

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 20, 2021

Findings Date: January 20, 2021

Project Analyst: Misty L. Piekaar-McWilliams

Team Leader: Gloria C. Hale

Project ID #: G-11944-20

Facility: Lexington Dialysis Center

FID #: 944660

County: Davidson

Applicant(s): Wake Forest University Health Sciences

Lexington Dialysis Center of Wake Forest University

Project: Add no more than 3 dialysis stations (2 in-center stations and 1 dedicated home hemodialysis training station) pursuant to Condition 2 of the facility need methodology for a total of no more than 49 dialysis 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 and Lexington Dialysis Center of Wake Forest University (the applicants) operate a 37-station dialysis facility, Lexington Dialysis Center (LDC), in Lexington, Davidson County. The facility has been approved two (2) previous certificates of need to add four (4) dialysis stations in Project ID #G-11639-18 and an additional five (5) dialysis stations in Project ID #G-11674-19 for a total of 46 approved dialysis stations. In this application, the applicants propose to add no more than three (3) dialysis stations (2 in-center stations and 1 dedicated home hemodialysis training station)

pursuant to Condition 2 of the facility need methodology for a total of no more than 49 dialysis stations upon project completion.

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations for Davidson County.

However, the applicants are eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the facility as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for LDC on page 154 of the 2020 SMFP is 82.43 percent or 3.297 patients per station per week, based on 122 in-center dialysis patients and 37 certified dialysis stations ($122 \text{ patients} / 37 \text{ stations} = 3.297$; $3.297 / 4 = 82.43\%$).

As shown in Table 9E, on page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to three (3) additional stations; thus, the applicants are eligible to apply to add up to three (3) dialysis stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicants propose to add no more than three (3) new stations to the facility, which is consistent with the 2020 SMFP calculated facility need determination for up to three (3) dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP applicable to this review. Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 SMFP states:

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

In Section B, pages 14-23, the applicants explain why they believe their application is consistent with Policy GEN-3:

- The applicants describe their safety and quality record in Section O, pages 80-81, and the policies they have to ensure safety and quality in delivering care, including their Continual Quality Improvement Program, which is included in Exhibit O-1(i).
- The applicants state in Section B, pages 19-22, they will provide care to the broadest range of patients possible and state they help in assisting patients to complete the necessary steps to gain admission to the facility's services.
- The applicants state on page 23 the ways they believe their proposed project will maximize healthcare value for resources expended, including maintaining levels of high-efficiency, keeping utilization between 80% to 90% and complying with all Federal and North Carolina rules and laws.

The applicants adequately document how the project will promote safety and quality in the delivery of dialysis services in Davidson County, will promote equitable access to dialysis services in Davidson County while maximizing healthcare value for resources expended, and how their projected volumes incorporate these concepts in meeting the need identified in the 2020 SMFP as well as addressing the needs of all residents in Davidson County. Therefore, the application is consistent with Policy GEN-3.

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 based on the following:

- The applicants adequately demonstrate that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicants adequately demonstrate how LDC's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.
- The applicants adequately demonstrate that the application is consistent with Policy GEN-3 because the proposal demonstrates how it will promote safety, quality and access to dialysis services as 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 applicants propose to add no more than 3 dialysis stations (2 in-center stations and 1 dedicated home hemodialysis training station) pursuant to Condition 2 of the facility need methodology for a total of no more than 49 dialysis stations upon project completion.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility is Davidson County. Facilities may serve residents of counties not included in their service area.

On page 27, the applicants state there are three (3) distinct patient populations served at LDC: 1) In-center (IC) patients dialyzing in the facility’s bay treatment areas, 2) Peritoneal (PD) and home hemodialysis (HH) patients dialyzing at home and 3) Patients receiving training to perform their PD and HH dialysis treatments at home. The following table illustrates current patient origin and projected patient origin for IC patients at Lexington Dialysis Center.

