

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 14, 2015

Findings Date: December 14, 2015

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: G-11075-15

Facility: High Point Kidney Center

FID #: 945262

County: Guilford

Applicants: Wake Forest University Health Sciences, and
High Point Kidney Center of Wake Forest University

Project: Add 8 dialysis stations for a total of 40 dialysis stations upon completion of this project and Project ID #G-10262-14 (relocate 10 stations from High Point Kidney Center)

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

Wake Forest University Health Sciences (WFUHS) and High Point Kidney Center of Wake Forest University, also referred to as “the applicants”, propose to add eight dialysis stations for a total of 40 dialysis stations at the existing High Point Kidney Center (HPKC) facility upon completion of this project and Project ID #G-10262-14, which was approved to relocate 10 stations from HPKC to develop North Randolph Dialysis Center (NRDC) in Randolph County. HPKC is located at 1900 Westchester Drive, High Point, Guilford County.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 7 dialysis stations in Guilford County. Therefore, the July 2015 SDR does not indicate a need for additional stations in Guilford County based on the county need methodology.

However, the applicants are eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for HPKC in the July 2015 SDR is 3.38 patients per station. This utilization rate was calculated based on 142 in-center dialysis patients and 42 certified dialysis stations. (142 patients / 42 stations = 3.38 patients per station).

Application of the facility need methodology indicates eight additional stations are needed for this facility, as illustrated in the following table.

October 1 REVIEW-July 2015 SDR

Required SDR Utilization		80.00%
Center Utilization Rate as of 12/31/14		84.50%
Certified Stations		42
Pending Stations		0
Total Existing and Pending Stations		42
In-Center Patients as of 12/31/14 (SDR2)		142
In-Center Patients as of 6/30/14 (SDR1)		134
Step	Description	
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.1194
(ii)	Divide the result of Step (i) by 12	0.0100
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.1194
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	158.9552
(v)	Divide the result of Step (iv) by 3.2 patients per station	49.6735
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	7.67 (8 Stations)

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 8 stations. Step (C) of the facility need methodology states *“The facility may apply to expand to meet the need established ..., up*

to a maximum of ten stations.” The applicants propose to add eight stations. Therefore, the facility need determination for dialysis stations is applicable to this review.

In summary, the applicants are consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2015 SMFP that is applicable to this review, Policy GEN-3: Basic Principles. Policy GEN-3: Basic Principles, page 38 of the 2015 SMFP, states:

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

Promote Safety and Quality – The applicants describe how they believe the proposed project would promote safety and quality in Section B.4(a), pages 11-16; Section K.1(g), pages 60-61; Section N.1, page 78; and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote safety and quality.

Promote Equitable Access - The applicants describe how they believe the proposed project would promote equitable access in Section B.4(b), pages 16-21; Section N.1, page 78 and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote equitable access.

Maximize Healthcare Value - The applicants describe how they believe the proposed project would maximize healthcare value in Section B.4(c), page 21, Section F.1, page 37, and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would maximize healthcare value.

The applicants adequately demonstrate how their projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicants adequately demonstrate that the application is consistent with the facility need methodology in the July 2015 SDR and Policy GEN-3 and therefore is conforming to this criterion.

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

C

The applicants propose to add eight dialysis stations for a total of 40 dialysis stations at the existing HPKC facility upon completion of this project and Project ID #G-10262-14, which was approved to relocate 10 stations from HPKC to develop NRDC in Randolph County.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 30, the applicants provide a table showing the historical patient origin for in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients served by HPKC.

**Historical Patient Origin
HPKC
As of June 30, 2015**

County	IC	HH	PD
Davidson	8	0	13
Forsyth	2	0	1
Guilford	125	1	26
Randolph	18	0	7
Total	153	1	47

In Section C.1, page 23, the applicants identify the patient population proposed to be served for the first two years of operation following project completion on June 30, 2016, as summarized in the table below.

