

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 20, 2012
PROJECT ANALYST: Fatimah Wilson
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: G-10031-12 / Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University / Relocate six dialysis stations from Lexington Dialysis Center to Thomasville Dialysis Center for a total of 24 stations at Thomasville Dialysis Center / Davidson County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Wake Forest University Health Sciences (“WFUHS”) and Thomasville Dialysis Center of Wake Forest University (“TVDC”) propose to permanently relocate six (6) dialysis stations from Lexington Dialysis Center (“LXDC”) to the existing 18 station TVDC facility in Davidson County for a total of 24 dialysis stations at TVDC and 30 at LXDC. TVDC proposes expanding its service capacity to accommodate an influx of Davidson County patients who have been receiving their care outside of Davidson County at High Point Kidney Center (“HPKC”). TVDC proposes this in-county transfer of dialysis stations in order to serve Davidson County residents within their home county. This project is scheduled for completion on June 30, 2013. In this application, the applicants propose to relocate dialysis stations between facilities. Therefore, neither the county need nor facility need methodologies in the 2012 State Medical Facilities Plan (SMFP) are applicable to this review. Additionally, Policy GEN-3 is not applicable because neither need methodology is applicable to the review. However, Policy ESRD-2 is applicable to this review. Policy ESRD-2 states:

“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 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 Dialysis Report.”

In summary, the applicants propose to relocate six existing certified dialysis stations within the host county of Davidson. Consequently, there is no change in inventory in Davidson County, so the application is consistent with Policy ESRD-2 of the 2012 SMFP and is therefore 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

Wake Forest University Health Sciences (“WFUHS”) and Thomasville Dialysis Center of Wake Forest University (“TVDC”) propose to relocate six (6) dialysis stations from Lexington Dialysis Center (“LXDC”) to the existing 18 station TVDC facility in Davidson County for a total of 24 dialysis stations at TVDC upon project completion. The applicants do not propose to establish new dialysis stations. This project is scheduled for completion on June 30, 2013. TVDC has an agreement with LXDC to provide home training in peritoneal and/or home hemodialysis.

Population to be Served

In Section IV.1, page 28, the applicants identify the population it serves, as illustrated in the table below.

County of Residence	# of In-Center Patients Dialyzing 06-30-2012	Percent of Total
Davidson	42	76.36%
Guilford	1	1.82%
Randolph	9	16.36%
Forsyth	3	5.46%
TOTAL	55	100.0%

In Section III.7, pages 23-24, the applicants provide projected patient origin for the first two years of operation following completion of the proposed project, as illustrated in the following table:

TVDC -Projected Patient Utilization

COUNTY	TVDC RENO./CONSTR. ENDING 6/30/2014 TVDC END OF OY1		TVDC RENO./CONSTR. ENDING 6/30/2015 TVDC END OF OY2		COUNTY PATIENTS AS A % OF TOTAL	
	ICH	Home	ICH	Home	Year 1	Year 2
	Forsyth	3.07	0	3.11	0	3.69%
Guilford	1.02	0	1.03	0	1.22%	1.28%
Randolph	10.85	0	11.91	0	13.04%	14.90%
Davidson	44.82	0	46.30	0	53.85%	57.88%
Davidson from TVDC [HPKC]	23.48		24.25	0	28.20%	30.32%
Davidson to TVDC [HPKC]			-6.61			-8.27%
TOTAL	83.23	0	79.98	0	100%	100%

Craig Smith, CON Section Chief, has previously indicated that patients are not partial patients, but rather are whole and that financial and utilization projections are rounded down to the whole number.

The applicants adequately identified the population proposed to be served.

Demonstration of Need

In Section III.3, page, 21, the applicants state that TVDC is applying to receive 6 dialysis stations from LXDC in order to accommodate 22 Davidson County resident patients who currently receive care at HPKC. Approximately 15 of the 22 Davidson County resident patients are anticipated to remain at TVDC after HPKC's project is complete. On page 21, the applicants state,

“The TVDC project is necessary because the HPKC building is over 20 years old. With 42 certified stations and an ever-growing patient population in number and in individual patient size, additional ‘work space’ is required in the bay treatment areas.”

The applicants state that upon completion of the HPKC proposed project, the 18 dialysis stations and HPKC patients who temporarily transferred to TDC will transfer back to HPKC upon project completion. The goal of the applicants in both applications is to treat displaced HPKC patients during development of its Certificate of Need proposal at locations most convenient to patient needs. Thus, the approval of the TVDC is a necessary element in the development of the proposed HPKC project.