Lexington Dialysis Center Historical & Projected Patient Origin for IC patients

COUNTY	LAST FULL OPERATING YEAR (OY) CY 2019		SECOND FULL OY 7/1/2022-6/30/2023	
	# IC Pts.	% OF TOTAL	# IC Pts.	% OF TOTAL
Davidson	121	94.53%	142.89	94.64%
Davie	1	0.78%	1.19	0.79%
Forsyth	1	0.78%	1.14	0.76%
Rowan	5	3.91%	5.77	3.82%
Total	128	100.00%	150.99	100.00%

Source: Application pages 26-28

In Section C, pages 28-29 and Section Q, Form C, the applicants provide the assumptions and methodology used to project IC patient origin. The applicants’ assumptions are reasonable and adequately supported based on the following:

- The applicants project IC patient origin using their historical IC patient population as of June 30, 2020.
- The applicants project growth by using the 5-Year Average Annual Change Rate (AACR) for each respective county as published in the 2020 SMFP.

The following table illustrates historical and projected patient origin for HH and PD patients at Lexington Dialysis Center.

Lexington Dialysis Center Historical & Projected Patient Origin for HH and PD Patients

COUNTY	LAST FULL OPERATING YEAR (OY) 7/1/2019-6/30/2020				SECOND FULL OY 7/1/2022-6/30/2023			
	# HH Pts.	% OF TOTAL	# PD Pts.	% OF TOTAL	# HH Pts.	% OF TOTAL	# PD Pts.	% OF TOTAL
Davidson	3	60.00%	21	87.50%	3.54	60.20%	24.80	87.75%
Davie	1	20.00%	0	0.00%	1.19	20.18%	0	0.00%
Forsyth	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Rowan	1	20.00%	3	12.50%	1.15	19.62%	3.46	12.25%
Total	5	100.00%	24	100.00%	5.88	100.00%	28.26	100.00%

Source: Application pages 26-28

In Section C, pages 29-31, the applicants provide the following assumptions and methodology for PD training and in Section C, pages 31-32, for HH training. The applicants’ assumptions are reasonable and adequately supported for HH and PD home training based on the following:

- The applicants base the beginning HH and PD patient census on existing LDC patient volume.
- The applicants project the growth of HH and PD services by applying the 5-Year AACR to the county’s patient population census as of July 1, 2020.
- The applicants project the growth of HH and PD services using a growth rate of 7% based on growth of their home training program as a whole, factoring into their projected growth rate that 1) some HH and PD patients may not receive follow up care by the facility and 2) some home training patients may not elect to receive dialysis training the subsequent year.

Analysis of Need

In Section B, page 11 and Section C, pages 32-34, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services. The applicants discuss the need for additional IC dialysis stations and one (1) dedicated HH dialysis station based on LDC’s patient growth rate in Section C, pages 32-34, as follows:

- The applicants state the June 30, 2020 facility’s census was as follows: Davidson County – 121 patients, Davie County – 1 patient, Forsyth County – 1 patient, and Rowan County – 5 patients, for a total of 128 patients.
- The applicants state LDC’s patient population is expected to increase from 128 patients on June 30, 2020, to 142.90 patients by the end of the first operating year (OY1) for IC dialysis stations, including the one (1) dedicated HH training station.
- The applicants state LDC’s patient population is expected to increase from 128 patients on June 30, 2020, to 150.99 patients by the end of the second operating year (OY2) for IC dialysis stations, including the one (1) dedicated HH training station.
- The applicants use the 5-Year AACR for Davidson, Davie, Forsyth and Rowan counties to project growth for each county’s patient population for operating year 1 (OY1) and operating year 2 (OY2). The 5-Year AACRs are as follows: Davidson County - 5.7%, Davie County – 5.9%, Forsyth County – 4.5% and Rowan County – 4.9%.

- The additional three (3) dialysis stations are needed to preserve availability of services in Davidson County as patient population projects to grow.
- The 2021 SMFP shows a projected deficit of four (4) dialysis stations for Davidson County.

