

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 31, 2017

Findings Date: August 31, 2017

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: G-11355-17

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: Replace the existing facility on same site

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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 replace the existing LXDC facility on the same site. LXDC is a 37-station dialysis center developed in 1990 at 233 Anna Lewis Drive in Lexington, Davidson County.

Need Determination

The 2017 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. The applicants are proposing to replace the existing 37-station dialysis facility and are not

proposing to increase the number of dialysis stations; therefore, there are no need determinations in the 2017 SMFP applicable to the review of this application.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 33 of the 2017 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 33 of the 2017 SMFP states:

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

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

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

The proposed capital expenditure is greater than \$2 million, but less than \$5 million; therefore Policy GEN-4 is applicable to this review. In Exhibit B.5 the applicants provide a written statement from the architect describing how design and construction of the replacement facility will assure improved energy efficiency and water conservation. Therefore, the application is conforming to Policy GEN-4.

Conclusion

In summary, the applicants adequately demonstrate that the application is consistent with Policy GEN-4 and therefore is conforming to this criterion.

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

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The applicants propose to replace the existing 37-station facility at its current location. LXDC is located at 233 Anna Lewis Drive in Lexington, Davidson County. In Section K.3, pages 59-60, the applicants state that WFUHS owns the site where the existing facility and the replacement facility will be constructed “*with the exception of a small adjacent tract required to accommodate the new building footprint.*” The applicants provide a letter of availability for the additional land in Exhibit K-3(f). In Section C.13, page 30, the applicants state that the existing site with the additional adjacent tract provides adequate space for the applicants to construct the new building while the existing facility remains operational. The existing building will then be demolished to create additional parking and green space on the site.

LXDC has no projects currently under development. The following table, summarized from page 4 of the application, illustrates the current and projected number of dialysis stations at LXDC.

Stations	Description	Project ID #
37	Total existing certified stations as of the January 2017 SDR	
+0	Stations to be added at LXDC as part of this project	
-0	Stations to be deleted at LXDC as part of this project	
37	Total stations upon completion of proposed project	

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations 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.*” LXDC is located in Davidson County; 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 28, 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, 2017***

County	IC	HH	PD
Davidson	102	2	19
Forsyth	1	0	0
Guilford	0	0	1
Iredell	0	0	1
Randolph	0	0	3
Rowan	3	0	3
Total	106	2	27

*Actual data through 5/31/17, projected forward one month to 6/30/17

In Section C.1, page 22, the applicants identify the patient population proposed to be served for the first two years of operation following project completion on June 30, 2019, as shown in the table below.

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

County	Operating Year 1 (OY1) 7/1/19-6/30/20			Operating Year 2 (OY2) 7/1/20-6/30/21			County Patients as % of Total	
	ICH	PD	HH	ICH	PD	HH	OY1	OY2
Davidson	123.91	24.63	2.43	132.21	24.63	2.59	90.48%	90.24%
Forsyth	1.06	0	0	1.08	0	0	0.64%	0.61%
Guilford	0	1.17	0	0	1.17	0	0.68%	0.66%
Iredell	0	1.62	0	0	1.62	0	0.87%	0.92%
Randolph	0	3.56	0	0	3.56	0	2.07%	2.02%
Rowan	4.34	4.34	0	4.91	4.91	0	5.26%	5.56%
Total	129.30	33.39	2.43	138.19	35.89	2.59	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 of the application. On pages 24-25, the applicants provide the calculations for projecting the number of patients by county. The applicants inadvertently used an average annual change rate (AACR) of 12.80% for Iredell County. The correct AACR is 1.20%. The error does not affect the in-center patient origin and skews the second operating year PD patient projection by a total of only 0.57 patients; and is therefore insignificant.

The applicants adequately identify the population to be served.

Analysis of Need

The applicants propose to replace the existing 37-station LXDC facility in Davidson County at its current location, on existing owned property, augmented by the addition of an adjacent tract of land.

In Section C.13, page 30, the applicants discuss the need to replace the facility which was developed in 1990 and which the applicants state is approaching the end of its useful life. The applicants further state that when built, it worked well to accommodate existing technology and patient space requirements; however, it fails to meet the needs of 2017 medical standards. The applicants continue:

“New equipment, technology, CMS standards, and medical guidelines require more space per station than what the existing facility provides.”

The applicants also reference land erosion of the ravine behind the facility over the years causing the building to settle and creating a separation of the facility’s rear wall from the foundation. The applicants further state that the other side of the existing LXDC property is not on the edge of the ravine and is suitable for building.