In Section III.7, pages 23-27, the applicants provide the assumptions and methodology for the proposed project.

TVDC Projected Patient Utilization

County	5-Year AACR	Current 6/30/2012		TVDC Reno. / Constr. Ending 6/30/2014		TVDC Ending OY1 6/30/2015		TVDC Ending OY2 6/30/2016		County Patients as a % of Total	
		ICH	Home	ICH	Home	ICH	Home	ICH	Home	OY1	OY2
Forsyth	1.20%	3.00		3.07		3.11				3.69%	3.89%
Guilford	0.90%	1.00		1.02		1.03				1.22%	1.28%
Randolph	9.80%	9.00		10.85		11.91				13.04%	14.90%
Davidson	3.30%	42.00		44.82		46.30				53.85%	57.88%
Davidson from TVDC	3.30%			23.48		24.25				28.20%	30.32%
Davidson to TVDC	3.30%					-6.61					-8.27%
TOTAL		55.00		83.23		79.98				100.00%	100.00%
Projected Utilization of ICH Stations (3.2 Patients Per Station)		76.38%		86.70%		83.32%		N/A			
		18 Stations		24 Stations		24 Stations					

TVDC will keep the 6 ICH stations transferred from LXDC along with a majority of the Davidson County patients transferred from TVDC [HPKC]

LXDC Projected Patient Utilization

County	5-Year AACR	Current 6/30/2012		LXDC Reno. / Constr. Ending 6/30/2014		LXDC Ending OY1 6/30/2015		LXDC Ending OY2 6/30/2016		County Patients as a % of Total	
		ICH	Home	ICH	Home	ICH	Home	ICH	Home	OY1	OY2
Davidson	1.20%	103.00	16.00	109.91	17.07	113.54	17.84			94.80%	94.67%
Davie	2.80%	0.00	1.00	0.00	1.06	0.00	1.09			0.79%	0.78%
Forsyth	1.20%	1.00	0.00	1.02	0.00	1.04	0.00			0.76%	0.75%
Randolph	9.80%	0.00	1.00	0.00	1.21	0.00	1.32			0.90%	0.96%
Rowan	-0.50%	2.00	2.00	1.98	1.98	1.97	1.97			2.95%	2.84%
TOTAL		106.00	20.00	112.91	21.32	116.54	22.02			100.00%	100.00%
Projected Utilization of ICH Stations (3.2 Patients Per Station)		73.61%		94.10%		97.12%		N/A			
		36 Stations		30 Stations		30 Stations					

TVDC will keep the 6 ICH stations transferred from LXDC along with a majority of the Davidson County patients transferred from HPKC. As demonstrated above, the patients of LXDC will be well served by the stations remaining at the facility after transfer of six (6) ICH stations to TVDC.

“Methodology

1. The purpose of the three projects identified above and described below is to allow for physical improvements to the HPKC plant in order to better serve the existing and potential future patient populations.
2. Beginning patient population identified as of 06/30/2012 for each facility is the basis for determining future growth. (TDVC has 55 ICH patients as of that date.)
3. Application filed 9/15/2012 for 10/1/2012, review.
4. Decision for approval granted 90-150 days from beginning of review period (12/30/2012 – 02/28/2013.)
5. CON issued 31 days from date of approval (01/30/2013 – 03/29/2013.)
6. The base patient population was divided by county or origin and increased at the 5-year AACR by county as published in the July 2012 SDR.
7. Transfers of patients between facilities are demonstrated in the charts above and described more in detail below.
8. ...TVDC – Project complete. New stations (6 ICH) transferred from LXDC shall be certified, maximizing TVDC’s patient treatment capabilities to 24 ICH stations. Davidson County resident ICH patients from TVDC as demonstrated above shall transfer to TVDC. TVDC OY1 begins.

9. ...TVDC – OY2 begins less approximately 7 of the Davidson County resident patients transferred to HPKC 06/30/2013. The resulting utilization rate is reflected above. TVDC will keep all 6 stations it received from LXDC. LXDC's anticipated utilization rates are also demonstrated above.
10. ... TVDC – End of OY2.