**Projected HPKC Patient Origin
 By County of Residence**

County	Operating Year 1 (OY1)			Operating Year 2 (OY2)			County Patients as % of Total	
	IC	HH	PD	IC	HH	PD	OY 1	OY2
Davidson	9.16	0.00	14.88	9.80	0.00	15.93	12.77%	13.20%
Forsyth	2.02	0.00	1.01	2.03	0.00	1.02	1.61%	1.56%
Guilford	132.61	1.06	27.58	136.59	1.09	28.41	85.62%	85.24%
Total	143.79	1.06	43.48	148.42	1.09	45.35	100.00%	100.00%

Totals may not sum due to rounding

The applicants provide the assumptions and methodology for the above projected patient origin on pages 23-24 of the application.

The applicants adequately identify the population to be served.

Analysis of Need

The applicants propose to add eight dialysis stations to the existing HPKC facility in Guilford County for a total of 40 certified dialysis stations upon completion of this project and Project ID #G-10262-14 (relocate 10 stations from HPKC to develop NRDC). In Section C.1, page 23, the applicants state the need for the proposed project is to:

“... pre-emptively curtail the need for a third shift at HPKC upon completion of the NRDC Project ID# G-10262-14, which will result in the transfer of 10 ICH stations from HPKC, Guilford County to NRDC, Randolph County, by approximately 6/30/2016.”

Projected Utilization

In Section C.7, pages 29-30, the applicants provide the methodology and assumptions used to determine the need to add eight dialysis stations to HPKC. The project is based upon the facility need methodology. HPKC is eligible to add as many as eight stations.

The applicants’ methodology is summarized below:

- Group the June 30, 2015 patient census by county of origin and modality.
- Apply the July 2015 SDR 5-year Average Annual Change Rate (AACR), by county of patient origin, to the current patient populations to project patient census through the end of Operating Year 2.
- Remove the Randolph County resident patients from the HPKC facility census because those patients will not be served at this facility as of June 30, 2016.
- Project need based upon service to non-Randolph County resident patients.

The applicants' assumptions are summarized below:

- As of June 30, 2016, 10 stations will be relocated to NRDC (Project ID #G-10262-14) and 18 existing (19 projected) Randolph County resident patients will transfer to NRDC.
- Project completion is June 30, 2016; OY1 ends June 30, 2017; OY2 ends June 30, 2018. The 5-year AACR as published in the July 2015 will remain an accurate indicator of patient growth through OY2.
- The remaining 32 in-center stations are inadequate to serve the remaining 139.32 non-Randolph County resident patients projected as of June 30, 2016.
- The patients remaining at HPKC prefer to continue receiving care at HPKC.

In Section C.2, page 26, the applicants provide the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project. At the end of OY1, June 30, 2017, the applicants project serving 143.79 in-center dialysis patients on 40 dialysis stations for a utilization rate of 89.86% (143.79 patients / 40 stations = 3.59 patients per station / 4 = 0.8986). At the end of OY2, the applicants are projecting an in-center patient census of 148.42 for a utilization rate of 92.76% (148.42 / 40 = 3.71 / 4 = .9276). The projected utilization of 3.59 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The following table illustrates the applicants' projection of in-center dialysis patients at HPKC (page 26).

HPDC Projected In-Center Dialysis Utilization

County	SDR AACR	Beginning Census 6/30/15	Growth until 6/30/2016	End of OY1 6/30/2017	End of OY2 6/30/18
Davidson	7.00%	8.00	8.56	9.16	9.80
Forsyth	0.50%	2.00	2.01	2.02	2.03
Guilford	3.00%	125.00	128.75	132.61	136.59
Total		135.00	139.32	143.79	148.42

On page 27, the applicants state that HPKC's home-hemodialysis and peritoneal dialysis populations are expected to experience growth also and the addition of stations at HPKC

will benefit them at times when backup treatments are required. The applicants also provide the growth projections for the home patients (HH and PD) on page 26, using the same assumptions.

The applicants adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section C.3, page 27, the applicants state:

“HPKC accepts patients based on medically defined admission criteria. 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.”