In addition, the applicants discuss LXDC’s large home dialysis training and support program and the fact that it continues to grow and requires more space to accommodate home training services in a more efficient and effective manner, stating:

“Thus, due to the facility’s age, structural issues and physical obsolescence [sic] there is a great need to take action to replace the facility.”

In Section N.1, page 75, the applicants reiterate the need to replace the LXDC facility. The applicants state:

“... Replacement of the LXDC facility is necessary to serve the facility’s existing and projected patients. By approval of this project, LXDC will have the ability to continue serving its patient base at its current location for many years to come. Patients will be able to keep normal treatment schedules and experience no changes in transportation or other factors that could impact the overall cost-effectiveness, quality, and access to the proposed services.”

Patient support letters are provided in Exhibit C-7.

Projected Utilization

In Section C.2, page 24, the applicants state that the current utilization rate for LXDC, as of June 30, 2016 per the January 2017 SDR, is 69.59%. The applicants further state:

“By the end of OY1 and OY2 of the proposed project, facility ICH utilization by the projected patient census will be beyond 80%. The facility is well utilized and will likely need additional stations prior to completion of the proposed project.”

On page 25, the applicants state:

“If the facility’s existing patient population continues to grow at the 5-year AACR by county of origin, the potential exists for a need for up to 6 additional stations by the end of OY2 of the proposed project.”

The applicants provide the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project on pages 22 and 24 of the application, as summarized below.

LXDC Projected In-Center Dialysis Utilization

County	January 2017 SDR 5-Yr AACR	Beginning Census 6/30/17*	Interim 6/30/2018	Interim 6/30/2019	End of OY1 12/31/2020	End of OY2 12/31/21
Davidson	6.70%	102.00	108.83	116.13	123.91	132.21
Forsyth	1.90%	1.00	1.02	1.04	1.06	1.08
Rowan	13.10%	3.00	3.39	3.84	4.34	4.91
Totals		106.00	113.25	121.00	129.31	138.19

Totals may not sum due to rounding

*Census for 6/30/17 is projected based on actual census data as of 5/31/17, projected forward one month.

In Section C.7, pages 27-28, the applicants provide the methodology and assumptions used to project utilization at LXDC. The applicants’ methodology is summarized below:

- Group the existing May 31, 2016 patient census by county of origin and increase the census by 1/12 of the 5-year AACR by county or origin for the beginning census on June 30, 2017.
- Apply the January 2017 SDR 5-year AACR by county of patient origin, to the June 30, 2017 patient populations to project patient census through the end of Operating Year 2.
- Project utilization for potential future stations based on existing and projected patients at LXDC.

The applicants’ assumptions are summarized below:

- Projected completion of the project under review is June 30, 2019; OY1 ends June 30, 2020; OY2 ends June 30, 2021.
- The 5-year AACR for each county as published in the January 2017 SDR will remain an accurate indicator of patient growth through the project's second operating year.
- The existing 37 stations are adequate to serve the current and projected patients through June 30, 2019, at which time WFUHS anticipates filing additional CON applications to add stations to accommodate patient growth.
- Utilization rates for the existing 37 stations and existing and projected patient populations were calculated for an addition of zero to six stations to demonstrate the current and future potential utilization of the LXDC facility.

On page 25, the applicants provide a table with projected utilization for the proposed project, showing that by the end of the second operating year of operation, LXDC's utilization would be 93.37% with the existing 37 stations. The table also demonstrates the projected utilization with the potential addition of stations. With the addition of as many as six stations for a total of 43 stations, the utilization would be 80.35% ($138 \text{ patients} / 43 \text{ stations} = 3.21 \text{ patients per station} / 4 = .8035$). This exceeds the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b) to add stations.

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

Access

In Section C.3, page 26, 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 project payor mix in Section L.1(b), page 64 as summarized below:

**Projected Payor Mix
Project Year 2 (7/1/20 – 6/30/21)**

	Percent of Total Patients	Percent of In-center Patients
Private Pay	1%	1%
Medicare	15%	15%
Medicaid	5%	6%
Medicare / Medicaid	20%	22%
Commercial Insurance	9%	6%
Medicare / Commercial	23%	23%
VA	9%	9%
Medicare Advantage	17%	18%
TOTAL	100%	100%

Totals may not sum due to rounding.

In Section L.7, page 72, the applicants state that the projected payor mix is based upon the current five-year average annual payor mix.

