

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-11074-15

Facility: Lexington Dialysis Center of Wake Forest University

FID #: 944660

County: Davidson

Applicants: Wake Forest University Health Sciences, and
Lexington Dialysis Center of Wake Forest University

Project: Relocate 4 dialysis stations from Piedmont Dialysis Center for a total of 37
dialysis stations upon completion of this project and Project ID #G-11004-15

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 Lexington Dialysis Center of Wake Forest University (LXDC), also referred to as “the applicants”, propose to add four dialysis stations for a total of 37 dialysis stations at the existing LXDC facility via Policy ESRD-2 by relocating four stations from Piedmont Dialysis Center in Forsyth County. LXDC is located at 233 Anna Lewis Drive, Lexington, Davidson 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 deficit of 7 dialysis stations in Davidson County; however, the county need methodology states:

“If a county’s December 31, 2015 projected station deficit is less than 10 or if the utilization of any dialysis facility in the county is less than 80 percent, the county’s December 31, 2015 station need determination is zero.”

The projected deficit is less than 10; therefore, the July 2015 SDR does not indicate additional stations are needed based on the county need methodology.

The applicants are eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for LXDC in the July 2015 SDR is 3.50 patients per station, which is greater than the required 3.2 patients per station threshold. This utilization rate was calculated based on 105 in-center dialysis patients and 30 certified dialysis stations. (105 patients / 30 stations = 3.50 patients per station).

However, application of the facility need methodology indicates only one additional station is 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		87.50%
Certified Stations		30
Pending Stations		3
Total Existing and Pending Stations		33
In-Center Patients as of 12/31/14 (SDR2)		105
In-Center Patients as of 6/30/14 (SDR1)		103
Step	Description	
	Difference (SDR2 - SDR1)	2
(i)	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.0388
(ii)	Divide the result of Step (i) by 12	0.0032
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.0388
(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	109.0777
(v)	Divide the result of Step (iv) by 3.2 patients per station	34.0868
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	1.0868

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 1 station. 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 applicant proposes to add four stations per Policy ESRD-2 by relocating existing stations from an existing Forsyth County dialysis facility. Therefore, the facility need determination for dialysis stations is not applicable to this review.

In summary, neither the county nor the facility need methodologies in the 2015 SMFP are applicable to this review.

Policies

There is one policy in the 2015 SMFP which is applicable to this review. *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 32 of the 2015 SMFP 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 shall:

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

The applicants propose to relocate four stations from Forsyth County to Davidson County. Forsyth County is contiguous to Davidson County. WFUHS locations in Forsyth County currently serve Davidson County resident dialysis patients and LXDC currently serves Forsyth County resident dialysis patients. *Table B: ESRD Dialysis Station Need Determinations by Planning Area*, in the July 2015 SDR shows a surplus of 25 dialysis stations in Forsyth County; therefore, relocating four stations from Forsyth County (*“the county that would be losing stations”*) will not result in a deficit in Forsyth County. *Table B* in the July 2015 SDR shows a deficit of seven stations for Davidson County, therefore, adding four stations to Davidson County (*“the county that would gain stations”*) will not result in a surplus of dialysis stations. Therefore, the application is consistent with Policy ESRD-2 in the 2015 SMFP.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS*. Therefore, the application is conforming to this criterion.

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

C

The applicants propose to add four dialysis stations for a total of 37 dialysis stations at the existing LXDC facility via Policy ESRD-2 by relocating four stations from Piedmont Dialysis Center in Forsyth 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 Davidson 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 LXDC.

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

County	IC	HH	PD
Davidson	106	2	17
Forsyth	2	0	0
Randolph	0	0	1
Rowan	3	0	2
Union	0	0	1
Total	111	2	21

In Section C.1, page 22, the applicants identify the patient population LXDC proposes to serve for the first two years of operation following project completion on June 30, 2016, as summarized in the table below.