Exhibit L-3(a) contains the facility’s Referral/Admissions Policy. The applicants project payor mix in Section L.1(b), page 66 as follows:

**Projected Payor Mix
Project Year 2 (7/1/17 – 6/30/18)**

	Percent of Total Patients	Percent of In-center Patients	Percent of HH Patients	Percent of PD Patients
Commercial Insurance	7.95%	4.44%	0.00%	20.00%
Medicaid	5.11%	6.67%	0.00%	0.00%
Medicare	60.80%	62.96%	0.00%	55.00%
Medicare Advantage	21.02%	20.00%	100.00%	22.50%
VA	4.55%	5.19%	0.00%	2.50%
Private Pay	0.57%	0.74%	0.00%	0.00%
TOTAL	100.00%	100.00%	100.00%	100.00%

Totals may not sum due to rounding.

The applicants adequately demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicants adequately identify the population to be served, adequately demonstrate the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E.1, pages 33-35, the applicants discuss the alternatives considered prior to submitting this application, which include:

- 1) Maintain the Status Quo - the applicants state that upon relocation of the 10 stations and transfer of the 18 in-center and seven PD patients, the remaining HPKC patients cannot be adequately served by 32 dialysis stations. The utilization rate as of June 30, 2016 is projected to be 108.84%. Operations at greater than 100% leave no margin in patient shift scheduling to accommodate additional needs, which may arise. Thus, the applicants state that maintaining the status quo is not a viable option.
- 2) Submit an application for an in-county relocation of stations – the applicants state that relocating stations from Triad Dialysis Center, a WFUHS-owned facility in Guilford County, was considered. As of June 30, 2015, the facility's utilization rate was 84.09%. Relocating stations from Triad Dialysis Center would cause a need for additional stations at that location; therefore, the applicants state, an in-county relocation of stations is not a viable option.
- 3) Submit an application for additional stations based on Policy ESRD-2 – Policy ESRD-2 allows for relocation of dialysis stations within the host county and to contiguous counties currently served by the facility when a station deficit is not created in the county losing stations and a station surplus is not created in the county gaining stations. WFUHS owns operational dialysis facilities in

Davidson and Forsyth counties, both of which are contiguous to Guilford County. However, Guilford County has a 7-station surplus. Policy ESRD-2 does not allow a contiguous county transfer to create, or in this case increase, a county surplus in the county gaining stations; therefore this option is not viable.

- 4) Submit an application for additional stations based on the facility need methodology – the applicants state that the facility need methodology demonstrates that eight additional stations are needed at HPKC. Thus, the applicants state that utilizing the facility need methodology is the best option to serve HPKC’s existing and projected patient population.

After considering the above alternatives, the applicants state that adding stations based on the facility need methodology is the most cost-effective alternative for this project.

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 applicants adequately demonstrate that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Wake Forest University Health Sciences and High Point Kidney Center of Wake Forest University shall materially comply with all representations made in the certificate of need application.**
 - 2. Wake Forest University Health Sciences and High Point Kidney Center of Wake Forest University shall develop and operate no more than eight (8) additional dialysis stations for a total of 40 certified stations upon completion of this project and Project ID #G-10262-14 (relocate 10 stations to develop North Randolph Dialysis Center) which shall include any home hemodialysis training or isolation stations.**
 - 3. Wake Forest University Health Sciences and High Point Kidney Center of Wake Forest University shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicants propose to add eight dialysis stations to the existing HPKC facility for a total of 40 certified dialysis stations upon completion of this project and Project ID #G-10262-14, which relocates 10 stations from HPKC to develop a new dialysis facility in Randolph County.

Capital Costs

In Section F.1, page 36, the applicants project capital costs of \$133,600 for dialysis machines, equipment and furniture associated with the proposed project.

HPKC is an existing dialysis facility with an ongoing operation; therefore the applicants do not project any working capital needs.