The information is reasonable and adequately supported based on the following:

- The applicants adequately demonstrate the need to add three (3) dialysis stations pursuant to facility need.
- The 2021 SMFP shows a projected deficit of four (4) dialysis stations for Davidson County supporting the need for additional dialysis stations in this service area.
- The applicants provide supporting documentation in Exhibit C-4.

Projected Utilization – In-Center Patients

In Section Q, Form C Utilization, page 85, the applicants provide a table to illustrate their methodology used to project in-center utilization, as shown below:

Form C Utilization	Last Full OY 07/01/2019- 06/30/2020	Interim Year 07/01/2020- 06/30/2021	First Full OY 07/01/2021- 06/30/2022	Second Full OY 07/01/2022- 06/30/2023
In-Center Patients				
# of Patients at the Beginning of the Year	122	128	135	143
# of Patients at the End of the Year	128	135	143	151
Average # of Patients during the Year	125	132	139	147
# of Treatments / Patient / Year	150	150	150	150
Total # of Treatments	18,750	19,800	20,850	22,050

In Section Q, pages 85-86, the applicants provide the following assumptions and methodology.

- Begin with the patient volume by county as of June 30, 2020.
- Apply the 5-Year AACR from the 2020 SMFP for each county to the county’s patient volume.
- Sum the individual county patient volume by operating year.
- Average number of patients during the year equals the mean of the beginning and ending facility census by year.
- Number of billable treatments per patient per year equals 150 ((3 treatments per week x 52 weeks) – 4% (average number of missed treatments) = 150).
- Total treatments equal billable treatments x average number of patients during the year.

The applicants provide the calculation table for their projected utilization in Section C, page 33, with the results summarized in the table below.

County	AACR	June 30, 2020	June 30, 2021	June 30, 2022	June 30, 2023
Davidson	5.7%	121.00	127.90	135.19	142.89
Davie	5.9%	1.00	1.06	1.12	1.19
Forsyth	4.5%	1.00	1.05	1.09	1.14
Rowan	4.9%	5.00	5.25	5.50	5.77
Totals		128.00	135.25	142.90	150.99

Note: Totals may not sum due to rounding.

As the table above shows, using conventional rounding, the methodology used by the applicants achieve a projection of 143 in-center patients by the end of the first operating year, OY1 (June 30, 2022), for a utilization rate of 2.9 patients per station per week or 72.5% (143 patients / 49 stations = 2.9 patients per station per week/ 4 = 0.725). By the end of OY2 (June 30, 2023), following the applicants’ methodology and assumptions, LDC will have 151 in-center patients dialyzing at the center for a utilization rate of 77.5% (151 / 49 = 3.1/ 4 = .775). The projected utilization of 2.9 patients per station per week for OY1 satisfies the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

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

- The applicants base their beginning in-center patient census on existing LDC patient volume.
- The applicants project the growth of the patient census using each county’s 5-Year AACR, as reported in the 2020 SMFP.
- The projected utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Projected Utilization – Home Hemodialysis and Peritoneal Dialysis Patients

In Section Q, Form C Utilization, page 85, the applicants provide a table to illustrate their methodology used to project HH and PD utilization, as shown below:

Form C Utilization	Last Full OY 07/01/2019- 06/30/2020	Interim Year 07/01/2020- 06/30/2021	First Full OY 07/01/2021- 06/30/2022	Second Full OY 07/01/2022- 06/30/2023
HH Patients				
# of Patients at the Beginning of the Year	0	5	5	6
# of Patients at the End of the Year	5	5	6	6
Average # of Patients during the Year	3	5	5	6
# of Treatments / Patient / Year	150	150	150	150
Total # of Treatments	450	750	750	900
PD Patients				
# of Patients at the Beginning of the Year	22	24	25	27
# of Patients at the End of the Year	24	25	27	28
Average # of Patients during the Year	23	25	26	28
# of Treatments / Patient / Year	150	150	150	150
Total # of Treatments	3,450	3,750	3,900	4,200

