant adequately demonstrated that the temporary addition of 18 stations and transfer back of those stations to HPKC will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

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

C

In Section VII.1, page 43, the applicant provides the current and projected staffing for TDC as shown in the following table:

**TDC
 Current and Projected Staffing**

	# of Current (FTE) Positions	# of Projected (FTE) Positions OY1
Registered Nurse	2.50	9.00
Lic. Practical Nurse	2.00	4.00
Patient Care Tech.	7.50	26.00
Cert. Nurse Mgr.	1.00	2.00
Med. Dir.	Salary	Salary
Administrator	0.10	0.10
Dietician	1.00	3.00
Social Worker	1.00	3.00
HT Regis. Nurse	0.00	0.00
Biomed. Tech.	1.00	2.00
Dialysis Tech.	2.00	5.00
Clerical	2.00	5.00
Med. Records Clerk	Contract	Contract
Total	20.10	59.10

The applicant indicates a total of 59.10 current FTE positions and projects increases in staffing by the end of the first full year of operation. The applicant indicates in Section VII.4, page 46, that it does not expect any difficulty in recruiting staff should vacancies occur. The information regarding staffing provided in Section VII and the estimated annual salaries and revenues are reasonable and credible. The Medical Director of the facility is Board Certified in Internal Medicine – Nephrology. A copy of the Medical Director’s resume is included in Attachment Q. The applicant adequately documents the availability of resources, including health manpower and management personnel, for the provision of services to be provided. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1, page 30, the applicant provides a table indicating which of its services are provided on the premises of TDC and which are provided by others. Services not provided on site, including acute dialysis, emergency care, x-ray services, immunological, blood bank, and vascular surgery services are provided under agreement by both North Carolina Baptist Hospital and High Point Regional Hospital as indicated in

Attachment E. TDC has an agreement with North Carolina Baptist Hospital to provide kidney transplantation services to patients meeting assessment criteria. A copy of this agreement is included in Attachment F. Laboratory services will be provided by Meridian Laboratory Corporation. A copy of this agreement is provided in Attachment K.

In Section V.4 (a) and (b), page 33, the applicant discusses its long-standing working relationships with local physicians and healthcare organizations and provides a list of local referring physicians in Attachment S. TDC has *“developed relationships with these physicians to coordinate the care of the patient and routinely work with these local physicians for transfer of medical information to ensure a continuum of care.”*

Attachment R contains letters of support from area physicians. In addition, the applicant provides a list of Wake Forest Baptist Hospital physicians with privileges at the dialysis units and who refer patients to nephrologists listed in Attachment S. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

NA

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

C

In Section VI.1(a), page 36, the applicant discusses TDC's policy regarding service to underserved populations. The applicant states that it accepts all patients based on medically defined admission criteria, and further states,

“There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents with ESRD. Further, the facility also accepts the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need.”

A copy of TDC's Referral/Admissions Policy is included in Attachment S.

In supplemental information, the applicant reports the current and projected payor mix for ICH services provided by TDC, as shown in the following table. The applicant projects slight changes in reimbursement by payor for operating year one.

**Current and Projected TDC Payor Mix
 ICH Services
 Current Year (7/01/12 – 6/30/13) and
 Operating Year 1 (7/01/14 – 6/30/15)**

Payor Source	Current Year % of Total	Operating Year 1 % of Total
Private Pay	1.0%	1.0%
Commercial Insurance	6.0%	4.0%
Medicare	16.0%	16.0%
Medicaid	10.0%	10.0%
Medicare/Medicaid	24.0%	25.0%
Medicare/Commercial	28.0%	28.0%
State Kidney Program	0.0%	0.0%
VA	5.0%	5.0%
Medicare Advantage	10.0%	11.0%
Total	100.0%	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and provides estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2008-2009, respectively. The data in the table were obtained on November 28, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

Percent of Medicaid Eligibles and Percent Uninsured by County

County	Total # of Medicaid Eligible as % of Total Population June 2010	Total # of Medicaid Eligible Age 21 and older as % of Total Population June 2010	% Uninsured CY 08-09 (Estimate by Cecil G. Sheps Center)
Guilford	15.0%	5.89%	19.5%
Statewide	17.0%	6.7%	19.7%

Source: <http://www.ncdhhs.gov/dma/countyreports/index.htm> - Guilford and Davidson Counties, June 2010.