**Projected LXDC 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	121.36	2.29	19.46	129.85	2.45	20.83	83.73%	83.86%
Forsyth	2.02	0.00	0.00	2.03	0.00	0.00	1.18%	1.11%
Randolph	0.00	0.00	0.00	0.00	0.00	0.00	0.00%	0.00%
Rowan	3.29	0.00	2.20	3.45	0.00	2.30	3.21%	3.15%
Union	0.00	0.00	1.07	0.00	0.00	1.11	0.63%	0.61%
Davidson County Patients Dialyzing in Forsyth County	12.84	0.00	6.42	13.74	0.00	6.84	11.25%	11.27%
Total	139.51	2.29	29.15	149.07	2.45	31.11	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 22-23. Exhibit C-7 includes support letters from patients currently dialyzing at LXDC and letters from Davidson County residents currently dialyzing outside of Davidson County.

The applicants adequately identify the population to be served.

Analysis of Need

The applicants propose to relocate four dialysis stations from Piedmont Dialysis Center in Forsyth County to the existing LXDC facility in Davidson County for a total of 37 certified dialysis stations upon project completion. In Section C.2, pages 24-27, the applicants state the need for the proposed project is based on the following factors:

- The current in-center patient population at LXDC as of June 30, 2015.

- The Davidson County resident in-center patients dialyzing in Forsyth County.
- Growth in the home-hemodialysis and peritoneal dialysis populations.

Projected Utilization

In Section C.7, pages 29-30, the applicants provide the methodology and assumptions used to determine the need to relocate four dialysis stations to LXDC. The project is based upon Policy ESRD-2. Davidson County has a 7-station deficit that will decrease to 3. Forsyth County has a 25-station surplus that will decrease to 21.

The applicants' methodology is summarized below:

- Group the existing 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 and add the existing Davidson County resident patients currently receiving care in Forsyth County to the LXDC census as of June 30, 2016, using the Davidson County 5-year AACR of 7.0%, as published in the July 2015 SDR.

The applicants' assumptions are summarized below:

- As of June 30, 2016, 12 in-center and 6 PD patients dialyzing in Forsyth County are Davidson County residents and will transfer to LXDC with the relocation of the stations. Five of the 12 in-center patients will transfer from Piedmont Dialysis Center along with the relocation of the four stations. The other seven transfers are assumed to come from the other three WFUHS Forsyth County dialysis facilities.
- As of June 30, 2015, LXDC has a patient population of 111 in-center, 2 home hemodialysis and 20 peritoneal dialysis patients.
- The patient population as published in the July 2015 SDR will increase by the 5-year AACR by county of origin through Operating Year 2. Project completion is June 30, 2016; OY1 ends June 30, 2017; OY2 ends June 30, 2018.
- Randolph County resident patients will transfer to a Randolph County facility upon project completion, June 30, 2016.

In Section C.2, page 26, the applicants provide the calculations used to arrive at the projected in-center patient census for Operating Year 1, ending December 31, 2017 and Operating Year 2, ending December 31, 2018, as shown above and on page 22 of the application. At the end of Operating Year 1, the applicants project serving 139.51 in-center dialysis patients on 37 dialysis stations for a utilization rate of 94.26% ($139.51 \text{ patients} / 37 \text{ stations} = 3.770 \text{ patients per station} / 4 = 0.9426$). At the end of Operating Year 2, the applicants are projecting an in-center patient census of 149.08 for a utilization rate of 100.72% ($149.08 / 37 = 4.029 / 4 = 1.007$). The projected utilization of 3.77

patients per station per week for Operating Year 1 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 LXDC (page 26), by county of resident origin.

LXDC 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%	106.00	113.42	121.36	129.85
Forsyth	0.50%	2.00	2.01	2.02	2.03
Randolph	4.80%	0.00	0.00	0.00	0.00
Rowan	4.80%	3.00	3.14	3.29	3.45
Union	3.60%	0.00	0.00	0.00	0.00
Davidson Co. Patients Transferring from Forsyth Co. (12 patients as of 6/30/16)	7.00%	0.00	0.00	12.84	13.74
Total		111.00	118.57	139.51	149.08

The Project Analyst developed the following table using the applicants' methodology and assumptions and the applicable AACR for each county, as published in the July 2015 SDR. The following table shows the AACRs as published in the SDR. The applicants' table does not use the SDR published AACRs for Rowan and Union counties. As the totals of the two tables illustrate, the difference in the AACRs had an insignificant impact on the resulting projections and is therefore irrelevant.

