

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 23, 2019

Findings Date: April 23, 2019

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

Project ID #: G-11639-18

Facility: Lexington Dialysis Center

FID #: 944660

County: Davidson

Applicants: Wake Forest University Health Sciences

Lexington Dialysis Center of Wake Forest University

Project: Relocate no more than four dialysis stations from High Point Kidney Center (Guilford County) for a total of no more than 41 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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 (LDCWFU), collectively referred to as “the applicant”, proposes to relocate four dialysis stations from High Point Kidney Center (HPKC) to Lexington Dialysis Center (LXDC), pursuant to Policy ESRD-2, for a total of 41 stations at LXDC upon project completion. WFUHS is the sole owner of LXDC and HPKC and contracts with Health Systems Management, Inc., (HSM) to operate the facilities.

Need Determination

The applicant does not propose to increase the number of licensed beds in any category, add any new health services, or acquire equipment for which there is a need determination in the

2018 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2018 SMFP that are applicable to this review.

Policies

There is one policy in the 2018 SMFP which is applicable to this review:

Policy ESRD-2: Relocation of Dialysis Stations, on page 27 of the 2018 SMFP, states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate four existing dialysis stations from HPKC to LXDC, pursuant to Policy ESRD-2, for a total of 41 stations at LXDC. LXDC is located in Davidson County and HPKC is located in Guilford County.

Davidson County and Guilford County are contiguous counties. According to Table A of the July 2018 Semiannual Dialysis Report (SDR), both LXDC and HPKC are currently serving residents of Davidson County.

According to Table D of the July 2018 SDR, Guilford County has a projected surplus of eleven dialysis stations. Following the applicant’s proposed relocation of four existing stations from HPKC in Guilford County to LXDC in Davidson County, Guilford County would have a surplus of seven dialysis stations ($11 - 4 = 7$). The proposal will not result in a deficit, or increase an existing deficit, in the number of dialysis stations in the county that would be losing stations.

According to Table D of the July 2018 SDR, Davidson County has a projected deficit of four dialysis stations. Following the applicant’s proposed relocation of four existing stations from HPKC in Guilford County to LXDC in Davidson County, Davidson County would have no deficit or surplus of dialysis stations ($4 - 4 = 0$). The proposal will not result in a surplus, or increase an existing surplus, in the number of dialysis stations in the county that would be gaining stations.

Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

The applicant proposes to relocate four existing dialysis stations from HPKC in Guilford County to LXDC in Davidson County, pursuant to Policy ESRD-2, for a total of 41 stations at LXDC upon project completion. The applicant currently offers home hemodialysis and peritoneal dialysis training and follow-up care at LXDC.

The following table, summarized from the table in Section B, 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 July 2018 SDR	
+4	Stations to be added as part of this project	G-11639-18
41	Total stations upon completion of proposed project	

Patient Origin

On page 365, the 2018 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 review is Davidson County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 30, the applicant provides the historical patient origin for LXDC for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients as of August 31, 2018 as follows:

County	IC Patients	HHD Patients	PD Patients
Davidson	117	2	20
Forsyth	1	1	0
Randolph	0	0	2
Rowan	6	0	5
Totals	124	3	27

Source: Section C.8, page 30.

In Section C.1, page 23, the applicant provides the projected patient origin for LXDC for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

County	End of Operating Year 1 8/31/2020			End of Operating Year 2 8/31/2021			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Davidson	134.20	2.29	22.94	143.73	2.46	24.57	81.91%	81.94%
Forsyth	1.08	1.08	0.00	1.12	1.12	0.00	1.11%	1.07%
Randolph	0.00	0.00	2.05	0.00	0.00	2.08	1.05%	1.00%
Rowan	6.99	0.00	5.82	7.54	0.00	6.28	6.58%	6.63%
Davidson Transfers (HPKC)	8.57	0.00	9.64	9.18	0.00	10.32	9.35%	9.36%
Total	150.83	3.37	40.45	161.56	3.58	43.25	100.00%	100.00%

Source: Section C.1, page 23.

