ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming CA = Conditional NC = Nonconforming NA = Not Applicable

DECISION DATE:

FINDINGS DATE:

PROJECT ANALYST:

CON CHIEF:

December 18, 2012

December 18, 2012

Gloria C. Hale

Craig R. Smith

PROJECT I.D. NUMBER: G-10029-12/ High Point Kidney Center of Wake Forest University

d/b/a High Point Kidney Center/ Temporarily relocate 18 stations

to Triad Dialysis Center during renovations / Guilford County

FID # 945262

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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The applicant, Wake Forest University Health Sciences d/b/a High Point Kidney Center of Wake Forest University, proposes to renovate the existing 20 year old facility due to physical obsolescence, requiring a temporary transfer of 18 of its 42 dialysis stations at Westchester Drive in High Point, Guilford County, to Triad Dialysis Center at Regency Drive in Guilford County, and transfer back of those 18 stations upon project completion. The CON application for temporary relocation of the 18 dialysis stations is under concurrent review [Project ID# F-10028-12]. The remaining 24 stations at High Point Kidney Center (HPKC) will be put in storage until the project is completed. In addition, a CON application to relocate 6 dialysis stations from Lexington Dialysis Center to Thomasville Dialysis Center, [Project ID# F-10031-12 within Davidson County], is also under concurrent review. Thomasville Dialysis Center would serve some of the relocated patients from HPKC as well. 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 HPKC 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 HPKC is operating at 3.38 patients per station with a utilization rate of 84.52% which exceeds the minimum operating standard of 3.2 patients per station with a utilization rate of 80%. This application is for the renovation and expansion of the facility on the same site, which will house 42 dialysis stations upon completion. The facility currently has 42 stations, therefore the number of dialysis stations will remain the same.

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 renovate HPKC and temporarily relocate 18 of its 42 dialysis stations to Triad Dialysis Center, both of which are located in Guilford County. 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.

In summary, the applicant proposes to renovate and expand its High Point Kidney Center facility on site to better accommodate patients utilizing the facility's 42 existing stations located in Guilford County. Consequently, there will be no change in the dialysis station inventory in Guilford County. Therefore, the applicant is conforming to this policy.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES of the SMFP 2012, page 40, is applicable to this review. Two portions of this policy are applicable as follows:

"Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The total capital costs of the proposed project to renovate and expand HPKC and temporarily relocate 18 dialysis stations to Triad Dialysis Center will exceed \$2 million as stated in Section VIII, page 51. Therefore the application is subject to Policy GEN-4. The applicant includes a signed letter in Attachment T from Greensboro Engineering PLLC that states,

"The new building/renovation will comply with the newly passed NC State Building Code: Energy Conservation Code. This new code requires energy efficient lighting with occupancy sensors in certain areas, minimum of 13 SEER HVAC equipment, and water conserving faucets/fixtures. The PM&E drawings will incorporate design features:

- *High output T8 lamps with program/instant start ballasts*
- Occupancy Sensors will be utilized in classrooms, conference/meetings rooms, employee lunch and break rooms, private offices, storage rooms over 100 square feet, and computer rooms over 100 square feet.
- Water conserving 1.28 gpm flush valves for water closets
- High efficiency HVAC units with 13 SEER or above performance with approximately half of the units utilizing hot gas reheat for humidity control
- Higher efficiency domestic hot water heaters and Single Zone VAV HVAC equipment will be evaluated during the design phase."

Therefore, the application is conforming to this policy.

- (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 42 certified dialysis stations at High Point Kidney Center (HPKC). In this application, HPKC will renovate the facility to better accommodate dialysis patients. Eighteen stations will be temporarily relocated to Triad Dialysis Center

(TDC) during the renovation/expansion and the remaining 24 stations will be placed in storage. No new stations will be added once the project is complete. The 18 stations temporarily relocated to TDC will be returned to HPKC once the project is completed.

