

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 5, 2015

Findings Date: June 5, 2015

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: G-11004-15

Facility: Lexington Dialysis Center

FID #: 944660

County: Davidson

Applicant: Wake Forest University Health Sciences and Lexington Dialysis Center of Wake Forest University

Project: Proposes to add 4 dialysis stations for a total of 34 stations; Approved to add 3 dialysis stations for a total of 33 stations upon project completion

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.

CA

Wake Forest University Health Sciences (WFUHS) and Lexington Dialysis Center of Wake Forest University (Lexington Dialysis) propose to add four dialysis stations to the existing facility for a total of 34 certified dialysis stations upon completion of this project. Lexington Dialysis is located at 233 Anna Lewis Drive, Lexington, Davidson County.

Need Determination

The 2015 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations.

According to the January 2015 SDR, the county need methodology indicates there is no need for additional stations in Davidson County. However, the applicants are eligible to apply for additional stations based on the facility need methodology, because the utilization rate reported for Lexington Dialysis in the January 2015 SDR is 3.43 patients per station. This utilization rate was calculated based on 103 in-center dialysis patients and 30 certified dialysis stations as of June 30, 2014 (103 patients / 30 stations = 3.43 patients per station).

Application of the facility need methodology indicates Lexington Dialysis has the potential need for three additional stations, as illustrated in the following table.

April 1 Review – January SDR		
Required SDR Utilization		80.00%
Center Utilization Rate as of 6/30/14		85.83%
Certified Stations		30
Pending Stations		0
Total Existing and Pending Stations		30
In-Center Patients as of 6/30/14 (SDR2)		103
In-Center Patients as of 12/31/13 (SDR1)		100
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.0600
(ii)	Divide the result of step (i) by 12	0.0050
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.0300
(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	106.09
(v)	Divide the result of step (iv) by 3.2 patients per station	33.15
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed (31 stations)	3.15

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

ten stations.” However, the applicants propose to add four stations based on their calculations in the table provided in Section III.2, page 20 of the application. An analysis of the table shows that the applicants did not follow the steps, as described on page 365 of the 2015 SMFP, for calculating the facility need. Step 3.b.iii states:

“The quotient from 3.B.ii is multiplied by 6 (the number of months from June 30, 2014 until December 31, 2014) for the January 2, 2015 SDR and by 12 (the number of months from December 31, 2014 until December 31, 2015) for the July 1, 2015 SDR.”
[emphasis added]

Step 4 of the applicants’ table on page 20 corresponds to Step 3.b.iii in the 2015 SMFP methodology. The applicants erroneously multiplied by 12 instead of 6, as described in the SMFP. This results in a factor of 0.06, instead of the correct factor of 0.03, inflating the applicants’ Step 5 (Step 3.b.iv in the 2015 SMFP methodology) to 109.18 and resulting in a potential need for four stations, instead of three.

Based on the facility need methodology for dialysis stations, as described in the 2015 SMFP and calculated above by the Project Analyst, the potential number of stations needed is three stations; therefore, the applicants are limited to the addition of a maximum of three stations.

The applicants are consistent with the facility need determination for dialysis stations, subject to Conditions (2) and (3) in Criterion (4).

Policies

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

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

Promote Safety and Quality – The applicants describe how they believe the proposed project would promote safety and quality in Section II, pages 16-17, Section XI.6(g), page 69, and referenced attachments. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote safety and quality.

Promote Equitable Access - The applicants describe how they believe the proposed project would promote equitable access in Section VI, pages 33-40, and referenced attachments. The information provided by the applicants is reasonable and adequately supports the determination that the applicants' proposal would promote equitable access.

Maximize Healthcare Value - The applicants describe how they believe the proposed project would maximize healthcare value in Section II, pages 18-19, Section VIII, page 48, and referenced attachments. The information provided by the applicants is reasonable and adequately supports the determination that the applicants' proposal would maximize healthcare value.