In Section C, pages 29-31, the applicants provide the following assumptions and methodology for PD patients and in Section C, pages 31-32, for HH patients in addition to pages 86-88 of the application:

- Begin with the patient volume by county as of June 30, 2020.
- The applicants projected utilization of HH and PD dialysis services by applying the 5-Year AACR from the 2020 SMFP for each county patient population.
- The applicants then project future growth at 7% each subsequent year. The applicants state on pages 29 (for PD services) and 31 (for HH services) that many factors go into projected growth for PD or HH training since the growth of the home training program is not dependent on the number of training patients by county due to 1) some patients who receive training at the facility may not receive follow up care by the facility and 2) home training patients who train one year may elect not to receive dialysis training the subsequent year.
- Applicants project that the average training days per patient by modality remains consistent until end of OY2 but that average training days per patient includes a “*range of training sessions of variable length transformed into a usable statistic*”.

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

- The applicants base their beginning HH and PD patient census on existing LDC patient volume.
- The applicants apply the 5-Year AACR for each county patient population from the 2020 SMFP to project utilization.
- The applicants project the growth of the patient census using a growth rate of 7% based on growth of their home training program as a whole, factoring into their growth rate that 1) some patients who receive HH and PD training may not receive follow up care

by the facility and 2) some of these patients may not elect to receive dialysis training the subsequent year.

Access to Medically Underserved Groups

In Section C.7, pages 36-38, the applicants discuss access to services at LDC. On page 36, the applicants state:

“Admission of a patient is based solely upon medical necessity and not the patient’s ability to pay. Patients may only access the facility’s services via physician referral due to a diagnosis of ESRD. The majority of patients are covered by Medicare, Medicaid, or some other form or combination of healthcare coverage. The facility’s social worker assists patients in seeking out and obtaining coverage for their care when necessary. However, should a circumstance arise in which a patient is ineligible for healthcare coverage, that patient is not turned away due to a lack of ability to pay.”

On pages 36-37, the applicants provide the following estimated percentages for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons*	30.00%
Racial and ethnic minorities	61.00%
Women	38.22%
Persons with Disabilities	Facility does not track
The elderly	45.22%
Medicare beneficiaries*	82.00%
Medicaid recipients*	30.00%

*IC patients only

The applicants adequately describe the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicants project estimated percentage of total patients for each group using current patient population data.

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 applicants adequately identify the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services and adequately support their 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.

NA

The applicants do not propose a reduction, elimination or relocation of a facility or service; therefore, Criterion (3a) is not applicable to this review.

(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 applicants propose to add no more than 3 dialysis stations (2 in-center stations and 1 dedicated home hemodialysis training station) pursuant to Condition 2 of the facility need methodology for a total of no more than 49 dialysis stations upon project completion.

In Section E, pages 44-45, the applicants describe the alternatives they considered and explain 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:

- *Transfer stations from a contiguous county*- The applicants state the 2020 SMFP indicates a surplus of dialysis stations in Davidson County so transferring stations from a contiguous county is not feasible.
- *Add less than three (3) dialysis stations* – The applicants state that this alternative was deemed to be less effective because of the growth of the patient census at the facility.

On pages 44-45, the applicants state that the proposal to add three (3) dialysis stations to LDC pursuant to Condition 2 of the facility need methodology is the most effective alternative to meet the needs of the dialysis patients served at the facility because it helps meet the growing demand for dialysis services at LDC.

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

- The applicants provide credible information to explain why they believe the proposed project is the most effective alternative.
- The application is conforming to all statutory and regulatory review criteria. Therefore, the application can be approved.