Population to be Served

In Section III.7, page 23, and in supplemental information, the applicant provides the current patient origin for services provided at HPKC, the projected patient origin during the renovation/construction phase, and the projected patient origin for the first two operating years after the project has been completed, as illustrated in the following table:

HPKC Projected Patient Utilization

County 5-Year Current Reno./Constr. Ending OY1 Ending OY2 County											
County	AACR	6/30/2		End 6/30/	ling	6/30/2			/2016	Patients	
		ICH	Home	ICH	Home	ICH	Home	ICH	Home	OY1	OY2
Forsyth	1.20%	0.00	3.00	0.00	3.07	0.00	3.11	0.00	3.15	1.62	1.59
Davidson	3.30%	22.00	7.00	23.48	7.47	6.61	7.72	6.83	7.97	20.06	20.19
Davidson to TVDC	3.30%			-23.48		-24.25		-25.05		-12.61	-12.70
Davidson back from TVDC	3.30%					6.61		6.83			
Guilford	0.90%	105.00	33.00	106.90	33.60	107.86	33.90	108.83	34.20	73.72	72.49
Guilford to TDC	0.90%			- 106.90							
Guilford back from TDC	0.90%					107.86		108.83			
Randolph	9.80%	18.00	7.00	21.70	8.44	23.83	9.27	26.16	10.17	17.21	18.42
Randolph to TDC	9.80%			-21.70							
Randolph back from TDC	9.80%					23.83		26.16			
Total		145.00	50.00	0.00	51.58	138.30	53.99	141.83	55.50	100	100
Projected U of 42 ICH (3.2 Patie Statio	Stations ents Per	86.3	0%	0.00	0%	82.3	2%	84.4	12%		•

As the table above depicts, most of the current patients receiving services at HPKC will relocate to TDC and return to HPKC once the project is completed. However, a majority of patients from Davidson County who currently utilize services at HPKC will relocate to

Thomasville Dialysis Center (TVDC) and will continue to receive services at TVDC once the project is completed. TVDC is located in Davidson County. The applicant states in Section III.3(d), page 22, that both TDC and TVDC are located within 10 minutes from HPKC and therefore, "will provide an excellent alternative to HPKC during this project."

The applicant projected patient origin for HPKC for Operating Year One, 7/1/2013 – 6/30/2014, and Operating Year Two, 7/1/2014 – 6/30/2015, to be the same with the exception of approximately 15 patients from Davidson County who will continue to be served at TVDC once the project is completed rather than be transferred back to HPKC. In Operating Year One (2014) and Operating Year Two (2015), the applicant projects that HPKC 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, the HPKC building 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 Service 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 operating year one, HPKC projects that 81%

of its patients receiving in-center hemodialysis will be covered by Medicare while 10% will be covered by Medicaid. For in-home hemodialysis, 70% are expected to be covered by Medicare.

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 renovation and expansion of the facility. In addition, the applicant demonstrated that all of its existing patients will be adequately served in alternate locations during the facility's renovation and expansion and that these temporary locations will be in close proximity to the existing 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.

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The applicant proposes a temporary relocation of services provided at HPKC while the facility undergoes reconstruction. HPKC currently serves 145 patients in its in-center hemodialysis (ICH) services and 50 patients in its Home Therapy (HT) services. Only the ICH services will be affected by the proposed project. There will be no disruption in services currently offered to HPKC's Home Therapy patients. Eighteen stations will be temporarily relocated to TDC from HPKC to provide ICH services to 123 patients currently receiving ICH at HPKC. 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. Upon completion of the project HPKC will operate 42 dialysis stations, the same number as currently certified. 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.

In Section III.9, pages 26-27, of the application, 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 this alternative due to the lack of patient treatment space and potential for overcrowding.
- 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 High Point Kidney 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 High Point Kidney Center of Wake Forest University shall materially comply with the last made representation.
- 2. Wake Forest University Health Sciences d/b/a High Point Kidney Center of Wake Forest University shall be certified for no more than 42 dialysis stations, which shall include any home hemodialysis or isolation stations.

- 3. Wake Forest University Health Sciences d/b/a High Point Kidney Center of Wake Forest University shall provide electrical wiring and plumbing through the walls to accommodate the back transfer of 18 existing dialysis stations from Triad Dialysis Center (G-10028-12) and the re-installation of 24 existing dialysis stations in temporary storage for a total of no more than 42 dialysis stations, which shall include any home hemodialysis or isolation stations.
- 4. Wake Forest University Health Sciences d/b/a High Point Kidney 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 agreement 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.