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, demonstrate the need the population to be served has for the proposed services, based on reasonable and supported utilization projections and assumptions; 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 E.1, pages 32-33, the applicants discuss the alternatives considered prior to submitting this application, which include:

- 1) Maintain the Status Quo – the applicants state that due to site topography issues, the age of the facility, and the growth of the home dialysis training program, maintaining the status quo is no longer a viable option.
- 2) Divide the stations and create two smaller facilities, one on site and one in another area of Davidson County – the applicants state that this option would require finding and purchasing a new site, likely require a larger budget, and the need for additional staffing could be an issue; therefore the applicants do not consider this the most effective alternative.
- 3) Relocate the entire facility to a new site in Davidson County – the applicants state that no other sites were found to be as patient friendly and cost-effective as the existing site; therefore, this option was not considered an effective alternative.
- 4) Replace the facility on-site as proposed – the applicants state this will allow patient treatment to continue in the existing facility while the replacement facility is under construction. The applicants state that the new facility will eliminate the existing space and erosion issues, house a larger home training department, allow patients to keep their current travel patterns, and require no changes in Medicare certification or insurance credentialing; therefore it is more effective than any other option.

After considering the above alternatives, the applicants state that the project as proposed is the least costly or most cost-effective alternative for this project.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

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

- 1. Wake Forest University Health Sciences and Lexington Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Wake Forest University Health Sciences and Lexington Dialysis Center of Wake Forest University shall materially comply with the last made representation.**

2. **Wake Forest University Health Sciences and Lexington Dialysis Center of Wake Forest University shall develop a new building on the existing site and install plumbing and electrical wiring through the walls for no more than 37 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 3. **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 replace the existing 37-station LXDC facility by constructing a new building at the existing location for a total of 37 certified dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 35, the applicants project the total capital cost of the proposed project will be \$4,724,102, including:

Costs	Total Costs
Land and Site Costs	\$ 374,400
Construction Contract	\$ 3,898,000
Water Treatment Equipment	\$ 261,365
Equipment/Furniture	\$ 190,337
Total Capital Costs	\$ 4,724,102

In Section F.10-13, pages 38-39, the applicants state there are no start-up or initial operating expenses for this project because LXDC is an existing dialysis facility.

Availability of Funds

In Section F.5, pages 36-38, the applicants refer to Exhibit F-5 for a commitment letter of WFUHS funds and Exhibit F-7(a) for a copy of the June 30, 2016 Wake Forest University consolidated balance sheet, which includes WFUHS. The Corporate Chief Executive Officer’s commitment letter in Exhibit F-5 states, “*Wake Forest University Health Sciences commits to provide monies to its subordinates in order to fund project costs.*” The consolidated balance sheet provided in Exhibit F-7(a) is for the period ending June 30, 2015. In supplemental information requested by the Project Analyst during the expedited review of this application, the applicants submitted the Wake Forest University consolidated balance sheet for the period ended June 30, 2016, which documents WFUHS had \$32,338,000 cash and cash equivalents, \$1,293,109,000 in total assets and \$466,836,000 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 operating needs of the project.

Financial Feasibility

In Section R, Form C, pages 89-90, the applicants provide the allowable charge per treatment for each payment source for in-center and home dialysis patients, respectively. The revenue assumptions are provided in Section R, pages 91-93.

The applicants provide the following assumptions for patient treatments:

- Average annual patients per month calculations (pages 91)
- 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) (page 91)
- Home treatments = patients x 7 x 52 (364 treatments per patient), reduced by 10% for missed treatments (328 treatments per patient) (pages 91-92)

The applicants project revenues and summarize operating expenses in Section R, Form B, page 88, as summarized in the table below.

Lexington Dialysis Center	Operating Year 1 7/1/19-6/30/20	Operating Year 2 7/1/20-6/30/21
Total Gross Revenue	\$ 42,571,461	\$ 46,036,852
Deductions from Gross, including Contractual Allowances, Charity Care and Bad Debt	35,940,137	38,849,661
Net Revenue	6,631,324	7,187,191
Total Operating Expenses	4,827,726	5,113,864
Net Profit	\$ 1,803,598	\$ 2,073,328

Totals may not sum due to rounding

As shown in the table above, the applicants project a positive net income in each of the first two operating years of the project. The assumptions used by the applicants in

preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. In Section, H-1, page 43, the applicant provides projected staffing and salaries. Form A in Section R, shows budgeted operating costs adequate to cover the projected staffing. The discussions regarding projected utilization found in Criterion (3) and staffing found in Criterion (7) are incorporated herein by reference. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital and operating needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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 373, the 2017 SMFP defines the service area for dialysis stations 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.”* LXDC is located in Davidson County; 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 replace the existing 37-station LXDC at the same location in Davidson County. The January 2017 SDR indicates there are two dialysis facilities in Davidson County, as shown below.