Project Analyst's Calculations

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%	106.00	113.42	121.36	129.85
Forsyth	0.50%	2.00	2.01	2.02	2.03
Randolph	4.80%	0.00	0.00	0.00	0.00
Rowan	8.60%	3.00	3.26	3.54	3.84
Union	4.10%	0.00	0.00	0.00	0.00
Davidson County Patients Dialyzing in Forsyth County	7.00%	0.00	0.00	12.84	13.74
Total		111.00	118.69	139.76	149.47

An analysis of the table in Section C, page 26, shows that on June 30, 2016, upon the relocation of the four stations and prior to any transfer of patients, the utilization at LXDC is 80.12%, based on the growth of the current existing patient population only.

On page 27, the applicants state that LXDC’s home-hemodialysis and peritoneal dialysis populations are expected to experience growth also and the addition of stations at LXDC will benefit them at times when backup treatments are required.

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:

“LXDC 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 further state that 94% of all services provided is to those without commercial insurance coverage, including but not limited to low income persons, racial and ethnic minorities, women, the handicapped, and the elderly as well as other underserved groups. The applicants project payor mix on page 69 as follows:

**Projected Payor Mix
Operating 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	6.58%	5.60%	0.00%	11.11%
Medicaid	4.61%	5.60%	0.00%	0.00%
Medicare	54.61%	55.20%	100.00%	44.44%
Medicare Advantage	24.34%	23.20%	0.00%	29.63%
VA	9.21%	8.00%	0.00%	14.81%
Private Pay	0.66%	0.80%	0.00%	0.00%
TOTAL	100.00%	100.00%	100.00%	100.00%

Totals may not sum due to rounding. Percent of In-center patients sums to a total of only 98.4%.

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.

C

The applicants propose to add four dialysis stations to the existing Lexington Dialysis Center for a total of 37 stations upon completion of this project by relocating four existing dialysis stations from Piedmont Dialysis Center in Forsyth County. The July 2015 SDR states that Piedmont Dialysis Center had 62 certified dialysis stations with 145 in-center patients for a utilization rate of 58.47%, as of December 31, 2014. According to *Table B: ESRD Dialysis Station Need Determinations by Planning Area* in the July 2015 SDR, the AACR for the past five years for Forsyth County is only 0.5%.

In Section D, page 33, the applicants state:

“PDC, the host facility, as of 6/30/2015, serves 136 ICH patients with 62 stations at a utilization rate of 54.84%. With the removal of 5 Davidson County resident ICH patients and 4 ICH stations, the resulting census and patient utilization would be 131 ICH patients / 58 stations / 56.47% utilization or 1.77 patients per stations.

...

The proposed project will have no impact on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care.”

Based on the applicants’ data on Piedmont Dialysis Center’s June 30, 2015 utilization and the utilization published in the last six SDRs, utilization has declined from 139 patients and 56.05% utilization on 62 stations as of June 30, 2012 to 136 patients and 54.84% utilization as of June 30, 2015.

The applicants adequately demonstrate that the needs of the population presently served at Piedmont Dialysis Center will be adequately met following the relocation of four stations to LXDC. 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.

CA

In Section E.1, pages 34-37, the applicants discuss the alternatives considered prior to submitting this application, which include:

- 1) Maintain the Status Quo - the applicants state that failure to develop additional capacity at the LXDC facility would result in utilization rates near 100% and require the operation of a third shift, which the applicants state can be *“trying on patients, caregivers, and transportation resources particularly in winter months”*

The applicants state, *“... it is evident that LXDC has a need for at least 4 additional ICH stations.”* 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 Thomasville Dialysis Center in Davidson County was considered. As of June 30, 2015, the facility’s utilization rate was 90.6%. The applicants expect 16 Randolph County in-center patients dialyzing at Thomasville to transfer to North Randolph Dialysis Center upon its certification in 2016. However, with the projected growth of the facility’s non-Randolph County resident patient population, once the Randolph County patients transfer out, Thomasville Dialysis Center will have a projected utilization rate of 79.14%, or almost 80%. Relocating stations from Thomasville Dialysis Center would cause a need for additional stations at that location; therefore, an in-county relocation of stations is not a viable option.
- 3) Submit an application for additional stations based on the facility need methodology – the applicants state that once the three CON-approved stations at LXDC are certified, the facility need methodology will only allow for an increase of 1 additional station for a total of 34 stations. Thus, the applicants state that utilizing the facility need methodology is not the best option to serve LXDC’s existing and projected patient population.
- 4) 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 Guilford and Forsyth counties, both of which are contiguous to Davidson County.