In Section C, pages 23-24, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.2, pages 24-25, the applicant discusses the need for the relocation of dialysis stations to LXDC. The applicant states:

“The population to be served by this proposed project is the current and projected patients of LXDC, as well as WFUHS’ Davidson County resident patients served outside of Davidson County. As of 8/31/2018, there were 60 Davidson County resident patients (29 ICH and 31 home dialysis) traveling outside of Davidson County for their care as depicted in the [table on page 25 of the application]. ... HPKC, the host facility for this project, provides services to 35 of those 60 patients (16 ICH and 19 home dialysis.)”

On pages 24-25, the applicant states that the need the projected population has for the proposed project is supported by the following factors:

- The LXDC facility’s patient census increased by 29 patients, or 20.18 percent, from August 31, 2017 to August 31, 2018.
- The LXDC facility’s inability to file for additional stations based on facility need methodology because its utilization rate at December 31, 2017 was less than the 80% utilization required to apply for additional stations via facility need methodology.

Projected Utilization

In Section C, pages 23 and 25, the applicant provides projected utilization as summarized in the following table.

**LXDC
 In-Center Patient Census**

		Prior Year	Current Year	As of Certification	End of OY1	End of OY2
County	AACR	8/31/17	8/31/18	8/31/19	8/31/20	8/31/21
Davidson	7.1%	95.00	117.00	123.31	134.20	143.73
Forsyth	3.8%	0.00	1.00	1.04	1.08	1.12
Guilford	3.4%	0.00	0.00	0.00	0.00	0.00
Iredell	1.6%	0.00	0.00	0.00	0.00	0.00
Randolph	1.3%	0.00	0.00	0.00	0.00	0.00
Rowan	7.9%	4.00	6.00	6.47	6.99	7.54
Davidson Transfers from HPKC	7.1%	0.00	0.00	8.00	8.57	9.18
Total		99.00	124.00	140.82	150.83	161.56

Source: Section C.1, pages 23 and 26.

In Section C, pages 28-29, the applicant provides the assumptions and methodology it uses to project patient utilization, which are summarized below.

- Existing patient population for LXDC as of 8/31/18 is grouped by county of origin.
- Existing patient population is increased by the 5-yr AACR by county of origin published in the July 2018 SDR and added to the patient population for each 12-month period identified in the tables on pages 23 and 25.
- Based on the number of Davidson County residents served outside of the county and their residence locations within the county, the applicant projects that there will be at least eight Davidson County residents who transfer their care from HPKC to LXDC upon project completion or sooner.
- The project is scheduled for certification on August 31, 2019.

The applicant projects to serve 151 patients on 41 stations, which is 3.68 patients per station per week (151 patients / 41 stations = 3.68), by the end of OY1 and 162 patients on 41 stations, which is 3.95 patients per station per week (162 patients / 41 stations = 3.95), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant projects future utilization based on the patients currently being served at LXDC, and the Davidson County residents who are projected to transfer their dialysis care from HPKC to LXDC in their county of residence.
- The applicant uses the 5-year AACR for each LXDC patient’s county of origin, as published in the July 2018 SDR, to project patient utilization for both in-center and home dialysis patients.
- The applicant’s projected patient utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C.3, page 27, the applicant states:

*“LXDC accepts patients based on **medically defined admission criteria** [emphasis in original]. There is no discrimination based on race, sex, age, national origin, ability to pay, nor disability. Services are available to all area residents with ESRD.”*

In Section L, page 74, the applicant provides the historical payor mix, as of August 31, 2018, and projected payor mix during the first and second full years of operation following completion of the project, as illustrated in the following table.

**Lexington Dialysis Center
Percent of Total Patients**

Payment Source	OY2018	OY2020	OY2021
Private Pay	1%	1%	1%
Medicare	13%	12%	12%
Medicaid	4%	4%	4%
Medicare/Medicaid	17%	18%	18%
Commercial Insurance	12%	11%	11%
Medicare/Commercial	25%	25%	25%
VA	9%	10%	10%
Medicare Advantage	20%	19%	19%
Total	100%	100%	100%

The applicant provides the assumptions used to project payor mix on pages 73-74, stating that the projected payor mix represents the five year average payor mix based on monthly capture of patient payor data. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
 - The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