Davidson County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/16	In-Center Patients 6/30/16	Percent Utilization	Patients Per Station
Lexington Dialysis Center (WFUHS)	37	103	69.59%	2.7838
Thomasville Dialysis Center (WFUHS)	24	95	98.96%	3.9583

Source: January 2017 SDR, Table A.

WFUHS operates both Davidson County dialysis centers. As illustrated above, both dialysis centers are operating at or above 70% utilization. In Section G.1, page 42, the applicants state that as of May 31, 2017, both facilities are operating above 70%

utilization, with the recent certification of an additional eight stations at Thomasville Dialysis Center. On page 42, the applicants further state:

“LXDC does not propose to serve patients currently utilizing another facility. LXDC proposes to serve its current and projected patients.

The replacement of LXDC is not due to projected patient growth and no additional stations are requested at this time. ... The existing plant is nearing 30 years old, it is suffering structural issues and is physically obsolete. Replacement of the LXDC facility at its existing location will not duplicate services. It will replace existing services at the existing location in Davidson County.”

The applicants adequately demonstrate the need to replace the existing LXDC facility based on the inadequacy of the existing building to meet current and future patient needs. 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 applicants provide the current and proposed staffing in Section H.1, page 43, as summarized in the table below.

	Current FTE Positions	FTE Positions to be added	Total Projected FTE Positions	Current Annual Salary / FTE	Projected Salary PY2 /FTE
RN	5.50	0	5.50	\$56,074	\$71,227
LPN	1.25	0	1.25	\$40,966	\$52,463
Pt Care Technician	10.80	0	10.80	\$28,974	\$32,750
Clinical Nurse Manager	1.00	0	1.00	\$58,240	\$84,096
Dietician	0.80	0	0.80	\$54,226	\$61,033
Social Worker	0.80	0	0.80	\$59,280	\$66,720
Home Training Nurse	2.00		2.00	\$59,550	\$67,024
Dialysis Tech	2.00	0	2.00	\$31,044	\$34,940
Biomed	1.00	0	1.00	\$54,600	\$61,453
Clerical	3.00	0	3.00	\$30,040	\$33,810
Total FTE Positions	28.15		28.15		

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

In Sections H.2 and H.3, pages 44-48, 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 53, the applicants state that Alison Jo Fletcher, M.D. will serve as the Medical Director for the facility. In Exhibit I-3(a), the applicants provide a letter signed by Dr. Fletcher confirming a commitment to continue to serve as Medical Director. Exhibit H-2 includes a copy of Dr. Fletcher’s curriculum vitae. In Section I.3(b), page 54, the applicants state that medical coverage is provided seven days per week and 24 hours a day by WFUHS physicians on a rotation basis or by local area nephrologists with privileges at the facility. Exhibit I-3(b) contains a list of referral physicians and physician letters of support.

The applicants 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 51-53, the applicants describe the necessary ancillary and support services and indicate how they will be provided. Exhibit I.2(a) contains a copy of the affiliation agreement between the facility and North Carolina Baptist Hospital. Exhibit I.2(b) contains a copy of the transplant agreement. Exhibit I.2(c) contains a copy of a reciprocal services agreement with Thomasville Dialysis Center. The applicants discuss coordination with the existing health care system on pages 53-55. 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.

C

In Section K.2, pages 59-60, the applicants state that the replacement facility consists of 7,715 square feet of treatment area. The proposed floor plan is provided in Exhibit K-1(a), which also contains the construction company's letter documenting construction and demolition costs of \$3,898,000 for the proposed 16,000 square foot building. In Exhibit B.5 the applicants provide a written statement from the architect describing how design and construction of the replacement facility will assure improved energy efficiency and water conservation.

Costs and charges are described by the applicants in Section R of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, page 63, 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.”

In Section L.3(b), page 66, the applicants further state that the admission of a patient is based upon medical necessity and not the patient's ability to pay. Exhibit L-3(a) contains a copy of LXDC's Referral/Admissions Policy.

In Section L.7, page 71, the applicants report that during the last full operating year, 67% 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 summarizes the facility's historical payment sources.