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

Conclusion

In summary, the applicants adequately demonstrate that the application is consistent with the facility need methodology in the January 2015 SDR and Policy GEN-3 and therefore is conforming to this criterion, subject to Conditions (2) and (3) of Criterion (4), limiting the addition of stations to "no more than three additional dialysis stations for a total of no more than 33 certified dialysis stations,"

- (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

WFUHS and Lexington Dialysis propose to add four dialysis stations to the existing Lexington Dialysis facility for a total of 34 dialysis stations upon completion of this project. However, as discussed in Criterion (1), application of the facility need methodology results in the potential need for a maximum of three stations; therefore, the applicants are limited to the addition of three stations for a total of 33 dialysis stations.

Population to be Served

In Section IV.1, page 25, the applicants state the number of patients served at Lexington Dialysis, as of February 28, 2015, as illustrated below.

County of Residence	Number of ICH Patients*	Number of Home Patients
Davidson	103	19
Forsyth	2	0
Randolph	0	2
Rowan	4	1
Union	0	1
Total	109	23

* In-Center Hemodialysis (ICH)

In Section III.7, page 22, the applicants identify the projected patient origin for Lexington Dialysis’s patients for the first two years of operation following completion of the project, as illustrated below.

County	Operating Year 1 (OY 1)		Operating Year 2 (OY 2)		County ICH Patients	
	(1/16 – 12/16)		(1/17 – 12/17)		as a % of Total	
	ICH	Home	ICH	Home	OY 1	OY 2
Davidson	105.88	20.12	108.95	20.70	95.15%	95.11%
Forsyth	1.00	0.00	1.00	0.00	0.90%	0.87%
Rowan	4.39	1.10	4.60	1.15	3.95%	4.02%
Union	0.00	1.07	0.00	1.11	0.00%	0.00%
Randolph	0.00	0.00	0.00	0.00	0.00%	0.00%
Total	111.28	22.29	114.56	22.96	100.00%	100.00%

The applicants adequately identify the population Lexington Dialysis proposes to serve.

Analysis of Need

The applicants propose to add four additional stations; however, the facility need methodology limits the facility to an additional three stations, as discussed in Criterion (1). In Section III.7, pages 22-23, the applicants provide the assumptions and methodology used to determine the need for additional stations and to project Lexington Dialysis’s patient utilization as summarized below.

1. The applicants identify a beginning patient population of 100 in-center patients, as of December 31, 2014.

2. The beginning patient population is increased per year by the Five Year Average Annual Change Rate (5-year AACR) published in the January 2015 SDR, by county of patient origin, through the end of OY 2.
3. The 5-year AACR accounts for patient deaths and indicates the net average patient growth.
4. There are no outside indicators to suggest uncalculated growths or deaths.
5. The project is scheduled for completion and certification of stations on December 31, 2015.
6. OY 1 is the period from January 1, 2016 through December 31, 2016, and OY 2 is the period from January 1, 2017 through December 31, 2017.
7. Randolph County home patients will transfer to the CON-approved North Randolph Dialysis Center in Randolph County once that facility is certified in 2016; thus, they are removed from projections and pro forma calculations for OY1 and OY2.

Projected Utilization

Using the beginning patient population and increasing it per year by the published 5-year AACR by county of patient origin, the following table demonstrates the applicants' calculations used to arrive at the projected in-center patient census for the first two operating years.

County	5 Yr AACR	Current		Interim Year		Operating Year 1 (OY 1)		Operating Year 2 (OY 2)		County ICH Patients	
		12/31/2014 ICH	Home	1/1/15-12/31/15 ICH	Home	1/1/16-12/31/16 ICH	Home	1/1/17-12/31/17 ICH	Home	OY 1 as a % of Total	OY 2 as a % of Total
Davidson	2.90%	100.00	19.00	102.90	19.55	105.88	20.12	108.95	20.70	95.15%	95.11%
Forsyth	0.00%	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	0.90%	0.87%
Rowan	4.80%	4.00	1.00	4.19	1.05	4.39	1.10	4.60	1.15	3.95%	4.02%
Union	3.60%	0.00	1.00	0.00	1.04	0.00	1.07	0.00	1.11	0.00%	0.00%
Randolph	5.70%	0.00	2.00	0.00	2.11	0.00	0.00	0.00	0.00	0.00%	0.00%
Total		105.00	23.00	108.09	23.75	111.28	22.29	114.56	22.96	100.00%	100.00%

Assuming the addition of three stations for a total of 33 stations, at the end of operating year one, the applicants are projecting an in-center patient census of 111 patients for a utilization rate of 84.09% or 3.36 patients per station ($111 / 33 = 3.36$; $3.36 / 4 = .8409$). At the end of operating year two, the applicants are projecting an in-center patient census of 115 patients for a utilization rate of 87.12% or 3.48 patients per station ($115 / 33 = 3.48$; $3.48 / 4 = .8712$).