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. Therefore, the application is approved subject to the following conditions:

- 1. Wake Forest University Health Sciences and Lexington Dialysis Center of Wake Forest University (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than three (3) additional dialysis stations (2 In-Center stations and 1 Home-Hemodialysis training station) pursuant to Condition 2 of the facility need methodology at Lexington Dialysis Center for a total of no more than 49 stations upon project completion.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on June 1, 2021. The second progress report shall be due on October 1, 2021 and so forth.**
- 4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicants propose to add no more than 3 dialysis stations (2 in-center stations and 1 dedicated home hemodialysis training station) pursuant to Condition 2 of the facility need methodology for a total of no more than 49 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicants project the total capital cost of the project, as shown in the table below:

ITEM	COST
Medical Equipment	\$29,000
Furniture	\$4,600
Total	\$33,600

In Section Q, the applicants provide the assumptions used to project the capital cost. The applicants adequately demonstrate that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicants project each IC dialysis station machine will cost \$14,500. The one (1) dedicated HH training station does not require a fixed dialysis machine since the Centers for Medicare and Medicaid Services (CMS) requires each HH training patient to have their own portable machine for dialysis.
- The applicants project each IC dialysis station to require a chair and TV to accommodate the patients while dialyzing.

In Section F.3, pages 48-49, the applicants state there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

Availability of Funds

In Section F, page 46, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DaVita	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$33,600	\$33,600
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$33,600	\$33,600

* OE = Owner's Equity

Exhibit F contains the Consolidated Financial Statements for year ending June 30, 2019, that shows Wake Forest University, parent company to the applicants, currently has over \$64 million in cash and cash equivalents and over \$3 billion in total assets. These amounts include financial data from Wake Forest University Health Sciences and Reynolda Campus. Exhibit F.2 provides a letter dated September 1, 2020 and signed by Wake Forest University Health Services Chief Executive Officer that commits the capital to the project.

The applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicants submitted documentation from their parent company showing sufficient funds in their accumulated reserves or owner's equity for the capital needs of the project.
- The applicants submitted a letter from their Chief Executive Officer committing the required capital towards the project.

Financial Feasibility

The applicants provide pro forma financial statements for the first two full operating years following completion of the project. In Section Q, the applicants project that revenues will exceed operating expenses in the first two (2) operating years of the project, as summarized in the table below.

Lexington Dialysis Center Projected Revenue and Operating Expenses

	OY 1 7/1/2021- 6/30/2022	OY 2 7/1/2022- 6/30/2023
Total Treatments*	25,677	27,340
Total Gross Revenue (charges)**	\$58,098,348	\$61,859,777
Total Net Revenue	\$8,731,391	\$9,317,651
Average Net Revenue per Treatment	\$340	\$341
Total Operating Expenses (costs)	\$7,242,755	\$7,700,310
Average Operating Expense per Treatment	\$282	\$282
Net Income	\$1,488,636	\$1,617,340

*Includes treatment from all billing sources

** Includes revenue from all treatments provided by the facility including HH and PD training days billing plus drug administration fee

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The applicants adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicants project that revenues will exceed operating expenses in the first two (2) operating years of the project.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 applicants adequately demonstrate that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicants adequately demonstrate availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicants adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (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 applicants propose to add no more than 3 dialysis stations (2 in-center stations and 1 dedicated home hemodialysis training station) pursuant to Condition 2 of the facility need methodology for a total of no more than 49 dialysis stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Davidson County. Facilities may serve residents of counties not included in their service area.

There are two (2) dialysis centers in Davidson County. The applicants operate both dialysis centers in Davidson County. Utilization of both dialysis centers is shown in the following table from the 2020 SMFP and page 51 of the application:

Davidson County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CENTER PTS.	% UTILIZATION	# PTS. / STATION PER WEEK
Lexington Dialysis Center of Wake Forest University	37	122	82.43%	3.3
Thomasville Dialysis center of Wake Forest University	32	93	72.66%	2.9
Total	69	215		

Source: 2020 SMFP, Table 9B and application, page 51.