HISTORICAL PAYOR MIX
7/1/16-6/30/17

	Percent of IC Patients	Percent of Total Patients
Private Pay	1%	0%
Medicare	11%	16%
Medicaid	6%	3%
Medicare / Medicaid	20%	16%
Commercial Insurance	7%	22%
Medicare / Commercial	26%	19%
VA	8%	11%
Medicare Advantage	21%	13%
TOTAL	100%	100%

Totals may not sum due to rounding.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Davidson	17%	51%	19%	17%	12%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable... The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from

all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The applicant adequately demonstrates that it currently provides 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;

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In Section L.3(d) page 69, 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**, [emphasis in original] and strives to provide services to all patients with End Stage Renal Disease.”*

In Section L.6, page 70, 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 last five years.”*

The application is conforming to this criterion.

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

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

C

In Section L.1(b), page 64, the applicants provide the projected payor mix for the proposed services at LXDC, as summarized below.

**Projected Payor Mix
 Project Year 2 (7/1/20 – 6/30/21)**

	Percent of Total Patients	Percent of In-Center Patients	Percent of HH Patients	Percent of PD Patients
Private Pay	1%	1%	0%	0%
Medicare	15%	15%	50%	13%
Medicaid	5%	6%	0%	3%
Medicare / Medicaid	20%	22%	0%	14%
Commercial Insurance	9%	6%	50%	18%
Medicare / Commercial	23%	23%	0%	26%
VA	9%	9%	0%	10%
Medicare Advantage	17%	18%	0%	16%
TOTAL	100%	100%	100%	100%

Totals may not sum due to rounding.

In Section L.7, page 72, the applicants state that the projected payor mix is based upon LXDC’s current five-year average annual payor mix.

In Section L.1(a), page 64, 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 64, the applicants report that LXDC expects 84% of the in-center patients and 80% of its total 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 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.

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In Section L.4, page 69, 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.

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In Section M, page 74, the applicants state:

“WFUHS dialysis units make every attempt to provide onsite educational experiences to local training programs in the area. ... Therefore, all WFUHS dialysis facilities will provide these experiences to not only health professional training programs in the area, but other applicable training programs as well.

...

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

Exhibit M-1 contains a copy of the professional training agreement between the Davidson Community College and LXDC. The information provided in Section M and the referenced exhibit is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services

proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

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On page 373, the 2017 SMFP defines the service area for dialysis stations 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.”* LXDC is located in Davidson County; 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 replace the existing Davidson County 37-station LXDC on the current site augmented by the purchase of an adjacent tract of land. The January 2017 SDR indicates there are two dialysis facilities in Davidson County, as shown below.

Davidson County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/16	In-Center Patients 6/30/16	Percent Utilization	Patients Per Station
Lexington Dialysis Center (WFUHS)	37	103	69.59%	2.7838
Thomasville Dialysis Center (WFUHS)	24	95	98.96%	3.9583

Source: January 2017 SDR, Table A.

WFUHS operates both Davidson County dialysis centers. As illustrated above, both dialysis centers are operating at or above 70% utilization. In Section G.1, page 42, the applicants state that as of May 31, 2017, both facilities are operating above 70% utilization, with the recent certification of an additional eight stations at Thomasville Dialysis Center. On page 42, the applicants further state:

“LXDC does not propose to serve patients currently utilizing another facility. LXDC proposes to serve its current and projected patients.”

The replacement of LXDC is not due to projected patient growth and no additional stations are requested at this time. ... Replacement of the LXDC facility at its existing location will not duplicate services. It will replace existing services at the existing location in Davidson County.”

In Section N.1, page 75, 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. Patients utilize a facility based upon physician preference, geographical location, or other reasons of convenience. Replacement of the LXDC facility is necessary to serve the facility’s existing and projected patients.”

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

The information provided by the applicants in the sections referred to above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicants adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need, alternatives, and costs found in Criteria (3), (4) and (5), 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 (13) 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.

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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.1, page 77, the applicants refer to Section B.4(a) and Exhibit O-1 for LXDC’s methods used to insure and maintain quality. In Section O.2, the applicants refer to LXDC’s most recent CMS Survey and Plan of Correction in Exhibit O-2. In Section O.3(a), the applicants provide a list of the 11 WFUHS dialysis facilities which were surveyed during the last 18 months. In Section O.3(b), pages 78-79, the applicants summarize the deficiencies cited at nine of the 11 facilities. The facilities were cited for

standard level deficiencies and complaint investigations. In Section O.3(c), page 79, 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.

NA