Projected patient in-center utilization at the end of operating year one is 3.36 in-center patients per station per week which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The applicants adequately demonstrate the need the population has for the proposed services.

Access

In Section VI, page 33, the applicants state

“The WFUHS dialysis centers accept 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, WFUHS dialysis facilities also accept the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need.”

The applicants project 83% of their in-center patients will be covered primarily by Medicare and Medicaid payors (Medicare, Medicaid, Medicare/Medicaid, Medicare/Commercial and Medicare Advantage). 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

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

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

NA

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

CA

In Section III.9, pages 23-24, the applicants discuss the alternatives considered prior to submission of this application, which include:

- 1) Maintain the status quo – the applicants state Lexington Dialysis could continue to operate with the existing 30 stations and reach greater than 90% utilization. The applicants state this alternative is not effective because it will require action later. The applicants further state that failure to act now could soon result in utilization rates approaching 100%. Additionally, WFUHS serves 12 Davidson County residents at other kidney disease treatment centers in neighboring counties as well as 21 Davidson County resident home patients. The applicants state if any of these patients want to transfer to Lexington Dialysis or the home patients need in-center services, there would be few, if any, daytime treatment slots available.
- 2) Add less than the maximum number of stations allowable under the facility need methodology calculations - the applicants state that the cost and time involved in filing a CON application and the minimal impact on utilization rates which would be achieved by filing for less than the maximum number makes this alternative less cost-effective than filing for the maximum allowed.
- 3) Relocate one or more stations from Piedmont Dialysis Center via Policy ESRD-2 - the applicants state this alternative is not as effective because Lexington Dialysis needs more stations than could be relocated from Piedmont. Additionally, Piedmont Dialysis Center is not currently serving any Davidson County residents who wish to transfer their care.

The applicants state that the chosen alternative, to apply to expand the existing Lexington Dialysis facility by adding the maximum allowable stations under the facility need methodology (add three stations for a total of 33), is the most effective or least costly alternative for meeting the needs of the patients projected to receive treatment at Lexington Dialysis based on the following:

- It prevents the inevitable rise in utilization beyond 90%;
- It allows patients greater service options during normal business hours and keeps them off dangerous wintertime roads at night;
- It will not create a surplus of dialysis stations in Davidson County;
- It will correct the existing facility utilization rate to a more manageable level; and
- It is the most economical alternative long term.

Furthermore, the application is conforming or conditionally 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 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 and Lexington Dialysis Center of Wake Forest University shall develop and operate no more than three additional dialysis stations for a total of no more than 33 certified dialysis stations upon completion of this project, which shall include any isolation or home hemodialysis stations.**
 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 three additional dialysis stations for a total of no more than 33 certified dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **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 Certificate of Need Section 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

In Section VIII, page 48, the applicants project a capital cost of \$70,800 for the project, which includes \$62,000 for dialysis machines, \$4,800 for dialysis chairs, \$3,200 for televisions and \$800 for plumbing expenses. In Section IX, page 53, the applicants state that start-up and initial operating expenses would not apply to this project because Lexington Dialysis is not a new facility.

On page 50, the applicants indicate the project will be funded with accumulated reserves from Wake Forest University Health Sciences. Attachment D contains a letter on Wake Forest Medical Center letterhead, dated March 15, 2015, from the Chief Financial Officer, which states:

"Lexington Dialysis Center is a non-profit subordinate of Wake Forest University Health Sciences. Wake Forest University Health Sciences commits to provide monies to its subordinates in order to fund these costs."

Attachment D also contains the audited financial statements for Wake Forest University Health Sciences and Affiliates for the years ended June 30, 2014 and 2013. Page 8 of the notes to the

financial statements provides information on an “Integration Agreement” bringing Wake Forest University Baptist Medical Center and Wake Forest University Health Sciences, along with other university entities, under a single management and debt structure, operated by Wake Forest Baptist.