Assumptions

1. The current patient population as of publication of the most recent SDR (July 2012) shall increase by the 5-year AACR by county of origin for at least the period of project development, OY1, and OY2.
2. The 5-year AACR accounts for patient deaths, and by design it indicates net average patient growth.
3. There are no outside indicators to suggest uncalculated growth or deaths shall occur.
4. Ending OY1 projected patient numbers were increased by the 5-year AACR by county of origin in order to project the ending OY2 patient population.”

As previously stated, patients are not partial patients, but rather are whole and that financial and utilization projections are rounded down to the whole number. The project analyst notes that the tables above do not include PY 2013; however the applicants confirmed that utilization projections for OY1 2014 include both the current and PY2013 patient utilization projections. The applicants project the facility will serve 83 in-center patients or 3.45 in-center patients per station per week ($83 / 24 = 3.4583$) by the end of Year One, which exceeds the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

In summary, the applicants adequately identify the population to be served, demonstrates the need the population has for six additional stations and the extent to which all residents of the area are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

C

In Section III.3(c), page 22, the applicants state that patient census and utilization rates for LXDC currently and projecting forward through OY1 and OY2 of the proposed project are included in Section III.7, page 24 as follows:

LXDC Projected Patient Utilization

County	5-Year AACR	Current 6/30/2012		LXDC Reno. / Constr. Ending 6/30/2014		LXDC Ending OY1 6/30/2015		LXDC Ending OY2 6/30/2016		County Patients as a % of Total	
		ICH	Home	ICH	Home	ICH	Home	ICH	Home	OY1	OY2
Davidson	1.20%	103.00	16.00	109.91	17.07	113.54	17.84			94.80%	94.67%
Davie	2.80%	0.00	1.00	0.00	1.06	0.00	1.09			0.79%	0.78%
Forsyth	1.20%	1.00	0.00	1.02	0.00	1.04	0.00			0.76%	0.75%
Randolph	9.80%	0.00	1.00	0.00	1.21	0.00	1.32			0.90%	0.96%
Rowan	-0.50%	2.00	2.00	1.98	1.98	1.97	1.97			2.95%	2.84%
TOTAL		106.00	20.00	112.91	21.32	116.54	22.02			100.00%	100.00%
Projected Utilization of ICH Stations (3.2 Patients Per Station)		73.61%		94.10%		97.12%		N/A			
		36 Stations		30 Stations		30 Stations					

TVDC will keep the 6 ICH stations transferred from LXDC along with a majority of the Davidson County patients transferred from HPKC. As demonstrated above, the patients of LXDC will be well served by the stations remaining at the facility after transfer of six (6) ICH stations to TVDC.

On page 23, the applicants state:

“The policy of WFUHS’s dialysis centers to accept patients based on medical necessity and not their ability to pay is in effect system-wide. Patients will continue to receive the same exemplary standard of care before, during, and after completion of this project. The Social Worker staff members at HPKC, TVDC, and TDC are already working in unison to prepare patients for the impending changes that will be necessary to ensure their care and will continue to strive to assist all patients, including underserved groups, in obtaining the care they need.”

Included is the payor mix for TVDC, which remains unaffected with the transfer in of TVDC Davidson County resident patients. A measure of care to underserved groups has long been the payor mix percentages contained in Section IV.1. Included in Section IV.1 is the payor mix for HPKC, currently, the payor mix for TDC, currently, and upon acceptance of the HPKC patients and stations, the payor mix for both facilities after transfer of stations and patients back from TDC to HPKC. The measure of care to those with some form of Medicare or Medicaid is greater than 80% of all patients, demonstrating a commitment to care for underserved groups.”

In summary, the applicants state that TVDC is applying to receive six (6) dialysis stations from LXDC in order to accommodate 22 Davidson County resident patients who currently receive care at HPKC. Approximately 15 of the 22 Davidson Country resident patients are anticipated

to remain at TVDC after HPKC's project is complete. Further, the applicants can demonstrate 3.2 patients per station for 30 stations (36 certified stations – 6 relocated stations to TVDC) at LXDC upon project completion. Although LXDC will be losing stations, the applicants have further demonstrated that the needs of the population presently served at both facilities will continue to be adequately met following the relocation of six stations to TVDC. Therefore, the application 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.