- a. Contiguous County of Guilford – The July 2015 SDR shows Guilford County has a 7-station surplus. However, the applicants state that both WFUHS facilities in Guilford County are at greater than 80% utilization. Therefore relocation of stations from either of those facilities would increase their utilization rates and diminish their ability to provide services to their existing patients.
- b. Contiguous County of Forsyth – The July 2015 SDR shows Forsyth County has a 25-station surplus. The WFUHS facility, Piedmont Dialysis Center, provides in-center and home dialysis services to Davidson County residents with ESRD. The applicants state:

“With 62 ICH stations and a utilization rate of approximately 54%, PDC can provide stations for this project without hampering its ability to care for the patients it currently serves.”

Based on the December 31, 2014 data in the July 2015 SDR, reducing the Piedmont Dialysis Center stations to 58 with no reduction in in-center patients results in a utilization rate of only 62.5% ($145 / 58 = 2.5 / 4 = 62.5\%$). The Forsyth County five-year AACR of 0.50% would project a utilization rate of only 63.4% by the end of the proposed project’s second year of operation.

After considering the above alternatives, the applicants state that a relocation of stations from Piedmont Dialysis Center in Forsyth County to LXDC in Davidson County is the most cost-effective and the most viable option for this project; it reduces a surplus of stations in Forsyth County and reduces a deficit of stations in Davidson County.

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 Lexington Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application.**

- 2. Wake Forest University Health Sciences shall relocate no more than four (4) certified dialysis stations to Lexington Dialysis Center of Wake Forest University for a total of no more than 37 certified dialysis stations, which shall include any home hemodialysis training or isolation stations, upon completion of this project and Project ID #G-11004-15.**
 - 3. Wake Forest University Health Sciences and Lexington Dialysis Center of Wake Forest University shall install plumbing and electrical wiring through the walls for no more than four (4) additional dialysis stations for a total of 37 dialysis stations, which shall include any home hemodialysis training or isolation stations.**
 - 4. Wake Forest University Health Sciences shall take the necessary steps to decertify four (4) dialysis stations at Piedmont Dialysis Center for a total of no more than 58 dialysis stations at Piedmont Dialysis Center upon project completion.**
 - 5. Wake Forest University Health Sciences and Lexington Dialysis 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 four dialysis stations to the existing LXCD facility for a total of 37 certified dialysis stations upon project completion.

Capital Costs

In Section F.1, pages 38-39, the applicants state that there are no capital cost associated with the proposed project.

LXDC 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 39, the applicants refer to Exhibit F-5 for a commitment letter acknowledging the proposed project 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 92-94.

The applicants provide the following assumptions for patient treatments:

- Average annual patients per month calculations – page 92
- 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.

Lexington Dialysis Center	Operating Year 1 7/1/16-6/30/17	Operating Year 2 7/1/17-6/30/18
Total Gross Revenue	\$ 47,335,631	\$ 50,787,839
Deductions from Gross	\$ 40,494,262	\$ 43,402,696
Net Revenue	\$ 6,841,369	\$ 7,385,143
Total Operating Expenses	\$ 4,670,140	\$ 4,896,299
Net Profit	\$ 2,171,229	\$ 2,488,844

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 47, 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 Davidson County. Facilities may also serve residents of counties not included in their service area.

The applicants propose to add four dialysis stations to the existing Lexington Dialysis Center in Davidson County. The July 2015 SDR indicates there are two dialysis facilities in Davidson County, as shown below. Both facilities are WFUHS facilities.

Davidson County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/14	Percent Utilization	Patients Per Station
Lexington Dialysis Center*	30	87.50%	3.50
Thomasville Dialysis Center	24	88.54%	3.54

Source: July 2015 SDR, Table A.

*Certificate issued June 15, 2015 (G-11004-15) to add 3 stations for a total of 33.