As of June 30, 2014, Wake Forest University Health Sciences and Affiliates had \$51,439,000 in cash and cash equivalents, \$2,990,464,000 in total assets and \$1,775,344,000 in net assets (total assets less total liabilities). The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 54, the applicants project the allowable charges per treatment for each payment source, based on allowable rates in effect for WFUHS dialysis facilities as of March 15, 2015, as shown below.

Payor	Allowable ICH Charge per Treatment	Allowable Home Charge per Treatment
Private Pay	\$1,500.00	\$641.10
Medicare	\$238.00	\$103.00
Medicaid	\$180.00	\$77.00
Medicare / Medicaid	\$238.00	\$103.00
Commercial	\$1,057.00	\$455.00
Medicare / Commercial	\$238.00	\$103.00
VA	\$246.00	\$106.60
Medicare / Advantage	\$281.75	\$120.75

On pages 54-63, the applicants project revenues and expenses for dialysis treatments for the first two operating years, as shown in the following two tables.

Lexington Dialysis Gross Revenue by Modality

	Current		Operating Year 1 (OY 1) 1/1/16-12/31/16		Operating Year 2 (OY 2) 1/1/17-12/31/17	
	ICH	Home	ICH	Home	ICH	Home
Projected Gross Revenue	\$23,593,500	\$4,836,458	\$25,467,750	\$4,857,450	\$27,470,441	\$5,332,175

WFUHS dialysis facilities’ billable revenue, which is used to calculate gross revenue, is increased by 5% in OY1 and OY2.

**Lexington Dialysis Projected Revenue
 In-center and Home Dialysis Services**

	Current	Operating Year 1 (OY 1) 1/1/16-12/31/16	Operating Year 2 (OY 2) 1/1/17-12/31/17
Projected Gross Revenue*	\$ 28,429,958	\$ 30,325,200	\$ 32,802,616
Projected Deductions**	\$ 23,024,945	\$ 24,856,799	\$ 27,180,971
Projected Net Revenue	\$ 5,405,014	\$ 5,468,401	\$ 5,621,644
Projected Operating Costs	\$ 4,029,556	\$ 4,329,515	\$ 4,419,714
Projected Net Profit	\$ 1,375,458	\$ 1,292,129	\$ 1,308,433

Totals may not sum due to rounding.

*WFUHS dialysis facilities' billable revenue, which is used to calculate gross revenue, is increased by 5% in OY1 and OY2.

**Projected deductions include Indigent/Charity Care, Bad Debt, and Contractual Allowances from page 55 of the application.

As illustrated in the tables above, the applicants project revenues will exceed operating expenses in each of the first two operating years following completion of the project. In checking the figures provided by the applicant on pages 55 and 62, the Project Analyst found errors in the calculations for operating years one and two. Total operating costs on page 62 were overstated by the applicant by \$103,266 and \$89,759 (approximately 2%) in the first and second year of operation, respectively. Furthermore, additional calculation errors result in the applicant overstating profit in the second operating year by \$16,744 (1.3%). These calculation errors are insignificant and do not affect the financial feasibility of the project.

The applicants' projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. Operating costs and revenues are based on reasonable assumptions including projected utilization. See Section X.3, pages 59-61, for the applicants' assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section VII.1, page 41, the applicants provide projected staffing and salaries. The financials in Section X.4-5, pages 62-63, budget adequate operating costs to cover the projected staffing.

In summary, the applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project. The applicants also adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of operating costs and charges. Therefore, the application is conforming with 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 and Lexington Dialysis propose to add four dialysis stations to the existing Lexington Dialysis facility for a total of 34 certified dialysis stations; however, as discussed in Criterion (1) and incorporated herein by reference, the facility need methodology limits the facility to the addition of no more than three dialysis stations for a total of no more than 33 certified dialysis stations, upon completion of this project.

The January 2015 SDR reports two approved and operational kidney dialysis treatment centers in Davidson County: Lexington Dialysis Center and Thomasville Dialysis Center, both owned and operated by WFUHS. Based on the facility need methodology, the applicants are eligible to add three additional stations to their existing facility. The applicants adequately demonstrate the need for three additional stations based on the number of in-center patients they proposed to serve. The discussions regarding analysis of need and competition found in Criteria (3) and (18a), respectively, are 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. 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 current and projected staffing for Lexington Dialysis, as provided by the applicants in Section VII.1, page 41.