Availability of Funds

In Section F.5, page 37, the applicants refer to Exhibit F-5 for a commitment letter of WFUHS funds and Exhibit F-7(a) for a copy of the most recent Wake Forest University consolidated balance sheet, which includes WFUHS. As of June 30, 2014, WFUHS had \$9,301 cash, \$1,432,129 in total assets and \$440,754 in unrestricted net assets (total assets less total liabilities less restricted net assets). The applicants adequately demonstrate the availability of funds for the capital and working capital needs of the project.

Financial Feasibility

In Exhibit R, Form C, the applicants provide the allowable charge per treatment for each payment source for both in-center and home dialysis patients. The revenue assumptions are provided in Section R, pages 89-91.

The applicants provide the following assumptions for patient treatments:

- Average annual patients per month calculations – page 89
- In-center treatments = patients x 3 treatments per week x 52 weeks (156 treatments per patient), reduced by 6% for missed treatments (147 treatments per patient)
- Home treatments = patients x 7 treatments per week x 52 weeks (365 treatments per patient), reduced by 10% for missed treatments (328 treatments per patient)

The applicants project revenues and summarize operating expenses in Exhibit R, Form B, as presented in the table below.

High Point Dialysis Center	Operating Year 1 7/1/16-6/30/17	Operating Year 2 7/1/17-6/30/18
Total Gross Revenue	\$ 53,386,072	\$ 54,830,095
Deductions from Gross	45,762,619	46,958,549
Net Revenue	7,623,453	7,871,546
Total Operating Expenses	5,851,590	5,993,746
Net Profit	\$ 1,771,863	\$ 1,877,800

Totals may not sum due to rounding

The applicants project that revenues will exceed operating expenses in each of the first two operating years. The applicants’ projections of treatments and revenues are reasonable based on the number of in-center, home hemodialysis and peritoneal patients projected for the first two operating years. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

In Section H.1, page 45, the applicants provide current and projected staffing and salaries. Form A in Exhibit R shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

In summary, the applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project. The applicants also adequately demonstrate that the financial feasibility of the project is based on reasonable projections of revenues and operating costs. 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

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

The applicants propose to add eight dialysis stations to the existing HPKC in Guilford County. The July 2015 SDR indicates there are seven dialysis facilities in Guilford County, as shown below. Two facilities are WFUHS facilities.

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/14	Percent Utilization	Patients Per Station
BMA of Greensboro (BMA)	56	74.11%	2.96
BMA of South Greensboro (BMA)	59	77.12%	3.08
BMA of Southwest Greensboro (BMA)	31	81.45%	3.26
FMC of East Greensboro (BMA)	35	75.00%	3.00
High Point Kidney Center (WFUHS)	42	84.52%	3.38
Northwest Greensboro Kidney Center (BMA)	25	87.00%	3.48
Triad Dialysis Center (WFUHS)	22	79.55%	3.18

Source: July 2015 SDR, Table A.

As illustrated above, each Guilford County facility is utilized above 70% as of December 31, 2014. Per the applicants, both WFUHS facilities are operating above the 3.2 patients per station or 80% utilization threshold as of June 30, 2015. In Section G, page 43, the applicants state that the June 30, 2015 utilization is 91.07% for HPKC and 84.09% for Triad Dialysis Center. On page 44, the applicants further state:

“HPKC’s need is real and immediate. HPKC does not project to serve patients currently served at other locations within Guilford County at WFUHS or competitor locations. HPKC projects to serve its current patient population plus growth based upon the 5-year AACR projected for its current patient base by county of origin as outlined in the most recent (July 2015) SDR.

...

Because ten (10) stations from HPKC are transferring from Guilford County into Randolph County, an add-back of eight (8) stations at HPKC to serve HPKC patients is actually a net two (2) station decrease for the service area of Guilford County. This further negates any notion that the proposed project is a duplication of existing or approved services in the proposed service area. The current projected Guilford County surplus of seven (7) stations will be reduced to a surplus of five (5) stations upon completion of this project (add back 8 stations) and Project ID#G-10262-14 (subtract 10 stations).”

The applicants adequately demonstrate the need for additional stations at HPKC based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicants adequately demonstrate that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Guilford County. Consequently, the application is conforming to this criterion.