As illustrated above, both facilities are well-utilized, operating at 3.5 patients per station or 88% utilization. In Section G, pages 45-46, the applicants state that the June 30, 2015 utilization is 92.5% for LXDC and 90.6% for Thomasville Dialysis Center. The applicants further state:

“LXDC does not project to serve patients currently served at other locations within Davidson County nor Randolph County patients projected to transfer to NRDC upon its certification. LXDC 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 along with Davidson County ESRD patients currently receiving care at WFUHS locations in Forsyth County.

...

Because Davidson County has a seven (7) station deficit [sic] the notion that the proposed project is a duplication of existing or approved services in the proposed service area is further negated. The current projected Davidson County deficit of

seven (7) stations will be reduced to a deficit of three (3) stations upon completion of this project and the surplus of 25 stations in Forsyth County will be reduce [sic] to a surplus of 21 stations. Thus, this project through its provision of services to existing LXDC patients and Davidson County ESRD patients traveling to Forsyth County for ESRD services does not result in an unnecessary duplication of the existing and approved facilities in the proposed service area. There will still be a three (3) station deficit in the proposed service area once this project is complete.”

The applicants adequately demonstrate the need for additional stations at LXCD 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 Davidson 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 LXDC, as provided by the applicants in Section H.1, page 47.

	Current FTE Positions	FTE Positions to be added	Total FTE Positions	Current Annual Salary / FTE	Projected Salary Yr 2 /FTE
RN	4.75	0.00	4.75	\$52,349	\$57,203
LPN	1.80	0.00	1.80	\$40,752	\$44,531
Pt Care Tech	12.75	0.00	12.75	\$25,733	\$28,119
Clinical Nurse Manager	1.00	0.00	1.00	\$75,122	\$82,088
Dietician	0.80	0.00	0.80	\$50,748	\$55,453
Social Worker	1.00	0.00	1.00	\$44,427	\$48,547
Home Training Nurse	1.00	0.00	1.00	\$55,857	\$61,037
Dialysis Tech	3.00	0.00	3.00	\$27,962	\$30,555
Biomed	1.00	0.00	1.00	\$50,001	\$54,637
Clerical	3.00	0.00	3.00	\$29,312	\$32,030
Total FTE Positions	30.1		30.1		

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 LXDC for Operating Year 2, per page 53 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 Annual 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	4.75	2,080	9,880	3,198	3.09
LPN	1.80	2,080	3,744	3,198	1.18
Patient Care Tech	12.75	2,080	26,520	3,198	8.29
HT Nurse	1.00	2,080	2,080	3,198	0.65
Total	21.30	2,080	44,304	3,198	13.85

* 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 48-52, the applicants describe LXDC’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 57, the applicants state that Amret Hawfield, M.D. will serve as the Medical Director for the facility. In Exhibit I-3(a), the applicants provide a letter signed by Dr. Hawfield confirming his commitment to continue to serve as Medical Director. Exhibit H-2 contains a copy of Dr. Hawfield’s curriculum vitae. In Section I.3(b), page 58, the applicants state that medical coverage is provided by Wake Forest physicians on a rotation basis, seven days per week and 24 hours a day.

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 55-59, 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 LXDC 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 56-59. 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 68, the applicants state:

“LXDC 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 72, 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 LXDC’s Referral/Admissions Policy.

In Section L.7, page 77, the applicants report that during the last full operating year, 83.58% of the patients who were receiving treatments at LXDC 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

SOURCE OF PAYMENT	Percent of Total Patients
Commercial Insurance	6.72%
Medicaid	5.22%
Medicare	53.73%
Medicare Advantage	24.63%
VA	9.70%
Total	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 Davidson, Forsyth, Randolph, Rowan and Union 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) *
Davidson	17.2%	6.9%	18.4%
Forsyth	16.1%	5.6%	19.5%
Randolph	18.6%	7.2%	19.5%
Rowan	18.7%	7.6%	19.0%
Union	10.9%	3.4%	18.0%
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

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:

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

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 LXDC 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;

C

In Section L.3(d) page 75, 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.”

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

In Section L.6, page 76, 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 69, the applicants provide the projected payor mix for the proposed services at LXDC, combined and by patient category. The combined payor mix for all patients is shown below.