Position	Current and Projected Full-Time Equivalent (FTEs)
RN	6.25
Patient Care Technician	1.75
Clinical Nurse Manager	12.50
Medical Director	Contract Position
Director of Nursing	1.00
Dietician	0.80
Social Worker	1.00
Home Training RN	1.00
Dialysis Technician	3.00
Biomedical Technician	1.00
Clerical	3.00
Total FTEs	31.30

As shown in the above table, the applicants propose to continue to employ the same number of FTE positions, a total of 31.30, to staff Lexington Dialysis upon completion of the proposed project.

The applicants provide the projected number of direct care staff for each shift offered at Lexington Dialysis in the second year of operation, as indicated in the table below.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6:30 am – 12:00 pm	12	12	12	12	12	12
Afternoon	12:01 pm – 5:00 pm	12	4	12	4	12	4
Evening	N/A	0	0	0	0	0	0

The applicants discuss the staffing schedule in Section VII.10, pages 45-47, noting on page 46, that with the addition of stations, the same number of direct care staff can care for a greater number of patients per shift and continue to maintain a 3:1 patient to staff ratio. On page 47, the applicants further state:

“Once the project is approved and the new stations are operational, the Nurse Administrator and Medical Director will assess the shift schedule and assign appropriate times for dialysis and staffing. As patient census increases, staffing numbers will be adjusted accordingly to ensure safe, quality care of the patients.”

The applicants project 113 average patients (111 and 115 at the beginning and end of the year, respectively) and 34 total stations in the second operating year. However, the applicants will have a total of 33 stations for the projected 113 average patients; therefore, changes in the proposed staffing schedules would be reasonable and expected.

In Section V.4, page 31, the applicants state that Amret Hawfield, M.D. will serve as medical director of the facility. Attachment R contains a letter from Dr. Hawfield stating his intention to continue as the medical director for Lexington Dialysis. Attachment R also contains physician letters of support and referrals. See Attachment S for a list of Wake physicians with privileges at WFUHS kidney disease treatment centers and a list of local referring physicians.

The applicants document 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 V, page 27, the applicants provide information regarding the provision of necessary ancillary and support services at Lexington Dialysis. Attachment K contains a copy of a Meridian Laboratory agreement for lab services. Attachments E and F respectively, contain copies of an affiliation agreement and a transplant agreement with North Carolina Baptist Hospital. Attachment L contains documentation from providers of transportation services. The applicants discuss coordination with the existing health care system in Section V, pages 28-32. The applicants adequately demonstrate that the necessary ancillary and support services will continue to be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

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

C

In Section VI.1(b), page 33, the applicants state that 83% of the in-center patients who received treatment at Lexington Dialysis had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical payment sources for the facility.

Lexington Dialysis Payor Mix

Sources of Payment	ICH %	Home%
Private Pay	1.00%	0.00%
Medicare	17.00%	10.00%
Medicaid	8.00%	4.00%
Medicare/Medicaid	20.00%	18.00%
Commercial Insurance	6.00%	13.00%
Medicare Commercial	22.00%	30.00%
VA	10.00%	12.00%
Medicare Advantage	16.00%	13.00%
Total	100.00%	100.00%

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 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 County	17.0%	6.9%	18.4%
Statewide	17.0%	6.7%	19.7%

*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 dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).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. However, a direct comparison to the applicants’ current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, minorities or women utilizing health services.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis”*² (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.” (p. 216).

¹ <http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

² www.usrds.org/adr.aspx

The 2013 *USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

The applicants demonstrate that they currently provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

- (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, page 37, the applicants state

“The facility has no obligation to provide uncompensated care or community service. The facility is accessible to minorities and handicapped persons... .”

In Section VI.6, page 39, the applicants state there have been no patient civil rights or equal access complaints filed within the last five years. Therefore, 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, page 33, the applicants provide the projected payor mix for the proposed services at Lexington Dialysis, which is shown below.