In Section G.2, page 51, the applicants explain why they believe their proposal would not result in the unnecessary duplication of existing or approved dialysis services in Davidson County. The applicants list a series of statements regarding Davidson County dialysis patients and the proposed addition of the stations prior to stating:

“It is the projected patient census by this project’s end of OY1 for which this CON must demonstrate utilization of 2.8 PPS (patients per station) according to the ESRD Performance Standards, thereby, proving the additional stations are ‘needed’[emphasis in original].”

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

- The applicants adequately demonstrate that LDC will be operating above 2.8 patients per station per week in its projected utilization, which is based on historical patient utilization increased annually at the individual county 5-Year Average Annual Growth Rate.
- Based on the facility need methodology in the 2020 SMFP under Condition 2, LDC qualifies to add up to three (3) dialysis stations.
- The applicants adequately demonstrate that the three (3) proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

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.

- (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 propose to add no more than 3 dialysis stations (2 in-center stations and 1 dedicated home hemodialysis training station) pursuant to Condition 2 of the facility need methodology for a total of no more than 49 dialysis stations upon project completion.

In Section Q, Form H Staffing, page 103, the applicants provide a table showing current and projected staffing in full time equivalent (FTE) positions for LDC, as summarized below.

Lexington Dialysis Center Current and Projected Staffing

POSITION	CURRENT FTE POSITIONS JUNE 30, 2020	PROJECTED FTE POSITIONS June 30, 2021	PROJECTED FTE POSITIONS June 30, 2022	PROJECTED FTE POSITIONS June 30, 2023
RN	5.00	5.75	6.80	7.25
LPN	1.25	1.50	1.50	1.50
Patient Care Tech	15.25	16.00	16.50	16.75
Clinical Nurse Manager (DON)	1.00	1.00	1.00	1.00
Dietician	1.45	1.50	1.50	1.50
Social Worker	1.60	1.75	1.75	1.75
HT Nurse	1.00	1.25	1.50	1.75
Dialysis Tech	1.60	1.75	2.00	2.00
Bio-med Technician	1.00	1.00	1.00	1.00
Clerical	3.00	3.25	3.75	4.00
Total	32.15	34.75	37.30	38.50

Source: Section Q, Form H of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, page 53, the applicants describe the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibits H-3 and H-4 provide supporting documentation.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicants base their projections on experience operating multiple dialysis facilities in the same service area as this facility.
- The dialysis facility is an existing facility with a training and recruitment process already existing in the service area.

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

The applicants propose to add no more than 3 dialysis stations (2 in-center stations and 1 dedicated home hemodialysis training station) pursuant to Condition 2 of the facility need methodology for a total of no more than 49 dialysis stations upon project completion.

Ancillary and Support Services

In Section I, page 57, the applicants identify the necessary ancillary and support services for the proposed services as shown in the table below:

Lexington Dialysis Center	
ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
(a) In-center dialysis/maintenance	On Premises
(b) Self-care training (performed in-center)	On Premises
(c) Home training	
(1) Hemodialysis	On Premises
(2) Peritoneal dialysis	On Premises
(3) Accessible follow-up program	On Premises
(4) Sister-Facility Agreement	On Premises
(d) Psychological counseling	On Premises
(e) Isolation-hepatitis	On Premises
(f) Nutritional counseling	On Premises
(g) Social work services	On Premises
(h) Acute dialysis in an acute care setting	Wake Forest Baptist Hospital
(i) Emergency care	Wake Forest Baptist Hospital
(j) Blood bank services	Wake Forest Baptist Hospital
(k) Diagnostic and evaluation services	On Premises by Wake Forest Baptist Hospital
(l) X-ray services	Wake Forest Baptist Hospital
(m) Laboratory services	On Premises by Wake Forest Baptist Hospital Meridian Lab Contract/On Premises
(n) Pediatric nephrology	On Premises by Wake Forest Baptist Hospital
(o) Vascular surgery	Wake Forest Baptist Hospital
(p) Transplantation services	Wake Forest Baptist Hospital
(q) Vocational rehabilitation counseling & services	On Premises with appropriate referral after evaluation by MSW
(r) Transportation	Davidson County Transportation Services

On pages 57-60, the applicants explain how each ancillary and support service is or will be made available and provide supporting documentation in Exhibits I-1 and I-2. The applicants adequately demonstrate that the necessary ancillary and support services will be made available based on the following:

- The applicants identify the necessary ancillary and support services for dialysis patients located in or near Davidson County and how these will be made available.