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 TDC.

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.

In Section VI.1 (d), page 37, the applicant states that TDC's admission for services is based upon medical necessity and not the patient's ability to pay. The applicant further states that a patient "*is not turned away due to a lack of ability to pay*" and that the facility's social worker assists the patients in obtaining health care coverage when necessary.

According to the Centers for Medicare and Medicaid Services (CMS) website, in 2008 about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as a secondary payor. Also, the CMS website states:

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

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

Additionally, the Southeastern Kidney Council, Inc. 2011 Annual Report included statistics on the prevalence of ESRD dialysis patients by race for North Carolina, as depicted in the following table:

**Percent of Dialysis Patients by Race
 in North Carolina
 12/31/2011**

RACE	% OF DIALYSIS POPULATION
White	33.7%
Black or African American	63.3%
American Indian/ Alaska Native	1.5%
Native Hawaiian or Other Pacific Islander	0.3%
Asian	1.0%
More than one race selected	0.2%
Total	100%

**Percent of Dialysis Patients by Age
 In North Carolina
 12/31/2011**

AGE GROUP	% OF DIALYSIS POPULATION
0 – 19	0.5%
20 – 44	14.8%
45 – 64	45.4%
65 – 74	22.4%
75 +	16.9%

In addition, pertinent national statistics are provided from the 2012 USRDS Annual Data Report as follows:

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

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 applicant demonstrates that medically underserved populations currently have adequate access to services available at TDC. Based on historic facility utilization data, information from CMS, and projections from the applicant, 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;

C

In application Section VI.1 (f), page 39, the applicant states:

“The facility has no obligation to provide uncompensated care or community service. The facility will be accessible to minorities and handicapped persons as further described in Section VI., #2 and Section VI., #1(a), and strives to provide services to all patients with End Stage Renal Disease.”

In Section VI.6 (b), page 42, the applicant states there have been no civil rights or equal access complaints filed against TDC or any of the facilities owned by its parent company in North Carolina in the last five years.

The application is conforming to this criterion.

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

C

In Section VI.1(b)(c), page 36, the applicant reports TDC’s current and projected payer mix for ICH services. The applicant projects a slight change in payor mix for ICH services in operating year one as stated in Criterion (13a) above. The applicant reports approximately 95% of ICH patients [55.0% Medicare, including Medicare/Commercial and Medicare Advantage, 10.0% Medicaid, 25.0% Medicare/Medicaid, and 5.0% VA = 95.0%] who receive ICH services at HPKC have some or all of their services paid for by Medicare, Medicaid or other government sources. The applicant demonstrates that medically underserved patients will have adequate access to proposed services.

Therefore, the application is conforming with 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 40, the applicant states that personal physicians may refer new patients and that admission must be made by nephrologists with admitting

privileges to the facility. In Section VI.5 (b), the applicant states that referrals are received from Wake Forest University Health Services Nephrology Department staff, other local physicians, including nephrologists, in addition to a variety of community services such as social service agencies, home health services, and retirement homes. In addition, referrals are received from other dialysis facilities for patients who wish to transfer their care.

The applicant adequately demonstrates that it will provide a range of means by which a person can access TDC dialysis services. Therefore, the application is conforming to this criterion.

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

C

In application Section V.3 (a), page 32, the applicant states, “*WFUHS dialysis units make every attempt to provide onsite educational experiences to local training programs in the area.*” Those having access to educational opportunities at the dialysis units are third year medical students and students from high schools who are invited to tour the unit and to learn about the roles of the various health care and ancillary health care staff working there.

The information provided in application Section V is reasonable and credible and is conforming to this criterion.