Lexington Dialysis Payor Mix

Sources of Payment	ICH %	Home%
Private Pay	1.00%	0.00%
Medicare	17.00%	10.00%
Medicaid	8.00%	4.00%
Medicare/Medicaid	20.00%	18.00%
Commercial Insurance	6.00%	13.00%
Medicare Commercial	22.00%	30.00%
VA	10.00%	12.00%
Medicare Advantage	16.00%	13.00%
Total	100.00%	100.00%

The applicants project no change from the current payor mix for dialysis services. Approximately 83% of the in-center patients and 75% of the home patients are projected to have some or all of their services covered by Medicare and Medicaid. The applicants demonstrate that medically underserved populations would 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 VI.5, pages 37-38, and Attachments E, F and S, the applicants describe the range of means by which patients will have access to the proposed services. The applicants adequately demonstrate that Lexington Dialysis will offer a range of means by which a person can access the 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, pages 29-30, the applicants state the Wake Forest Outpatient Dialysis Program participates with multiple community colleges and university systems in North Carolina to provide clinical observation and hands-on learning experiences for students. See Attachment Y for a copy of the Agreement of Affiliation with Davidson Community College. The information provided in Section V.3 and the referenced attachment 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

Lexington Dialysis proposes to add four dialysis stations to the existing Davidson County facility for a total of 34 stations; however, the facility need methodology results in a potential need for

three stations. The discussion regarding the facility need methodology in Criterion (1) is incorporated herein by reference. Therefore, the applicants are limited to the addition of no more than three stations for a total of no more than 33 stations, upon completion of the project. According to the January 2015 SDR, WFUHS is the only provider of existing or approved kidney disease treatment in Davidson County, operating both Lexington Dialysis Center and Thomasville Dialysis Center.

In Section V.7, page 32, the applicants discuss how any enhanced competition in the service area will promote the cost effectiveness, quality and access to the proposed services. The applicants state that WFUHS provides dialysis services at two facilities in the county, one in the western portion of the county and one in the eastern portion of the county. The applicants further state that because WFUHS is the only dialysis provider in Davidson County, competition is not a factor. The applicants state *“The additional stations will provide greater access to services within western Davidson County, which will allow LXDC to better serve its existing patient base as well [sic] the projected future patient growth.”* See also Sections II, III, V, VI, and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and credible 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 the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate that they will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicants demonstrate that they will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

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 I.13 and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care 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 regulatory review criteria. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

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 III.7, pages 22-23, the applicants state that as of December 31, 2014, Lexington Dialysis had a utilization rate of 87.5% with 105 in-center patients dialyzing on 30 stations ($105 / 30 = 3.5$; $3.5 / 4.0 = .875$). As of June 30, 2014, the January 2015 SDR indicates Lexington Dialysis had a utilization rate of 85.83% with 103 in-center patients dialyzing on 30 stations ($103 / 30 = 3.43$; $3.43 / 4 = 0.8583$).

.2202(a)(2) Mortality rates;

- C- In Section IV.2, page 25, the applicants report Lexington Dialysis' 2012, 2013 and 2014 facility mortality rates, as 18.43%, 22.32%, and 15.94% respectively.

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

- C- In Section IV.3, page 25, the applicants state that Lexington Dialysis is certified to provide home dialysis training and support and had 23 home dialysis patients in 2014.

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

- C- In Section IV.4, page 26, the applicants indicate that Lexington Dialysis had two in-center patients and one home patient with transplants performed or referred in 2014

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

- C- In Section IV.5, page 26, the applicants state that Lexington Dialysis has six in-center patients and 7 home patients on the transplant waiting list.

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

- C- In Section IV.6, page 26, the applicants report that Lexington Dialysis had a total of 275 hospital admissions for in-center dialysis patients during 2014; 82 (29.81%) were dialysis-related admissions and 193 (70.19%) were non-dialysis related admissions. The applicants also report that nine of 26 (34.62%) of its home patients' hospitalizations were 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 IV.7, page 26, the applicants report that in 2014, Lexington Dialysis had four patients with AIDS, eight patients with Hepatitis C and one patient with Hepatitis B. Zero patients converted to infectious status during 2014.