C

In a request for supplemental information, the applicants describe the alternatives considered prior to the submission of its application, which include:

- 1) Maintain the Status Quo – Do Nothing. This alternative is not consistent with Policy ESRD-2: Relocation of Dialysis Stations. The applicants are proposing to relocate existing stations within the host county in order to accommodate Davidson County residents who are currently being served at HPKC (Guilford County) in order to provide services within their host county.
- 2) Relocate six dialysis stations to TVDC from LXDC for a total of 24 stations at TVDC. The applicants state that the TVDC project is necessary because the HPKC building is over 20 years old and in need of renovation in order to accommodate the growing patient population in number and in individual patient size. The proposed project will serve displaced HPKC patients who wish to receive services within their county of residence, Davidson County. The applicants demonstrate that both facilities, TVDC and LXDC will be utilized at a rate greater than 80% upon project completion; therefore, as the ESRD patient population continues to increase, WFUHS must also provide access for the patients. The applicants believe that this is the most suitable alternative.

The applicants adequately demonstrated the need to relocate six additional dialysis stations based on the continued growth of the ESRD patient population in Davidson and surrounding counties and the facility's projected utilization. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable.

In summary, the applicants adequately demonstrate that the proposal is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application and in the supplemental information requested by the**

Certificate of Need Section. In those instances where representations conflict, Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University shall materially comply with the last-made representation.

- 2. Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University shall develop and operate no more than 24 dialysis stations at Thomasville Dialysis Center of Wake Forest University, which shall include any isolation stations.**
 - 3. Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University shall install plumbing and electrical wiring through the walls for six additional dialysis stations for a total of 24 dialysis stations which shall include any isolation stations.**
 - 4. Wake Forest University Health Sciences shall take the necessary steps to decertify six dialysis stations at Lexington Dialysis Center for a total of no more than 30 dialysis stations at Lexington Dialysis Center.**
 - 5. Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to insurance 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

In Section VIII.1, pages 49-50, the applicants states the capital cost is projected to be \$3,000. In Section IX, page 62, the applicants further state that there will be no start-up or initial operating expenses associated with the proposed project.

A letter dated September 10, 2012 was provided as supplemental information from the Chief Financial Officer and Executive Vice President of Wake Forest Baptist Medical Center, which states in part:

“...The project has been budgeted to cost approximately \$3,000, which consists of plumbing expenses associated with installing the transferred stations. Thomasville Dialysis Center is a subsidiary of Wake Forest University Health Sciences. Wake Forest University Health Sciences commits to provide monies to its subsidiaries in order to fund these cost.”

In Attachment D, the applicants provide audited financial statements for Wake Forest University Health Sciences for the years ended June 30, 2011 and 2010. As of June 30, 2011, WFUHS had cash and cash equivalents totaling \$36,418,000 with \$1,229,067,000 and \$669,880,000 in net assets (total assets less total liabilities). The applicants adequately demonstrated the availability of funds, if required for the proposed project.

In Section X.1, page 55, the applicants project the following charge per treatment for each payment source:

Source of Payment	Allowable Amount OY1 June 2015 (7/1/2013 – 6/30/2014)	Allowable Amount OY2 June 2016 (7/1/2014 – 6/30/2015)
Private Pay	\$1,019.70	\$1,050.29
Medicare	\$235.00	\$235.00
Medicaid	\$195.00	\$195.00
Medicare / Medicaid	\$235.00	\$235.00
Commercial Insurance	\$1,019.70	\$1,050.29
Medicare / Commercial	\$235.00	\$235.00
VA	\$252.00	\$252.00
Medicare Advantage	\$235.00	\$235.00

Source: Application pages 56-57

On page 55, the applicants state that revenue is calculated based on a bundled rate. The billable amount is the same for all payors, while the allowable amount varies according to contract terms.

On page 56, the applicants state that the drug administration, formerly a separate line item, is now included within the bundled billable and allowable rate by payor.

The applicants project net revenue in Section X.2, page 56 of the application and operating expenses in Section X.4, page 60 of the application. The applicants project revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	Operating Year 1	Operating Year 2
Net Revenue	\$3,281,236	\$2,949,062
Operating Expenses	\$2,611,605	\$2,569,636
Profit	\$669,631	\$379,426

The assumptions used in preparation of the *pro formas*, included in Section X.3, pages 56-59 are reasonable

In Section VIII.9, page 53, the applicants states, “*Equipment rates and management contract fees were negotiated at current industry market rates and through the experience of owning, operating, and managing freestanding dialysis facilities in excess of 20 years.*”

In Section VII.1, page 43 and Section X.4 and Section X.5 pages 60-61, the applicants provide projected staffing and salaries. On page 43, the applicants state that the facility is in compliance with all requirements of 42 C.F.R., Section 494 (formerly 405.2100). Staffing by shift is provided on page 48. The applicants project adequate staffing to provide dialysis treatments for the number of patients projected.