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

C

The following table illustrates the projected salaried staffing for HPKC, as provided by the applicants in Section H.1, page 45.

	Current FTE Positions	FTE Positions to be added	Total FTE Positions	Current Annual Salary / FTE	Projected Salary Yr 2 /FTE
RN	5.90	0.00	5.90	\$52,227	\$57,070
LPN	1.80	0.00	1.80	\$38,278	\$41,827
Pt Care Tech	17.20	0.00	17.20	\$26,606	\$29,073
Clinical Nurse Manager	1.00	0.00	1.00	\$82,796	\$90,473
Dietician	2.00	0.00	2.00	\$56,170	\$61,379
Social Worker	2.00	0.00	2.00	\$57,321	\$62,636
Home Training Nurse	3.00	0.00	3.00	\$62,238	\$68,009
Dialysis Tech	2.00	0.00	2.00	\$27,515	\$30,066
Biomed	1.00	0.00	1.00	\$36,350	\$39,721
Clerical	4.05	0.00	4.05	\$30,524	\$33,354
Total FTE Positions	39.95		39.95		

The Medical Director, Administration and Medical Records positions are contract positions and are not salaried employees.

The following table reflects the applicants’ projected number of direct care staff FTE positions at HPKC for Operating Year 2, per page 51 of the application.

Projected Direct Care Staff Hours – Operating Year 2

Direct Care Positions	# FTEs* [a]	Hours / Year / FTE [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Treatment Hours ** [d]	FTE Hours / Total Treatment Hours [e] = [c] ÷ [d]
DON (Clinical Nurse Mgr)	1.00	2,080	2,080	3,198	0.65
RN	5.90	2,080	12,272	3,198	3.84
LPN	1.80	2,080	3,744	3,198	1.17
Patient Care Tech	17.20	2,080	35,776	3,198	11.19
HT Nurse	3.00	2,080	6,240	3,198	1.95
Total Facility	28.90	2,080	60,112	3,198	18.80

* FTEs should match the direct care Total FTE Positions [a+c] listed in the Facility Staffing table in Section H, Question 1.

** Total annual treatment hours from the Proposed Hours of Operation table in Section H, Question 6.

In Sections H.2 and H.3, pages 46-50, the applicants describe HPKC’s staff positions and responsibilities, management’s experience, the process for recruiting and retaining staff,

and staff training and continuing education. In Section I.3, page 55, the applicants state that Vicki Stovall, M.D. will serve as the Medical Director for the facility. In Exhibit I-3(a), the applicants provide a letter signed by Dr. Stovall confirming her commitment to continue to serve as Medical Director. Exhibit H-2 contains a copy of Dr. Stovall's curriculum vitae. In Section I.3(b), page 56, the applicants state that medical coverage is provided seven days per week and 24 hours a day by WFUHS physicians on a rotation basis or by local area nephrologists with privileges at the facility. Exhibit I-3(b) contains a list of referral physicians and physician letters of support.

The applicants adequately demonstrate the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section I, pages 53-57, the applicants describe the necessary ancillary and support services and indicate how they will be provided. Exhibit I.2(a) contains a copy of the affiliation agreement between the facility and North Carolina Baptist Hospital. Exhibit I.2(b) contains a copy of the transplant agreement. The applicants discuss coordination with the existing health care system on pages 53-57. Exhibit I.3(b) contains a list of referring physicians and physician support letters. The applicants adequately demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and referenced Exhibits is reasonable and supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

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

NA

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

C

In Section L.1, page 65, the applicants state:

“HPKC accepts patients based on medically defined admission criteria. 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.”

On page 69, the applicants further state that the admission of a patient is based upon medical necessity and not the patient's ability to pay. Exhibit L-3(a) contains a copy of HPKC's Referral/Admissions Policy.

In Section L.7, page 74, the applicants report that during the last full operating year, 85.08% of the patients who were receiving treatments at HPKC had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the facility's historical payment sources.