In Section D.1, page 33, the applicant discusses the relocation of four dialysis stations from HPKC in Guilford County to LXDC in Davidson County, pursuant to Policy ESRD-2. The July 2018 SDR reported HPKC had 143 in-center patients dialyzing on 41 dialysis stations for a utilization rate of 87.20% as of December 31, 2017. The applicant states that the relocation of four stations from Guilford County to Davidson County will reduce the station surplus in Guilford County to seven stations and eliminate the four-station deficit in Davidson County. On page 32, the applicant states:

“In September 2018 WFUHS submitted a CON application to add 7 stations to HPKC via facility need methodology to better serve that facility’s current and projected patients. An addition of those stations will fill HPKC to its maximum capacity – 48 ICH stations. That application was recently approved. Upon certification (6/30/2019 from the HPKC CON) of the proposed stations, HPKC is projected to serve 156.54 ICH patients at 81.53% utilization.

Approval of this CON to transfer 4 ICH stations from HPKC to LXDC (certification date of 8/31/2019) would leave HPKC with 44 ICH stations. Even if no Davidson County residents transfer from HPKC to LXDC upon completion of this project, the resulting utilization rate at HPKC (based on HPKC’s projected facility census from its recent CON for near that same time period) is projected to be 88.94%. The patients at HPKC will continue to be adequately served by the remaining stations.”

On discussed above, based on the applicant's utilization projections for HPKC, that facility will have adequate capacity to meet the projected utilization following the proposed relocation of four stations to LXDC, even if no Davidson County patients transferred their care from HPKC to LXDC subsequent to the relocation.

In Section D.2, page 34, the applicant states that access to ESRD services is not dependent upon any demographic factor. It is dependent upon medically-defined criteria with the most basic condition being a diagnosis of ESRD and the transfer of stations will have no impact on the ability of ESRD patients at HPKC to obtain needed healthcare. Therefore, the applicant demonstrates that the needs of the population presently served at HPKC will be adequately met following the relocation of four stations from HPKC to LXDC.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated, or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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

The applicant proposes to relocate four existing dialysis stations from HPKC in Guilford County to LXDC in Davidson County, pursuant to Policy ESRD-2, for a total of 41 stations at LXDC upon project completion.

In Section E, pages 35-38, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: The applicant states that doing nothing to increase its service capabilities at LXDC at this time would be a true disservice to the WFUHS patients who require dialysis and make their homes in Davidson County. Thus the applicant determines the status quo is not a viable option.

- **In-County Transfer:** The applicant states that an in-county station transfer between LXDC and Thomasville Dialysis (TVDC) will not solve the Davidson County station deficit nor expand access to services for Davison County patients traveling outside of their home county for care. Thus the applicant determines an in-county station transfer is not a viable option.
- **Contiguous County Transfer:** WFUHS owns operational dialysis facilities in Davie, Forsyth, Guilford, and Randolph counties, which are all contiguous to Davidson County. The applicant states that an analysis of its facilities, their surpluses/deficits of stations, and the potential for relocating stations to LXDC indicates that relocating stations from HPKC was a viable alternative.
- **Facility Need Methodology:** The applicant states that the facility need methodology is not a viable option for LXDC at this time because LXDC was not operating at 80% utilization as of the data collection date for the July 2018 SDR.

On page 38, the applicant states that its chosen proposal to relocate four stations from HPKC in Guilford County to LXDC in Davidson County is the most effective alternative because the needs of the patient population at HPKC will continue to be well met while the needs of the current and future patients at LXDC along with other Davidson residents currently traveling outside of Davidson County for their care will also be met. The applicant states that the project proposes no capital cost; thus, this alternative is the most effective and least costly alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective and least costly alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is 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. Pursuant to Policy ESRD-2, Wake Forest University Health Sciences and Lexington Dialysis Center of Wake Forest University shall relocate no more than four dialysis stations from High Point Kidney Center for a total of no more than 41 dialysis stations**

- at Lexington Dialysis Center, which shall include any home hemodialysis training or isolation stations, upon project completion.**
- 3. Upon completion of this project, Wake Forest University Health Sciences shall take the necessary steps to decertify four dialysis stations at High Point Kidney Center for a total of no more than 41 dialysis stations upon completion of this project, Project I.D. # G-11587-18 (add seven stations) and Project I.D. # G-11651-19 (relocate three 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 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 applicant proposes to relocate four existing dialysis stations from HPKC in Guilford County to LXDC in Davidson County, pursuant to Policy ESRD-2, for a total of 41 stations at LXDC upon project completion.