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

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

C

Wake Forest University Health Sciences (“WFUHS”) and Thomasville Dialysis Center of Wake Forest University (“TVDC”) propose to permanently relocate six (6) dialysis stations from Lexington Dialysis Center (“LXDC”) to the existing 18 station TVDC facility in Davidson County for a total of 24 dialysis stations at TVDC upon project completion. The applicants state that TVDC will use the six (6) relocated dialysis stations to accommodate 22 Davidson County resident patients who currently receive care at HPKC. Approximately 15 of the 22 Davidson County resident patients are anticipated to remain at TVDC after HPKC’s project is complete. The applicants state renovations at HPKC are needed because the facility is over growing patient population in number and in individual patient size. The applicants project that during project duration, both Davidson County facilities will add patients needing dialysis and that both TVDC and LXDC will both be utilized at a rate greater than 80% by the end of OY1. This conforms to Criterion (6) as required by 10A NCAC 14C .2203(b). The applicants adequately demonstrated that the relocation of six (6) dialysis stations from LXDC to TVDC will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

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

C

In Section VII.1, page 43, the applicants provide the current and projected number of full-time equivalent (FTE) positions following completion of the proposed project, as illustrated in the table below:

POSITION	TOTAL FTES YEARS 1 AND 2
RN	4.00
LPN	1.00
PCT	8.00
CNM	1.00
Medical Director position is salaried	
Admin.	0.10
Diet.	0.50
SW	0.50
Biomed	0.50
Dial. Tech	1.00
Clerical	2.00
Med. Rec. Contract position	
TOTAL	18.60

In Section VII.10, page 48, the applicants provide the direct care staff for each shift offered in the facility as shown in the table below:

OY1 Projected Schedule

	Times	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
Morning	6:30 – 12:00	N/A	21/7	21/7	21/7	21/7	21/7	21/7
Afternoon	12:01 – 5:00	N/A	21/7	21/7	21/7	21/7	21/7	21/7
Evening	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

As shown the table above, the applicants do not propose a 3rd shift for the proposed project. The applicants state in Section V.4 (c), page 33 Dr. Scott Satko will serve as the Medical Director for the facility. In Attachment R, the applicants provide a letter from Dr. Satko in support of the proposed project. The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with this criterion.

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

C

In Section V.1, page 30, the applicants list the providers of the necessary ancillary and support services. The applicants state the method for providing these services in response to 10A NCAC 14C .2204, beginning on page 15 of the application. Acute dialysis, emergency care, x-ray, blood bank, and transplantation services will be provided by Wake Forest Baptist Medical Center. Attachments E, F, J, K, L and Y contain documentation on service agreements to include: hospital affiliation agreement, transplantation agreement, home training agreement, laboratory agreement, and health agency affiliation agreements. The information

provided in Section V is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

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

NA

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

NA

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

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

C

In Section VI.1(a), page, 36, the applicants discusses TVDC’s history of providing dialysis services to the underserved populations of North Carolina. The applicants state:

“TVDC 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. TVDC’s Referral/Admission Policy can be found at Attachment S.”

On page 36, the applicants state that the currently, 40% of patients at TVDC have some or all of their services paid for by Medicare, 35% have some or all of their services paid for by Medicaid. Thus, 75% of the center revenue is derived from government payors. The table below illustrates the current historical payor mix for the facility.

ICH – CURRENT YEAR (07/01/2012 – 06/30/2013)	
PAYOR SOURCE	IN-CENTER
Private Pay	2.0%
Commercial Insurance	18.0%
Medicare	2.0%
Medicaid	35.0%
Medicare/Medicaid	7.0%
Medicare/Commercial	29.0%
State Kidney Program	5.0%
Medicare Advantage	2.0%
TOTAL	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Davidson County and Statewide.

	2010 Total # of Medicaid Eligible as % of Total Population	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population	2008-2009 % Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Davidson	17%	6.9%	18.4%
Statewide	17%	6.7%	19.7%

Source: <http://www.ncdhhs.gov/dma/countyreports/index.htm>

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by the TVDC facility. In fact, only 5.8% of all 2011 ESRD patients in North Carolina's Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The Centers for Medicare & Medicaid Services (CMS) website states,

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

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”¹

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

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

The report validates the statistical constancy reported by CMS above. Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues

¹ www.cms.gov/medicare/end-stage-renal_disease/esrdnetworkorgainziations/downloads/esrdnetworkprogrambackgroundpublic.pdf

to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”

The report provides 2010 ESRD spending, by payor as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender demonstrating the following:

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

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access

by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1(f), page 40, 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 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 applicants state, *“There have been no Civil Rights complaints filed against the existing facility and/or any facilities owned by the parent company in North Carolina in the last five years.”* The application is conforming to this criterion.