HISTORICAL PAYOR MIX

	Percent of Total Patients	Percent of In-center Patients	Percent of HH Patients	Percent of PD Patients
Commercial Insurance	8.46%	4.58%	0.00%	21.28%
Medicaid	4.98%	6.54%	0.00%	0.00%
Medicare	59.20%	62.09%	0.00%	51.06%
Medicare Advantage	20.90%	19.61%	100.00%	23.40%
VA	5.97%	6.54%	0.00%	4.26%
Private Pay	0.50%	0.65%	0.00%	0.00%
TOTAL	100.00%	100.00%	100.00%	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Guilford, Davidson, and Forsyth counties and statewide.

County	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Guilford	15.3%	5.9%	19.5%
Forsyth	16.1%	5.7%	19.5%
Davidson	17.2%	6.9%	18.4%
Statewide	16.5%	6.7%	19.7%

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

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.²

The applicants demonstrate that HPKC currently 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 applicants;

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

C

In Section L.3(d) page 72, the applicants state:

“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 B, Section C, and Section L, and strives to provide services to all patients with End Stage Renal Disease.”

In Section L.6, page 73, the applicants state, *“There have been no civil rights or equal access complaints filed against the existing facility and/or any facilities owned by the parent company in North Carolina in the past 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 applicants’ proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.1(b), page 66, the applicants provide the projected payor mix for the proposed services at HPKC, combined and by patient category, as shown below.

**Projected Payor Mix
Project Year 2 (7/1/17 – 6/30/18)**

	Percent of Total Patients	Percent of In-center Patients	Percent of HH Patients	Percent of PD Patients
Commercial Insurance	7.95%	4.44%	0.00%	20.00%
Medicaid	5.11%	6.67%	0.00%	0.00%
Medicare	60.80%	62.96%	0.00%	55.00%
Medicare Advantage	21.02%	20.00%	100.00%	22.50%
VA	4.55%	5.19%	0.00%	2.50%
Private Pay	0.57%	0.74%	0.00%	0.00%
TOTAL	100.00%	100.00%	100.00%	100.00%

Totals may not sum due to rounding.

In Section L.1(a), page 66, the applicants state:

“WFUHS and HPKC are committed to admitting and providing 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.”

On page 66, the applicants report that HPKC expects over 89% of the in-center patients who receive treatments at HPKC to have all or part of their services paid for by Medicare or Medicaid, as indicated above.

The applicants adequately demonstrate that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 72, the applicants state:

“Patients desiring treatment at the facility receive consideration for admission by contacting the Nurse Administrator, Medical Director, or facility Social Worker. New patients may be referred by a personal physician. ... Admission to the facility must be by a nephrologist with admitting privileges to the facility and the patient must be certified as suffering from chronic, irreversible, End Stage Renal Disease (ESRD).”

The applicants adequately demonstrate that HPKC will offer a range of means by which patients will have access to the proposed 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 Section M, page 77, the applicants state:

“The dialysis facilities of WFUHS pursue and participate in encouraging applicable training programs to utilize their facilities.”

Exhibit M-1 contains a copy of a professional training facility agreement between the facility and High Point University. The information provided in Section M and the referenced exhibit is reasonable and supports a finding of conformity with this criterion.

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

C

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

The applicants propose to add eight dialysis stations to the existing HPKC facility in Guilford County. The July 2015 SDR indicates there are seven dialysis facilities in Guilford County, as shown below.

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/14	Percent Utilization	Patients Per Station
BMA of Greensboro (BMA)	56	74.11%	2.96
BMA of South Greensboro (BMA)	59	77.12%	3.08
BMA of Southwest Greensboro (BMA)	31	81.45%	3.26
FMC of East Greensboro (BMA)	35	75.00%	3.00
High Point Kidney Center (WFUHS)	42	84.52%	3.38
Northwest Greensboro Kidney Center (BMA)	25	87.00%	3.48
Triad Dialysis Center (WFUHS)	22	79.55%	3.18

Source: July 2015 SDR, Table A.