Capital and Working Capital Costs

In Section F, pages 40-44, the applicant states that the project requires no capital cost or working capital as LXDC is an existing facility and therefore, requires no funding.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full years of operation following completion of the project. In Section R, Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
LXDC	Operating Year 1 OY 2020	Operating Year 2 OY 2021
Total Treatments*	21,900	23,550
Total Gross Revenues (Charges)	\$51,119,277	\$54,928,337
Adjustments from Gross**	\$42,686,502	\$45,819,545
Total Net Revenue	\$8,432,775	\$9,108,792
Average Net Revenue per Treatment	\$385	\$387
Total Operating Expenses (Costs)	\$5,677,737	\$5,981,939
Average Operating Expense per Treatment	\$259	\$254
Net Income/Profit	\$2,755,038	\$3,126,853

*Treatments average 150 per patient per year (52 weeks x 3 treatments per week less 4% for missed treatments)

**Includes charity care and bad debt

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the project requires no capital or working capital.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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

The applicant proposes to relocate four existing dialysis stations from HPKC in Guilford County to LXDC in Davidson County, pursuant to Policy ESRD-2, for a total of 41 stations at LXDC upon project completion.

On page 369, the 2019 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 review is Davidson County. Facilities may serve residents of counties not included in their service area.

According to Table B of the July 2018 SDR, there are two existing or approved dialysis facilities in Davidson County which are operational. Information on both of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

Davidson County Dialysis Facilities Certified Stations and Utilization as of December 31, 2017				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Lexington Dialysis Center of Wake Forest University*	WFUHS	Lexington	37	72.97%
Thomasville Dialysis Center of Wake Forest University	WFUHS	Thomasville	32	68.75%

Source: July 2018 SDR, Table B.

* Approved to replace the existing facility on the same site for a total of 37 stations (Project ID #G-11355-17)

In Section G, page 50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Davidson County. The applicant states:

“LXDC’s need is real and immediate. Approval of LXDC’s CON proposal will not result in a surplus of stations in Davidson County. The requested number of dialysis stations have been shown to provide service at a level of 80% utilization by the end or OY1 based on growth of the facility’s current patient census, alone, and at an even greater rate when the projected Davidson county resident ICH patients transfers from WFUHS facilities in contiguous counties are included upon certification of the proposed stations. Approval of this project will not result in duplication of existing and approved services in the proposed service area – Davidson County.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant does not propose to create a surplus, or increase a surplus, in the projected number of stations needed in Davidson County.
- The applicant adequately demonstrates the need the population proposed to be served has for the proposed relocation of stations and demonstrates that the facility will be appropriately utilized. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section H, page 51, the applicant provides projected staffing for the proposed services, as summarized in the following table showing full-time equivalent (FTE) positions.

LXDC Projected Staffing	
	# FTE Positions
Registered Nurses	7.75
LPN	1.75
Patient Care Technician	14.00
DON	1.00
*Admin	7.50
Dietician	1.00
Social Worker	1.75
Dialysis Technician	3.00
Biomed	1.00
Clerical	3.00
TOTAL	41.75

*Admin is based on a pro rata share of Regional Admin costs and delegated at a rate of \$7.50 per treatment

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, pages 55-56, the applicant describes the methods used to recruit or fill new positions and its proposed training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2 and H-4. In Section I, page 61, the applicant identifies the proposed medical director. In Exhibit I-3(a), the applicant provides a letter from the medical director indicating an intent to continue to serve as medical director for the facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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, page 59, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

LXDC – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training Hemodialysis Peritoneal Dialysis Accessible follow-up program	On site
Psychological counseling	On site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Wake Forest Baptist Hospital (WFBH)
Emergency care	WFBH
Blood bank services	WFBH
Diagnostic and evaluation services	On site
X-ray services	WFBH
Laboratory services	On site by WFBH / Lab Contract
Pediatric nephrology	On site
Vascular surgery	WFBH
Transplantation services	WFBH
Vocational rehabilitation & counseling	Referral by MSW
Transportation	Multiple options -Referral by MSW

The applicant provides supporting documentation in Exhibits I-1 through I-3.

In Section I, pages 61-63, the applicant describes its relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-I, I-2 (a-c), I-3(a-b), and I.4(a).