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

C

In Section VI.1(c), page 36, the projected payor mix for OY1 as indicated in this table.

Payor Source	In-Center
Private Pay	2.0%
Commercial Insurance	18.0%
Medicare	2.0%
Medicaid	35.0%
Medicare / Medicaid	7.0%
Medicare / Commercial	29.0%
State Kidney Program	5.0%
Medicare Advantage	2.0%
Total	100.0%

The project analyst notes that the projected payor mix for OY1 is the same as the current payor mix for the facility; thus, the applicants do not anticipate any change to the future payor mix as indicated in the table above. The applicants project that 75% of all in-center patients will have some or all of their services paid for by Medicare or Medicaid.

In Section VI.1(d), page 37, the applicants state, “*Admission of a patient is based upon medical necessity and not the patient’s ability to pay.*”

In Section VI.2, page 40, the applicants state the facility is designed and constructed to accommodate handicapped persons and according to the construction guidelines set forth in the 1978 Edition of the North Carolina Building Code, Life Safety Code, 1991 Edition, and Guidelines for Construction and Equipment of Hospitals and Medical Facilities.

The applicants demonstrate it will provide adequate access to elderly and medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5(a), page 40, 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 maybe referred by a personal physician. Once the appropriate medical documentation has been received, it is reviewed and the patient is considered for admission. 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 it will provide a range of means by which a person can access 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 V.3(c), page 33, the applicants state,

“WFUHS dialysis facilities also provide onsite experience and utilization by members of Health Sciences professional staff in its training program for students, fellows, nurse practitioners, and other appropriate staff members.”

Attachment Y contains copies of health agency affiliation agreements with East Davidson High School and Thomasville Senior High School. The applicants adequately demonstrate that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion.

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

C

Wake Forest University Health Sciences (“WFUHS”) and Thomasville Dialysis Center of Wake Forest University (“TVDC”) propose to relocate six (6) dialysis stations from Lexington Dialysis Center (“LXDC”) to the existing 18 station TVDC facility in Davidson County for a total of 24 dialysis stations at TVDC.

In Section V.7, page 35, the applicants discuss the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicants state its proposal to relocate six (6) dialysis stations from LXDC will facilitate the improvements to be made at HPKC by providing a treatment option for Davidson County patients who have been receiving their care in Guilford County an opportunity to dialyze in their resident county, thus, enhancing the quality of the ESRD patients’ lives. The applicants further state:

“...The tiered levels of authority and accountability ensure protocol is designed, implemented, and carried out in a manner that is consistent among all facilities. This leads to a higher level of care and better patient outcomes in all locations.

...

This project will have not impact on competition in Davidson County. TVDC is an existing facility. This is an in-county transfer of existing stations in a county where WFUH is the sole provider of dialysis services.

...

The facility has been engineered and constructed utilizing the most modern technology and operations to maintain energy efficient operations and to control operating costs.”

See Sections II, III, V, VI and VII. The information provided by the applicants in those sections are reasonable and credible and adequately demonstrates that relocating six dialysis stations to the existing TVDC facility will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- ◆ The applicants adequately demonstrate the need to relocate six (6) dialysis stations for a total of 24 certified dialysis stations upon completion of the proposed project. The applicants also demonstrate that the proposed project is a cost-effective alternative to meet the need to provide additional access to TVDC patients;
- ◆ The applicants have and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 and VII, pages 30-32, 33-34 and 43-48, respectively, and referenced attachments are reasonable and credible and demonstrates the provision of quality care.

In Section II.3, pages 16-17, the applicants describe the methods used to insure and maintain quality care:

“...Continuous quality care begins by providing state of the art facilities and the pursuit to ensure those facilities maintains sufficient stations and staffing to provide care to the ever-growing ESRD population.

See Section III, which describes the methods by which the applicant analyzes patient utilization data to ensure availability of services for the broadest possible range of patients and at times convenient to the patient’s schedule. Monitoring of patient utilization is key in maintaining staffing ratios, which ensure superior patient outcomes.