Coordination

In Section I, pages 60-61, the applicants describe their existing and proposed relationships with other local health care and social service providers and provide supporting documentation in Exhibit I-2. The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system based on the following:

- The applicants operate additional dialysis stations in the same area as the dialysis facility and have established ancillary and support services in the area.

- The applicants have existing relationships with local healthcare providers in the area including but not limited to Wake Forest Baptist Hospital.

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 applicants do 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 applicants do 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 applicants are 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 applicants do not propose to construct any new space nor make any 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, page 68, the applicants provide the historical payor mix for LDC patients from July 1, 2019, to June 30, 2020, for its existing services, as shown in the table below:

Payment Source	# of Patients*	% of Total
Private Pay	1	1%
Medicare	14	9%
Medicaid	14	9%
Medicare / Medicaid	30	20%
Commercial Insurance	13	8%
Medicare / Commercial	34	23%
Medicare Advantage	45	30%
Total	151	100%

* Data is for IC, HH and PD patients

In Section L.1(a), page 67, the applicants provide the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED	PERCENTAGE OF THE POPULATION OF DAVIDSON COUNTY
Female	38.22%	51.1%
Male	61.78%	48.9%
Unknown	N/A	N/A
64 and Younger	54.78%	81.5%
65 and Older	45.22%	18.5%
American Indian	0.00%	0.8%
Asian	1.29%	1.6%
Black or African-American	33.12%	10.1%
Native Hawaiian or Pacific Islander	0.00%	0.1%
White or Caucasian	57.96%	79.4%
Other Race	7.01%	7.4%
Declined / Unavailable	0.64%	1.8%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

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 applicants adequately document the extent to which medically underserved populations currently use the applicants' existing services in comparison to the percentage of the population in the applicants' 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;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicants state in Section L, pages 68-70, that while the facility is not required or obligated to provide uncompensated care or community service, as a Medicare Participating Provider, they are at a minimum subject to Federal laws and regulations regarding equal access and non-discrimination.

In Section L, page 70, the applicants state that during the last five years no patient civil rights access complaints have been filed against the facility.

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.

- (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.3, page 71, the applicants project the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Lexington Dialysis Center Projected Payor Mix
7/1/2022 – 6/30/2023 (OY2)**

Payment Source	# of Patients*	% of Total
Private Pay	2	1%
Medicare	17	9%
Medicaid	17	9%
Medicare / Medicaid	36	20%
Commercial Insurance	16	9%
Medicare / Commercial	41	23%
Medicare Advantage	54	30%
Total	181	100%

* Data is for IC, HH and PD patients

Note: Totals may not sum due to rounding

As shown in the table above, in the second full year of operation, the applicants project that 82% of services will be provided to Medicare patients including Medicare/Medicaid, Medicare/Commercial and Medicare Advantage patients and 9% to Medicaid patients.

On page 71, the applicants provide the assumptions and methodology they use to project payor mix during the second full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicants' projected payor mix is based on the historical payor mix of LDC.

- The monthly ending payor mix percentage by payor type is captured the last day of each month of operation due to constant fluctuation in payor mix as a result of transfers and re-starts of dialysis patients.

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.

- (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, pages 74-75, the applicants adequately describe the range of means by which patients will have access to 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.

- (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

The applicants propose to add no more than 3 dialysis stations (2 in-center stations and 1 dedicated home hemodialysis training station) pursuant to Condition 2 of the facility need methodology for a total of no more than 49 dialysis stations upon project completion.