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In Section VIII.1, page 51, the applicant projects that the total capital cost of the project will be \$3,015,000. A breakdown of the capital cost is provided in the following table:

High Point Kidney Center of Wake Forest University Renovation and Expansion Capital Costs

Project Costs	Renovation & Expansion
Construction Contract	\$2,550,987
(RO) Water Treatment Equipment	\$ 144,000
Equipment/Furniture	\$ 256,013
Architect/Engineering Fees	\$ 64,000
Total	\$3,015,000

In Sections IX.1, page 55, the applicant indicates that there are no start-up or initial operating expenses. In Section X.2, page 52, 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 \$3,015,000. High Point Kidney 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 57-58, the applicant provides projected allowable charges per treatment for each payment source for both ICH and HT services. These are illustrated in the following tables:

HPKC In-Center Hemodialysis Allowable Charges by Payor Source July 1, 2012 – June 30, 2013

SOURCE OF PAYMENT	CHARGE PER TREATMENT
Private Pay	\$990.00
Medicare	\$235.00
Medicaid	\$195.00
Medicare/Medicaid	\$235.00
Commercial Insurance	\$990.00
Medicare/Commercial	\$235.00
VA	\$252.00
State Kidney Program	0
Medicare Advantage Plans	\$235.00

HPKC Home Therapy Allowable Charges by Payor Source July 1, 2012 – June 30, 2013

duly 1, 2012 dulie 30, 2013				
SOURCE OF PAYMENT	CHARGE PER TREATMENT			
Private Pay	\$423.12			
Medicare	\$100.44			
Medicaid	\$83.34			
Medicare/Medicaid	\$100.44			
Commercial Insurance	\$423.12			
Medicare/Commercial	\$100.44			
VA	\$107.70			
State Kidney Program	0			
Medicare Advantage Plans	\$100.44			

In regard to the charges displayed in the tables above, the applicant states that revenue is based on a bundled rate and that allowable charges per payor are variable based on contract terms. In Sections X.2 and X.4, pages 59 and 64, respectively, the applicant projects net revenues and operating expenses as follows:

HPKC
Projected Net Revenues, Operating Expenses and Net Profit
Operating Years 1 and 2

	OPERATING YEAR 1	OPERATING YEAR 2
	(7/1/2014 –6/30/2015)	(7/1/2015 –6/30/2016)
Net Revenue	\$7,162,355	\$7,393,712
Total Operating Expenses	\$5,016,247	\$5,121,236
Net Profit	\$2,146,108	\$2,272,476

HPKC 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 61-63, 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.

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The applicant proposes to renovate the 20 year old HPKC facility in order to provide larger treatment space for each of its 42 dialysis stations, benefiting both patients and

staff. HPKC operated at 85% of capacity as of December 31, 2011. There will be no increase in the number of dialysis stations. While renovations are being done, all existing patients will receive services at nearby dialysis centers also owned by Wake Forest University Health Services, the parent company of HPKC. Eighteen dialysis stations will be temporarily transferred to Triad Dialysis Center (TDC), also located within Guilford County, and six dialysis stations will be transferred from Lexington Dialysis Center to Thomasville Dialysis Center (TVDC), located in Davidson County. HPKC's existing Davidson County patients will be served at the TVDC facility. The applicant projects that all of its patients temporarily transferred to TDC will return to HPKC after the renovation is complete and all but approximately 15 of the Davidson County patients transferred to TVDC are expected to return to HPKC. The applicant states that both TDC and TVDC are within 10 minutes of the HPKC facility. Therefore patient access will be minimally affected. The applicant demonstrated the need to renovate and expand the replacement dialysis facility and considered alternatives. HPKC determined that the proposed project would accommodate current need and future growth. The applicant adequately demonstrated that the renovation and expansion of the facility 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.

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In Section VII.1, page 44, the applicant provides the current and projected staffing for HPKC as shown in the following table:

HPKC
Current and Projected Staffing

	Trojecteu Star	
	# of Current (FTE) Positions	# of Projected (FTE) Positions OY1
Registered Nurse	6.50	6.50
Lic. Practical Nurse	2.00	2.00
Patient Care Tech.	19.50	19.50
Cert. Nurse Mgr.	1.00	1.00
Med. Dir.	Salary	Salary
Administrator	0.10	0.10
Dietician	2.00	2.00
Social Worker	2.00	2.00
HT Regis. Nurse	3.00	3.00
Biomed. Tech.	1.00	1.00
Dialysis Tech.	3.00	3.00
Clerical	3.00	3.00
Med. Records Clerk	Contract	Contract
Total	43.10	43.10

The applicant indicates a total of 43.10 current FTE positions and projects no change in staffing by the end of the first full year of operation. The applicant indicates in Section VII.4, page 47, 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 with over 17 years of experience in the care of ESRD patients. 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

(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.

services to be provided. Therefore, the application is conforming to this criterion.