As illustrated above, each Guilford County facility is utilized above 70% as of December 31, 2014. Per the applicants, both WFUHS facilities are operating above the 3.2 patients per station or 80% utilization threshold as of June 30, 2015. In Section G, page 43, the applicants state that the June 30, 2015 utilization is 91.07% for HPKC and 84.09% for Triad Dialysis Center.

In Section N.1, page 78, the applicants discuss how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicants state,

“This project shall have no impact on competition in Guilford County. Patients utilize a facility based upon physician preference, geographical location, or other reasons of convenience. An addition of stations at HPKC is necessary to serve the facility’s existing and projected patients and stave off excessive utilization upon the transfer of stations to NRDC (6/30/2016). ... However, if HPKC’s project is not approved and its facility utilization rate is allowed to soar above 100%, cost-effectiveness, quality, and access to services could be negatively impacted as patients will have to be scheduled for treatment at times that could reduce their access to transportation availability, which would increase the occurrence of missed treatments and have a detrimental effect on patient outcomes.”

See also Sections C, F, G, H, L and P where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicants in the sections referred to above is reasonable and adequately demonstrates that any enhanced competition in the service area includes 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 applicants adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate HPKC will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicants demonstrate HPKC will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (6) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section A.11, pages 5-6, the applicants identify the 17 kidney disease treatment centers located in North Carolina, which are owned and operated by the applicants or an affiliated company.

In Section O, pages 80-81, the applicants refer to Section B.4(a) and Exhibit O-1 for HPKC's methods used to insure and maintain quality. In Section O.3, the applicants provide a list of the WFUHS dialysis facilities which were surveyed during the last 18 months, listing two with no deficiencies and stating the deficiencies cited for the other six facilities. Copies of the surveys, deficiencies and plans of correction were provided by the applicants in Exhibit O-3(b). The applicants further state: "*All facilities are now in compliance.*"

Based on a review of the certificate of need application and publicly available data, the applicants adequately demonstrate that quality care has been provided during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

-C- In Section C.1, page 25, the applicants provide the historical utilization rates for

HPKC. The June 30, 2015 utilization is 3.64 patients per station or 91.07% with 153 patients dialyzing on 42 certified and/or approved stations. In Section C.2, page 26, the applicants provide the projected utilization rates for HPKC. The June 30, 2017 utilization is 3.59 patients per station or 89.86% with 143.79 patients dialyzing on 40 certified and/or approved stations.

.2202(a)(2) Mortality rates;

- C- In Section C.9, page 30, the applicants provide the mortality rates for HPKC from July 2013 through June 2015.

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

- C- In Section C.2, page 27, the applicants state that as of June 30, 2015, HPKC had 48 dialysis patients who were home trained and dialyzing at home.

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

- C- In Section C.10, page 31, the applicants report that HPKC referred eight patients for transplant evaluation from July 2014 through June 2015.

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

- C- In Section C.10, page 31, the applicants report that HPKC has 47 transplant patients currently on the transplant list.

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

- C- In Section C.11, page 31, the applicants report a total of 357 hospital admissions from July 2014 through June 2015 with 87 (24.37%) being dialysis related.

.2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.

- C- In Section C.10, page 31, the applicants report that HPKC had 32 patients with infectious disease, e.g. hepatitis and there were no conversions to infectious status as of June 30, 2015.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written

agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).

-NA- HPKC is an existing facility.

.2202(b)(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) composition of the assessment/evaluation team at the transplant center,*
- (C) method for periodic re-evaluation,*
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
- (E) Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- HPKC is an existing facility.

.2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

-NA- HPKC is an existing facility.

.2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.

-C- Exhibit K-1(f) contains written policies and procedures for back up electrical service in the event of a power outage.

.2202(b)(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.

-NA- HPKC is an existing facility.

.2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section B.4, page 12, the applicants state, “*The facility will continue to provide services in conformity with all applicable laws and regulations.*” See also Section H.2, page 46; Section K.1 (g), pages 60-61; and Exhibits K-1(f) and K-1(g).