See Section IV, which describes the applicant’s historical experience in serving the ESRD patients of Guilford and surrounding counties. Close attention is paid to the indicators included in this section, and every effort is exhausted to ensure patient outcomes meet and/or exceed industry standards.

See Section V, which describes the applicant’s coordination with existing healthcare providers so that all patient care needs are encompassed through the care they receive at the facility. Patient care goes beyond the dialysis process undergone at the facility. WFUHS strives to address its patients’ overall state of well-being and undue stressors are alleviated when possible.

See Section VI, which describes the methods by which the facility's services are made available to patients. WFUHS offers services to the broadest range of patients possible. The dialysis facility staff assists patient sin completing the necessary steps to gain admission to the facility's services.

See Section VII, which describes the staffing complement of the facility and the qualification of key staffing members. Additionally, this section describes staffing ratios by the facility to maintain continuous quality care.

See Section VIII, which describes the financial responsibility of the proposed project and the commitment of the proponent to enhance access to services while maintaining a superior standard of care.

See Section X, which describes the detailed charges and annual operating costs. These charges and costs directly relate to the maintenance of patient care.

See Section XI, which describes site information, construction and design. The site chosen for the facility, as well as the construction and design of the facility, are all integral parts of the overall patient care experience.

See Section XII, which describes the proponent's efforts to deliver the proposed project in a timely manner."

- ◆ The applicants have and will continue to provide adequate access to medically underserved populations. In Section II.9, page 14, the applicants state:

"The facility is committed to admitting and providing dialysis services to patients who have no insurance or other source of payment, but for payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."

Therefore, the application is conforming to this criterion.

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

C

The applicant currently provides dialysis services as Thomasville Dialysis Center of Wake Forest University. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the

Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

Utilization rates;

.2202(a)(1)

- C- In Section IV.1, page 28, the applicants provide the current utilization rate for dialysis patients as of June 30, 2012 (55 patients / 28 stations = 3.0555 or 3.06 patients per station.)

Mortality rates;

.2202(a)(2)

- C- In Section IV.2, page 28, the applicants provide the mortality rates as 27.08%, 20.00%, 4.21% and 11.11% for 2009, 2010, 2011 and January 2012 – July 2012, respectively.

The number of patients that are home trained and the number of patients on home dialysis;

.2202(a)(3)

- NA- In Section IV.3, page 28, the applicants state that as of June 30, 2012, TVDC provides services to 0 HT patients. According to the applicants, TVDC is not certified for home training dialysis, only LXDC is certified for HT dialysis in Davidson County.

The number of transplants performed or referred;

.2202(a)(4)

- C- In Section IV.4, page 28, the applicants state from July 1, 2011 – June 30, 2012, there has been one patient at TVDC who has received kidney transplants.

The number of patients currently on the transplant waiting list;

.2202(a)(5)

-C- In Section IV.5, page 28, the applicants state, “As of July 2012, there are six (6) patients on the TVDC transplant waiting list.”

Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

.2202(a)(6)

-C- In Section IV.6, page 29, the applicants state that there were 115 total hospital admissions in 2011, 50 of which were dialysis related and 65 non-dialysis related.

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

.2202(a)(7)

-C- In Section IV.7, page 29, the applicants state that there were no patients with Hepatitis B or Tuberculosis, four patients with Hepatitis C and one HIV Positive patient at facility.

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

.2202(b)(1)

For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100

-NA-

Thomasville Dialysis Center of Wake Forest University 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-

Thomasville Dialysis Center of Wake Forest University 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-

Thomasville Dialysis Center of Wake Forest University 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-

See Attachment H for a copy of letter from Carolina Caterpillar documenting that electrical service will be provided for 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- Thomasville Dialysis Center of Wake Forest University 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 XI.6(g), page 66, the applicants state, "The facility will continue to provide services in conformity with all applicable laws and regulations. The management of the facility has already established the appropriate relationships with the appropriate community service providers such as transportation agencies, fire department, EMS, police, utility company, and community educators and leaders. These relationships not only ensure that the services are provided in conformity with applicable laws and regulations, but also serves to keep the community apprised of the services provided by the facility and to educate the community regarding the special needs of the ESRD patient."*
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section III.7, pages 23-27 for the methodology and assumptions the applicants used project patient origin as presented in the following table:

TVDC Projected Patient Utilization

County	5-Year AACR	Current 6/30/2012		TVDC Reno. / Constr. Ending 6/30/2014		TVDC Ending OY1 6/30/2015		County Patients as a % of Total	
		ICH	Home	ICH	Home	ICH	Home	OY1	OY2
Forsyth	1.20%	3.00		3.07		3.11		3.69%	3.89%
Guilford	0.90%	1.00		1.02		1.03		1.22%	1.28%
Randolph	9.80%	9.00		10.85		11.91		13.04%	14.90%
Davidson	3.30%	42.00		44.82		46.30		53.85%	57.88%
Davidson from TVDC	3.30%			23.48		24.25		28.20%	30.32%
Davidson to TVDC [HPKC]	3.30%					-6.61			-8.27%
TOTAL		55.00		83.23		79.98		100.00%	100.00%
<i>Projected Utilization of</i>		76.38%		86.70%		83.32%			

<i>ICH Stations (3.2 Patients Per Station)</i>	<i>18 Stations</i>	<i>24 Stations</i>	<i>24 Stations</i>
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TVDC will keep the 6 ICH stations transferred from LXDC along with a majority of the Davidson County patients transferred from TVDC [HPKC]

.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- Thomasville Dialysis Center of Wake Forest University is an existing facility

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

- C- In Section II, page 14, the applicants state, *“The facility is committed to admitting and providing dialysis services to patients who have no insurance or other source of payment.”*

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- Thomasville Dialysis Center of Wake Forest University is an existing facility
- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section III.7, page 23, the applicants project to serve 83 in-center patients by the end of Year 1, which is 3.45 patients per station ($83 / 24 = 3.4583$). Also, see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- The applicants provide all assumptions, including the methodology by which patient utilization is projected in Section III.7, pages 25-27. The applicants project an increase in its current Davidson County patient utilization using the county 5-year AACR.

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 Attachment E, the applicants provide a hospital agreement with Wake Forest Baptist Medical Center for the provision of inpatient care, and other hospital services to include x-ray services, blood bank, emergency care, acute dialysis, and vascular surgery.
- .2204(2) *Maintenance dialysis;*
 - C- In Section V.1, page 30, the applicants state that maintenance dialysis is present on the premises.
- .2204(3) *Accessible self-care training;*
 - C- Attachment J contains a copy of a home training center program agreement with LXDC.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- Attachment J contains a copy of a home training center program agreement with LXDC.
- .2204(5) *X-ray services;*
 - C- In Attachment E, the applicants provide a hospital agreement with Wake Forest Baptist Medical Center for the provision of inpatient care, and other hospital services to include x-ray services.
- .2204(6) *Laboratory services;*
 - C- Attachment K contains a copy of a laboratory agreement with Meridian Laboratory Corporation.
- .2204(7) *Blood bank services;*
 - C- In Attachment E, the applicants provide a hospital agreement with Wake Forest Baptist Medical Center for the provision of inpatient care, and other hospital services to include blood bank services.
- .2204(8) *Emergency care;*
 - C- In Attachment E, the applicants provide a hospital agreement with Wake Forest Baptist Medical Center for the provision of inpatient care, and other hospital services to include emergency care services.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- In Attachment E, the applicants provide a hospital agreement with Wake Forest Baptist Medical Center for the provision of inpatient care, and other hospital services to include x-ray services, blood bank, emergency care, acute dialysis, and vascular surgery.
- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- In Attachment E, the applicants provide a hospital agreement with Wake Forest Baptist Medical Center for the provision of inpatient care, and other hospital services to include vascular surgery.
- .2204(11) *Transplantation services;*
 - C- In Attachment F, the applicants provide a hospital agreement with Wake Forest Baptist Medical Center for the provision of transplantation services.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
 - C- In Section V.1, page 30, the applicants state that vocational rehabilitation and counseling services are provided on the premises with the appropriate referral after initial evaluation by the MSW.
- .2204(13) *Transportation*
 - C- Attachment L contains a copy of a letter from the Davidson County transportation manager documenting transportation services by the Davidson County Transportation System for dialysis 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.

-C- In Section VII.2, page 43, the applicants state that TVDC will comply with all staffing requirements set forth in 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.

.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 VII.5, page 46, the applicants state that staff members of the facility undergo an intensive training period and attend routine in-services provided in the facility as well as outside seminars and workshops applicable to their position and responsibilities. An outline of the training/orientation program and continuing education program offered at the facility can be found in Attachment M.