**LXDC Projected Payor Mix
Project Year 2**

SOURCE OF PAYMENT	Percent of Total Patients
Commercial Insurance	6.58%
Medicaid	4.61%
Medicare	54.61%
Medicare Advantage	24.34%
VA	9.21%
Private Pay	0.66%
Total	100.00%

In Section L.1(a), page 69, the applicants state:

“WFUHS and LXDC 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 69, the applicants report that LXDC expects over 83% of the dialysis patients who receive treatments at LXDC 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 75, 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 LXDC 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 80, 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 Davidson Community College. 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 Davidson County. Facilities may also serve residents of counties not included in their service area.

The applicants propose to add four dialysis stations to the existing Lexington Dialysis Center in Davidson County. The July 2015 SDR indicates there are two dialysis facilities in Davidson County, as shown below. Both facilities are WFUHS facilities.

Davidson County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/14	Percent Utilization	Patients Per Station
Lexington Dialysis Center*	30	87.50%	3.50
Thomasville Dialysis Center	24	88.54%	3.54

Source: July 2015 SDR, Table A.

*Certificate issued June 15, 2015 (G-11004-15) to add 3 stations for a total of 33.

As illustrated above, both facilities are well-utilized, operating at 3.5 patients per station or 88% utilization as of December 31, 2014. In Section G, pages 45-46, the applicants state that the June 30, 2015 utilization is 92.5% for LXDC and 90.6% for Thomasville Dialysis Center.

In Section N.1, page 81, 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 Davidson County. WFUHS is the sole provider of dialysis services. An addition of stations at LXDC is necessary to serve the facility’s existing and projected patients and stave off excessive utilization.

...

However, if LXDC’s project is not approved and its facility utilization rate is allowed to soar above 100%, cost-effectiveness, quality, and access to the proposed 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 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 LXDC will continue to provide quality services. The discussions regarding quality found in Criterion (20) are incorporated herein by reference.
- The applicants demonstrate LXDC 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 83-84, the applicants discuss the 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 of the eight facilities 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.2, page 26, the applicants provide the historical and projected utilization rates for LXDC. The June 30, 2015 utilization is 3.75 patients per station or 84.09% with 111 patients dialyzing on 33 certified and/or approved stations.

.2202(a)(2) Mortality rates;

- C- In Section C.9, page 31, the applicants provide the mortality rates for LXDC 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, LXDC had 23 dialysis patients who are 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 LXDC referred five 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 LXDC has 14 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 290 hospital admissions from July 2014 through June 2015 with 89 (30.69%) 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 LXDC has 12 patients with infectious disease, e.g. hepatitis and there were no conversions to infectious status from July 2014 through June 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- LXDC 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- LXDC 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- LXDC 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- LXDC 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 11, the applicants state, “*The facility will continue to provide services in conformity with all applicable laws and regulations.*” See also Section H.2, page 48; Section K.1 (g), pages 63-64; 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 22, the applicants provide projected patient origin by county for LXDC, based on the facility’s existing patient origin, adjusted for growth and transfer of patients to Randolph and Davidson counties. The applicants’ methodology and assumptions for its projections are provided on pages 22-23 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- LXDC 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 89, the applicants refer to Section L.1(a), page 68, where the applicants state:

“WFUHS and LXDC 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- LXDC 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 24, the applicants propose to serve 139.51 in-center patients on 37 dialysis stations at the end of Operating Year 1, which equates to a utilization rate of 3.77 patients per station ($139.5 / 37 = 3.77$).

.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 55, the applicants state that diagnostic and evaluation services are present on premises.

.2204(2) Maintenance dialysis;

- C- In Section I.1, page 55, the applicants state that maintenance dialysis services are present on premises.

.2204(3) Accessible self-care training;

- C- In Section I.1, page 55, 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 55, the applicants state that accessible follow-up is present on premises.

.2204(5) X-ray services;

- C- In Section I.1, page 55, 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 55, the applicants state Meridian Laboratory will provide on-site 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 55, 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 55, 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 55, 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 55, 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 55, 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 55, 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 a letter from the transportation manager at Carolina Custom Transportation documenting support for the project and a commitment to provide transportation services to LXDC 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 47, the applicants provide a current and proposed staffing chart. In Section H.2, page 48, 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 52, 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 LXDC staff.