(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- The applicants do not propose a new facility. Lexington Dialysis 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- The applicants do not propose a new facility. Lexington Dialysis 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- The applicants do not propose a new or replacement facility. Lexington Dialysis 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 Attachments H and P which contain copies of written policies and procedures, including back up procedures for 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- The applicants do not propose a new facility. Lexington Dialysis 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- See Sections II.1, page 14; VII.2, pages 41-42; and XI.6, page 69.

.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- The applicants provide the projected patient origin in Section III.7, page 22, as shown below.

County	Operating Year 1 (07/01/15 – 06/30/16)		Operating Year 2 (07/01/16 – 06/30/17)		County Patients as a Percent of Total	
	ICH	Home	ICH	Home	OY 1	OY 2
Davidson	105.88	20.12	108.95	20.70	95.15%	95.11%
Forsyth	1.00	0.00	1.00	0.00	0.90%	0.87%
Rowan	4.39	1.10	4.60	1.15	3.95%	4.02%
Union	0.00	1.07	0.00	1.11	0.00%	0.00%
Randolph	0.00	0.00	0.00	0.00	0.00%	0.00%
Total	111.28	22.29	114.56	22.96	100.00%	100.00%

In Section III.7, pages 22-24, the applicants provide the assumptions and methodology used to project patient origin. The discussion regarding patient origin 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- The applicants do not propose a new facility. Lexington Dialysis 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.1, page 14, the applicants state, “*The facility is committed to admitting and providing dialysis services to patients whom have no insurance or other source of payment, but for who payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

.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- The applicants do not propose a new facility. Lexington Dialysis 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 22, the applicants project serving 111 patients on 34 stations at the end of the first operating year. Based on the methodology and assumptions found on pages 22-24 of the application, and the addition of three stations for a total of 33 stations, the facility will have an in-center patient census of 111 patients for a utilization rate of 84.09% or 3.36 patients per station ($111 / 33 = 3.36$; $3.36 / 4 = .8409$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section III.7, pages 22-24, the applicants provide the assumptions and methodology used to project patient utilization. The discussion regarding projected utilization 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- See Section V.1, page 27. The applicants state they will provide diagnostic and evaluation services.

.2204(2) Maintenance dialysis;

-C- See Section V.1, page 27. The applicants state they will provide maintenance dialysis.

.2204(3) Accessible self-care training;

- C- See Section V.1, page 27. The applicants state they will provide self-care training.

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

- C- See Section V.1, page 27. The applicants state “*LXDC is certified to provide in-center services as well as home dialysis training, backup, and support services on site, offering the broadest range of treatment options to our patients.*”

.2204(5) X-ray services;

- C- See Section V.1, page 27, and Attachment E. The applicants state North Carolina Baptist Hospital will provide X-ray services based on their Affiliation Agreement in Attachment E.

.2204(6) Laboratory services;

- C- See Section V.1, page 27, and Attachments E and K. The applicants state North Carolina Baptist Hospital and Meridian Laboratory Corporation will provide lab services.

.2204(7) Blood bank services;

- C- See Section V.1, page 27, and Attachment E. The applicants state North Carolina Baptist Hospital will provide blood bank services.

.2204(8) Emergency care;

- C- See Section V.1, page 27, and Attachment E. The applicants state North Carolina Baptist Hospital will provide emergency care.

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

- C- See Section V.1, page 27, and Attachment E. The applicants state North Carolina Baptist Hospital will provide acute dialysis in an acute care setting.

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

- C- See Section V.1, page 27, and Attachment E. The applicants state North Carolina Baptist Hospital will provide vascular surgery for dialysis treatment patients.

.2204(11) Transplantation services;

- C- See Section V.1, page 27, and Attachment F. The applicants state North Carolina Baptist Hospital will provide transplantation services.

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

- C- See Section V.1, page 27. The applicants state they will provide vocational rehabilitation counseling and services with appropriate referral after the initial evaluation by the facility's MSW.

.2204(13) Transportation;

- C- See Section V.1, page 27, Attachment L for multiple providers of transportation services.

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 C.F.R. Part 494).

- C- In Section VII, pages 41-42, the applicants provide the proposed staffing and state they comply with all staffing requirements set forth in 42 C.F.R. Part 494 (formerly 42 C.F.R., Section 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

.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- See Section VII.3, pages 42-44, and Attachment M.