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In Section V.1, page 30, the applicant provides a table indicating which of its services are provided on the premises of HPKC 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. High Point Kidney Center has an agreement with North Carolina Baptist Hospital to provide kidney transplantation services to patients meeting assessment criteria. 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. HPKC 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 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.

The applicant proposes to reconstruct the HPKC facility at its current site. In Section XI.6(h), page 71, the applicant provides the current and projected square footage after renovation and expansion for ancillary and treatment areas. The estimated increase in square footage for the facility is 2,742 square feet (SF). The estimated construction cost is \$2,550,987. The cost per SF is approximately \$930.

HPKC Square Footage-Current and Proposed

THI KC Square Poolage-Current and Proposed					
Ancillary Areas	Current Facility	Proposed Facility			
Administration	1,091	1,543			
Public Lobby	1,157	1,455			
Mechanical Equipment	100	152			
Housekeeping	20	0			
General Storage	879	236			
Exam/Treatment	60	882			
Staff Lounge	553	679			
RO	296	551			
Reuse	154	140			
Biomedical	138	139			
Toilets	617	551			
Lab	40	86			
Warehouse	2,441	2,357			
Corridors / Circulation	1,985	2,176			
Sub-Total	9,531	10,947			
Treatment Areas					
Nurses Station	253	287			
Pre-Assess	100	159			
Dialysis Stations	3,618	4,579			
Home Training	200	490			
Isolation	240	222			
Sub-Total	4,411	5,737			
Total Square Feet	13,942	16,684			

In Section XI.6(d), page 69, the applicant states that the facility is utilizing the most modern technology to maintain energy efficient operations and that the construction guidelines set forth in the 1991 Edition of the North Carolina Building Code were used.

The applicant adequately addresses energy efficiencies and that the costs, design, and means of construction will not unduly increase the costs and charges of providing the proposed services. See Criterion (5) for discussion of costs and charges.

Therefore, the applicant is conforming with this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients,

racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

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In Section V1.1(a), page 36, the applicant discusses HPKC'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 HPKC's Referral/Admissions Policy is included in Attachment S.

In Section VI.1(c), pages 29-30, the applicant reports the current and projected payer mix for ICH and Home Therapy services provided by HPKC, as shown in the following tables. The applicant projects no change in reimbursement by payor for both ICH and HT services for operating year one.

Historic and Projected HPKC 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	4.0%	4.0%
Medicare	18.0%	18.0%
Medicaid	9.0%	9.0%
Medicare/Medicaid	23.0%	23.0%
Medicare/Commercial	25.0%	25.0%
State Kidney Program	0.0%	0.0%
VA	5.0%	5.0%
Medicare Advantage	15.0%	15.0%
Total	100.0%	100.0%

Historic and Projected HPKC Payor Mix Home Therapy 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	4.0%	4.0%
Commercial Insurance	10.0%	10.0%
Medicare	9.0%	9.0%
Medicaid	0.0%	0.0%
Medicare/Medicaid	16.0%	16.0%
Medicare/Commercial	29.0%	29.0%
State Kidney Program	0.0%	0.0%
VA	16.0%	16.0%
Medicare Advantage	16.0%	16.0%
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%
Davidson	17.0%	6.9%	18.4%
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 HPKC.

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 payer 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 HPKC'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 in 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 High Point Kidney Center. 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;

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In application Section VI.1 (f), page 40, 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 that there have been no civil rights or equal access complaints filed against HPKC 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

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In Section VI.1(c), pages 29-30, the applicant reports HPKC's current and projected payer mix for ICH and Home Therapy services. The applicant projects no change in payor mix for ICH or HT services as stated in Criterion (13a) above. The applicant approximately 95% of ICH patients [58.0%] Medicare, including Medicare Advantage, Medicare/Commercial and 9.0% Medicaid, 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. Seventy percent of HPKC's Home Therapy patients [54.0% Medicare, including Medicare/Commercial and Medicare Advantage, 0% Medicaid, 16.0% Medicare/Medicaid, and 16% VA = 70% have some or all of their services paid for by Medicare 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.

In Section VI.5 (a), page 41, the applicant states that personal physicians may refer new patients and that admission must be by nephrologists with admitting privileges to the facility. Referrals are received from Wake Forest University Health Services Nephrology Department staff, other local physicians, including nephrologists, as well as a variety of community services such as social service agencies, home health, 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 HPKC 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.