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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

The applicant does not propose any new construction or to make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

- (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.7, page 80, the applicant provides the historical payor mix, as of August 31, 2018 for LXDC, as shown in the table below.

LXDC Historical Payor Mix FY2018		
Payment Source	% IC Patients	% Total Patients
Private Pay	1%	1%
Medicare	11%	13%
Medicaid	6%	4%
Medicare/Medicaid	19%	17%
Commercial Insurance	8%	12%
Medicare/Commercial	22%	25%
VA	8%	9%
Medicare Advantage	25%	20%
Total	100%	100%

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**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Davidson	18%	51%	20%	15%	13%	13%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

¹<https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(d), page 78, the applicant states:

*“The facility has no obligation to provide uncompensated care or community service or access by minorities and handicapped persons. 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 79, the applicant states that there have been no civil rights access complaints filed against the facility or any facilities owned by the parent company in North Carolina within the last five years.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L.1(b), page 74, the applicant projects the following payor mix for the proposed services during the second full year of operation following completion of the project, as shown in the table below.

**Projected Payor Mix OY2
8/31/2020 - 8/31/2021
As a Percent of Total**

Payor Source	Percent of Total Patients	Percent of In-center Patients	Percent PD & HH Patients
Private Pay	1%	1%	0%
Medicare	12%	14%	10%
Medicaid	4%	6%	2%
Medicare / Medicaid	18%	20%	14%
Commercial Insurance	11%	7%	18%
Medicare / Commercial	25%	22%	30%
VA	10%	9%	11%
Medicare Advantage	19%	21%	15%
Total	100%	100%	100%

Source: Application page 74

As shown in the table above, during the second full calendar year of operation, the applicant projects that one percent of the dialysis patients will be private pay patients and 78 percent will have all or part of their services paid for by Medicare and/or Medicaid.

On pages 73-74, the applicant provides the assumptions and methodology used to project payor mix during the first and second full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant's proposed patient origin is comparable to its historical patient origin.
- The applicant projects future payor mix based on the facility's average monthly payor mix by payor type for each of the last five operating years.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L.4, pages 78-79, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 82, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate four existing dialysis stations from HPKC in Guilford County to LXDC in Davidson County, pursuant to Policy ESRD-2, for a total of 41 stations at LXDC upon project completion.

On page 369, the 2019 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 review is Davidson County. Facilities may serve residents of counties not included in their service area.

According to Table B of the July 2018 SDR, there are two existing or approved dialysis facilities in Davidson County which are operational. Information on both of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

Davidson County Dialysis Facilities Certified Stations and Utilization as of December 31, 2017				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Lexington Dialysis Center of Wake Forest University*	WFUHS	Lexington	37	72.97%
Thomasville Dialysis Center of Wake Forest University	WFUHS	Thomasville	32	68.75%

Source: July 2018 SDR, Table B.

* Approved to replace the existing facility on the same site for a total of 37 stations (Project ID #G-11355-17)

In Section N, pages 83-84, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 83, the applicant states:

“This project shall have no impact on competition in Davidson County. WFUHS is the sole provider of ICH services in Davidson County. Patients utilize a facility based upon physician preference, geographical location, or other reasons of convenience. An addition of stations at LXDC is necessary to serve the facility’s existing and projected patients and stave off excessive utilization.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrate:

- The cost-effectiveness of the proposal (see Section B, page 20, Sections F and R of the application and any exhibits).
- Quality services will be provided (see Section B, pages 10-20, Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section B, pages 15-20, Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section A.11, pages 5-6, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 18 WFUHS dialysis facilities located in North Carolina.

In Section O, pages 85-86, the applicant states that during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in eight of the 18 facilities. The applicant states that at the time of application submittal, all facilities are in compliance. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 18 facilities, the applicant provides sufficient evidence that quality care has been provided in the past.

Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

(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 applicant is not proposing to establish a new ESRD facility.

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

-C- In Section C.2, pages 25-26, the applicant provides 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. The applicant projects to serve 151 patients on 41 stations, which is 3.68 patients per station per week ($151 \text{ patients} / 41 \text{ stations} = 3.68$), by the end of OY1. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

-C- In Section C.1, pages 23-27, the applicant provides the assumptions and methodology used to project utilization of the facility.