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

C

The applicant proposes to temporarily add 18 dialysis stations for a total of 40 stations to serve patients currently receiving services at HPKC while HPKC is undergoing renovation. All of HPKC’s current dialysis patients will receive care at TDC and Thomasville Dialysis Center (TVDC). Lexington Dialysis Center is proposing to transfer six dialysis

stations to TVDC, (Project ID# G-10031-12), to accommodate the treatment needs of a portion of HPKC's patients during its renovation.

In addition to TDC, the other existing dialysis services in Guilford County are: BMA South Greensboro, Kidney Center of Greensboro (BMA), High Point Kidney Center (WFU), Northwest Greensboro Kidney Center (BMA), and FMC East Greensboro. HPKC expects to transfer back all of the approximately 123 patients temporarily receiving services at TDC during HPKC's renovation.

In Section V.7, page 35, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states, "*The temporary transfer of stations proposed by this project is to accommodate the development of improvements at HPKC.*" Furthermore, the applicant states that patient services at HPKC will be enhanced and overall patient satisfaction will be increased, which will, in turn, impact favorably on patient outcomes. In addition, the applicant states that cost-effectiveness will be achieved since the project will result in minimal cost compared to other alternatives, such as building a new facility at a new location, and will be able to accommodate additional patients in the future at the existing site. See also sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to temporarily add 18 dialysis stations to Triad Dialysis Center to serve patients during HPKC's renovation 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.

According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, TDC has operated in compliance with all Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy within 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) 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.

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 in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-C- In Section III.7, page 24, the applicant provides a utilization rate of 81.81% with 3.2 patients per station.

(2) *Mortality rates;*

-C- In Section IV.2, page 28, the applicant provides the mortality rates as 21.05%, 26.86%, and 21.54% for 2009, 2010, and 2011, respectively.

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

-NA- The applicant does not provide home dialysis services.

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

-C- In Section IV.4, page 28, the applicant states that from July 1, 2011 – June 30, 2012, there were three patients who had received kidney transplants.

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

-C- In Section IV.5, page 29, the applicant states, “As of July 2012, there are sixteen (16) patients on the TDC transplant waiting list.”

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

-C- In Section IV.6, page 29, the applicant states it had 64 dialysis related hospital admissions and 179 non-dialysis related hospital admissions for the past operating year.

(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

-C- In Section IV.7, page 29, the applicant indicates it had 25 patients with infectious diseases and one who converted to infectious status during the last calendar year.

(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:*

(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- TDC is an existing facility. However, the applicant provides copies of hospital agreements with both North Carolina Baptist Hospital and High Point Regional Hospital in Attachment E. Both of these agreements state the services that will be provided to TDC’s dialysis patients.

(2) *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 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- TDC is an existing facility. However, the applicant provides a copy of a transplantation agreement with North Carolina Baptist Hospital in Attachment F.

(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

-NA-The applicant proposes to temporarily add 18 dialysis stations to its existing facility.

(4) Copies of written policies and procedures for back up electrical service in the event of a power outage.

-C- In Section XI.6(f), page 66, the applicant states that the facility has a back up generator to provide power in the event of a loss of power in an emergency. A copy of the applicant's written policy and procedures is included in Attachment P.

(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.

-NA- The applicant proposes to temporarily add 18 dialysis stations to an existing facility while HPKC is being renovated.

(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- The applicant states in Section XI.6(g), page 67, "The facility will continue to provide services in conformity with all applicable laws and regulations." Furthermore, it states it has already established relationships with all of the appropriate service providers in the community.

(7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.

-C- Section III.7, pages 25-26, contains the methodology and assumptions the applicant uses to project patient origin. Section III.7, page 24. Projected patient origin is provided based, in part, on supplemental information provided by the applicant and is illustrated below from Section III.7, page 24.