In Section M, page 76, the applicants describe the extent to which health professional training programs in the area have access to the facility for training purposes and provide supporting documentation in Exhibit M-1. The applicants adequately demonstrate that health professional

training programs in the area have access to the facility for training purposes based on the following:

- The applicant submitted documentation showing an affiliation with Davidson County Community College (DCCC) to extend their services as a clinical training site at the dialysis facility to DCCC students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately demonstrate 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 applicants propose to add no more than 3 dialysis stations (2 in-center stations and 1 dedicated home hemodialysis training station) pursuant to Condition 2 of the facility need methodology for a total of no more than 49 dialysis stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Lexington Dialysis Center is located in Davidson County. Thus, the service area for this facility is Davidson County. Facilities may serve residents of counties not included in their service area.

There are two (2) dialysis centers in Davidson County. The applicants operate both dialysis centers in Davidson County. Utilization of both dialysis centers is shown in the following table from the 2020 SMFP and page 51 of the application:

Davidson County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CENTER PTS.	% UTILIZATION	# PTS. / STATION PER WEEK
Lexington Dialysis Center of Wake Forest University	37	122	82.43%	3.3
Thomasville Dialysis Center of Wake Forest University	32	93	72.66%	2.9
Total	69	215		

Source: 2020 SMFP, Table 9B and application, page 51.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 77, the applicants state:

“While this project will increase the number of dialysis stations at [LDC] and within Davidson County, utilization of those stations is based upon the projected growth of the existing patient base from physician referrals within the network of physicians who routinely refer patients to [LDC]. [LDC] does not project to capture market share from competitors, but merely projects to serve its proportional market share of the market(s) in which it currently operates.”

Regarding the impact of the proposal on cost effectiveness, in Section N.2, page 77, the applicants state:

“As demonstrated in the pro forma [documentation,] the cost of the service is not projected to dramatically increase, while the billable charge per treatment remains constant over all periods. Development of this project is cost-effective.”

See also Sections C, F and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N.2, page 78, the applicants state:

“Service quality will remain of the highest standard.”

See also Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N.2, page 78, the applicants state:

“Access to service is based upon a diagnosis of ESRD and appropriate referral. All patients have equal access regardless of their gender, age, race, ethnicity, or ability to pay. Expansion of health service resources at [LDC] will expand access of services to all ESRD patients.”

See also Sections B, C and L of the application and any exhibits.

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicants adequately demonstrate that:

- 1) The proposal is cost effective because the applicants adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicants' representations about how it will ensure the quality of the proposed services and the applicants' record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicants' representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described 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 Q, Form A Facilities, the applicants identify the dialysis facilities located in North Carolina and owned, operated or managed by the applicants or a related entity. The applicants identify a total of 19 existing and/or approved dialysis facilities located in North Carolina.

In Section O.2, page 81, the applicants provide a table showing that 13 dialysis facilities either owned, operated or affiliated with the applicants were surveyed within the last 18-month look-back period. During the 18 months immediately preceding the submittal of the application, one or more incidents related to quality of care occurred in 11 of the 13 facilities surveyed. These incidents were issued standard level deficiencies (not resulting in immediate jeopardy) and the table shows that the facilities were back in compliance at the time of application submittal, with the exception of the report pending for Salem Kidney Center (SKC). After

reviewing and considering information provided by the applicants and considering the quality of care provided at all facilities owned, operated or affiliated with the applicants, the applicants provide 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.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- The applicants are not proposing to establish a new kidney disease treatment center or dialysis facility.

(b) An applicant proposing to increase the number of dialysis stations in:

(1) an existing dialysis facility; or

(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;

shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C, page 33, the applicants project that LDC will serve 143 in-center patients on 49 dialysis stations, or a rate of 2.9 patients per station per week, as of the end of the first operating year following project completion. This meets the minimum performance standard of 2.8 patients per station per week. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

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

-C- In Section C.3, pages 27-32, the applicants provide the assumptions and methodology they use to project patient utilization of the facility.