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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.

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The applicant proposes to reconstruct HPKC due to physical obsolescence, requiring a temporary transfer of 18 of its 42 dialysis stations at Westchester Drive in High Point, Guilford County, to Triad Dialysis Center at Regency Drive in Guilford County, and

transfer back of those 18 stations upon project completion. All of HPKC's current dialysis patients will receive care at Triad Dialysis Center 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 and expansion.

In addition to HPKC, the other existing dialysis services in Guilford County are: BMA South Greensboro, Kidney Center of Greensboro (BMA), Northwest Greensboro Kidney Center (BMA), FMC East Greensboro, and Triad Dialysis Center (WFU). HPKC expects to transfer back all but approximately 15 of its existing patients upon completion of its renovation and expansion project. Approximately 15 patients who live in Davidson County are expected to continue receiving services at TVDC which is located in Davidson County. No additional stations are proposed at HPKC.

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 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, 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 renovate and expand HPKC and temporarily relocate 18 dialysis stations to Triad Dialysis Center and that it is a costeffective 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, HPKC 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 appropriate 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.

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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 II.7, page 23, the applicant provides a utilization rate of 86.30% with 3.2 patients per station.
 - (2) *Mortality rates*;
 - -C- In Section IV.2, page 28, the applicant provides the mortality rates as 17.39%, 17.63%, and 17.32% for 2009, 2010, and 2011, respectively.
 - (3) The number of patients that are home trained and the number of patients on home dialysis;
 - In Section IV.3, page 28, the applicant states that as of June 30, 2012, 50 patients at HPKC are home trained and are on home dialysis.

- (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 seven patients at HPKC who had received kidney transplants.
- (5) The number of patients currently on the transplant waiting list;
- -C- In Section IV.5, page 28, the applicant states, "As of July 2012, there are fifty-two (52) patients on the HPKC 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 70 dialysis related admissions and 365 non-dialysis related 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 states it had 39 patients with infectious diseases and none 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- HPKC 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 HPKC'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 reevaluated for transplantation, and
- (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.
- -NA- HPKC 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.
- -C- The applicant provides documentation that power and water will be available at the newly renovated and expanded HPKC facility in Section XI.6(f), page 69, and in Attachment H.
- (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 69, the applicant states that the facility has a back up generator to provide power in the event of an emergency. A copy of the written policy and procedures for Emergency/Disaster Situations, which includes back up electric service, 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.
- -C- The applicant proposes to renovate and expand HPKC, an existing facility. It will continue to be located at 1900 Westchester Drive, High Point, North Carolina.
- (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 70, "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- See Section III.7, page 23, for the methodology and assumptions the applicant uses to project patient origin as presented in the following table. Projected utilization is based, in part, on supplemental information provided by the applicant.

	Operating Year 1 June 30, 2015		Operating Year 2 June 30, 2016		County Patients as a Percent of Total	
County	ICH	Home	ICH	Home	Oper. Year 1	Oper. Year 2
Forsyth	0.00	3.11	0.00	3.15	1.62	1.59
Davidson	6.61	7.72	6.83	7.97	7.45	7.49
Guilford	107.86	33.90	108.83	34.20	73.72	72.49
Randolph	23.83	9.27	26.16	10.17	17.21	18.42
Total	138.30	53.99	141.83	55.50	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- HPKC is an existing facility that is being renovated and expanded. 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- HPKC 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- HPKC is an existing facility consisting of 42 dialysis stations. No additional stations will be added 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 HPKC in Section V.1, page 30.
- (2) maintenance dialysis;
- -C- The applicant indicates that these services will be available on the premises of HPKC in Section V.1, page 30.
- (3) accessible self-care training;
- -C- The applicant indicates that these services will be available on the premises of HPKC in Section V.1, page 30.
- (4) accessible follow-up program for support of patients dialyzing at home;
- -C- In Section V.2, page 32, the applicant provides a description of the home training agreement, including training and support services that are provided.
- (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 HPKC'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 HPKC'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 HPKC'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 HPKC'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 HPKC'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 available on the premises of HPKC in Section V.1, page 30.
- (13) transportation.

-C- The applicant provides a letter from the Regional Coordinated Area Transportation System in Attachment L that indicates public transportation is available to HPKC for residents living in Randolph County. 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 HPKC 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 VI.3, page 45, 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.