County	Operating Year 1 June 30, 2014	Operating Year 2 June 30, 2015	County Patients as a Percent of Total	
	ICH	ICH	Oper. Year 1	Oper. Year 2
Alamance	1.09	1.14	0.54	1.54
Forsyth	3.07	3.11	1.52	4.19
Rockingham	1.07	1.11	0.53	1.50
Guilford	175.11	68.83	86.67	92.77
Randolph	21.70	0.00	10.74	0
Total	202.05	74.19	100.0	100.0

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- TDC is an existing facility that is temporarily adding 18 dialysis stations to serve current patients of HPKC while HPKC is undergoing renovation. No changes in the anticipated patient population are expected.

(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 rate for such services.*

-C- In Section VI.1(d), page 37, the applicant states:

“Admission of a patient is based upon medical necessity and not the patient’s ability to pay. ...should a circumstance arise in which a patient is ineligible for healthcare coverage, that patient is not turned away due to a lack of ability to pay.”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(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- TDC does not propose to establish a new End Stage Renal Disease facility.

(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 is proposing to temporarily add 18 dialysis stations to serve some of HPKC's current patients while the facility undergoes renovation. TDC is an existing facility consisting of 22 dialysis stations. The 18 additional stations will be transferred back to HPKC once the renovation project is completed. No new stations will be developed at TDC as a result of this project.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section III.7, pages 25-26.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

(1) diagnostic and evaluation services;

-C- The applicant indicates that these services will be available on the premises of TDC in Section V.1, page 30.

(2) maintenance dialysis;

-C- The applicant indicates that these services will be available on the premises of TDC in Section V.1, page 30.

(3) accessible self-care training;

-C- The applicant indicates that these services will be available from HPKC. A copy of an agreement with HPKC to provide these services is provided in Attachment J.

(4) accessible follow-up program for support of patients dialyzing at home;

-C- The applicant indicates that this program will be available from HPKC. A copy of an agreement with HPKC to provide this program is provided in Attachment J.

(5) x-ray services;

- C- The applicant provides a copy of agreements with North Carolina Baptist Hospital and High Point Regional Hospital in Attachment E that include the provision of x-ray services for TDC's dialysis patients.

(6) laboratory services;

- C- The applicant provides a copy of a contractual agreement with Meridian Laboratory Corporation for laboratory services in Attachment K.

(7) blood bank services;

- C The applicant provides copies of agreements with North Carolina Baptist Hospital and High Point Regional Hospital in Attachment E that include the provision of blood bank services for TDC's dialysis patients.

(8) emergency care;

- C- The applicant provides copies of agreements with North Carolina Baptist Hospital and High Point Regional Hospital in Attachment E that include the provision for emergency care for TDC's dialysis patients.

(9) acute dialysis in an acute care setting;

- C- The applicant provides copies of agreements with North Carolina Baptist Hospital and High Point Regional Hospital in Attachment E that include the provision for acute dialysis at these acute care facilities for TDC's dialysis patients.

(10) vascular surgery for dialysis treatment patients;

- C- The applicant provides copies of agreements with North Carolina Baptist Hospital and High Point Regional Hospital in Attachment E that include the provision for vascular surgery for TDC's dialysis patients.

(11) transplantation services;

- C- The applicant provides a copy of an agreement with North Carolina Baptist Hospital in Attachment F to provide transplantation services.

(12) vocational rehabilitation counseling and services; and

- C- The applicant indicates that these services will be referred after initial evaluation by the social worker in Section V.1, page 30.

(13) transportation.

- C- The applicant provides a letter from CJ Medical Transportation Co, Inc. in Attachment L that indicates support for “*continuing our relationship with the clients & residents of Guilford County with this new endeavor.*” In addition, the applicant provides a letter from the City of High Point Public Transportation Division in Attachment L that indicates support for the project.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(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, page 44, the applicant states TDC is in compliance with all requirements of 42 C.F.R., Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.

The applicant adequately demonstrates it will meet the requirements of this rule.

(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- In Section VII.3, page 44, the applicant states “*Each employee undergoes intensive training upon employment and routinely is required to participate in continuing education provided onsite.*” Attachment M provides an outline of the training/orientation program in addition to the facility’s continuing education program.