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section C.1, page 23, the applicants provide projected patient origin by county for HPKC, based on the facility’s existing patient origin, adjusted for growth and relocation of stations and transfer of patients to Randolph County. The applicants’ methodology and assumptions for its projected patient origin are provided on pages 23-24 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- HPKC is an existing facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

-C- In Section P, page 86, the applicants refer to Section L.1(a), pages 65-66, where the applicants state:

“WFUHS and HPKC are committed to admitting and providing 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.”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- HPKC is an existing facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.2, page 26, the applicants propose to serve 143.79 in-center patients on 40 dialysis stations at the end of Operating Year 1, which equates to a utilization rate of 3.59 patients per station ($143.79 / 40 = 3.59$).

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

-C- In Section C.7, pages 29-30, the applicants provide the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) Diagnostic and evaluation services;

-C- In Section I.1, page 53, the applicants state that diagnostic and evaluation services are present on premises.

.2204(2) Maintenance dialysis;

-C- In Section I.1, page 53, the applicants state that maintenance dialysis services are present on premises.

.2204(3) Accessible self-care training;

-C- In Section I.1, page 53, the applicants state that accessible self-care training is present on premises.

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

-C- In Section I.1, page 53, the applicants state that accessible follow-up is present on premises.

.2204(5) X-ray services;

-C- In Section I.1, page 53, the applicants state that x-ray services will be provided by

Wake Forest Baptist Hospital. Exhibit I-2(a) contains an agreement documenting North Carolina Baptist Hospital's intention to provide the above services to the proposed facility.

.2204(6) Laboratory services;

- C- In Section I.1, page 53, the applicants state Wake Forest Baptist Hospital will provide lab services. Exhibit I-1(l) contains an agreement documenting Meridian Laboratory's intention to provide the above services to the proposed facility.

.2204(7) Blood bank services;

- C- In Section I.1, page 53, the applicants state that blood bank services will be provided by Wake Forest Baptist Hospital. Exhibit I-2(a) contains an agreement documenting North Carolina Baptist Hospital's intention to provide the above services to the proposed facility.

.2204(8) Emergency care;

- C- In Section I.1, page 53, the applicants state that emergency services will be provided by Wake Forest Baptist Hospital. Exhibit I-2(a) contains an agreement documenting North Carolina Baptist Hospital's intention to provide the above services to the proposed facility.

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

- C- In Section I.1, page 53, the applicants state that acute dialysis in an acute care setting will be provided by Wake Forest Baptist Hospital. Exhibit I-2(a) contains an agreement documenting North Carolina Baptist Hospital's intention to provide the above services to the proposed facility.

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

- C- In Section I.1, page 53, the applicants state that vascular surgery services will be provided by Wake Forest Baptist Hospital. Exhibit I-2(a) contains an agreement documenting North Carolina Baptist Hospital's intention to provide the above services to the proposed facility.

.2204(11) Transplantation services;

- C- In Section I.1, page 53, the applicants state that transplantation services will be provided by Wake Forest Baptist Hospital. Exhibit I-2(b) contains an agreement documenting North Carolina Baptist Hospital's intention to provide the above services to the proposed facility.

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

- C- In Section I.1, page 53, the applicants state that vocational rehabilitation counseling and services are present on premises and will be provided by appropriate referral after an initial evaluation by the social worker.

.2204(13) Transportation

- C- In Exhibit I.1(q), the applicants provide letters from various transportation providers in Guilford County documenting support for the project and a commitment to provide transportation services to HPKC patients.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).

- C- In Section H.1, page 45, the applicants provide a current and proposed staffing chart. In Section H.2, page 46, the applicants state the facility is in compliance with all requirements set forth in 42 C.F.R. Section 405 .2100, superseded by 42 C.F.R. Part 494. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference. Exhibit H-2 contains resumes of key staff.

.2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

- C- In Section H.4, page 50, the applicants discuss the required training for staff, and state that staff undergo intensive training and attend routine in-services and outside seminars and workshops, as applicable. Exhibit H-4 contains outlines of the OSHA In-Services and other annual in-services required for HPKC staff.