

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 9, 2021

Findings Date: February 9, 2021

Project Analyst: Misty L. Piekaar-McWilliams

Team Leader: Fatimah Wilson

Project ID #: G-11989-20

Facility: Highland Oaks Dialysis Center of Wake Forest University

FID #: 200885

County: Forsyth

Applicant(s): Wake Forest University Health Sciences

Highland Oaks Dialysis Center of Wake Forest University

Project: Develop a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

## 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.

NA

Wake Forest University Health Sciences and Highland Oaks Dialysis Center of Wake Forest University (“the applicants”) propose to develop a new kidney disease treatment center, Highland Oaks Dialysis Center of Wake Forest University (“Highland Oaks”), dedicated to providing home training and support services for peritoneal dialysis (PD) patients. The applicants propose to add five (5) PD training rooms. The applicants do not propose to include any certified in-center stations or home hemodialysis stations as part of the proposed project.

The applicants do not propose to add stations via either the facility need methodology, or the county need methodology published in the 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

The applicants do not propose to:

- develop any beds or services for which there is a need determination in the 2020 SMFP. The 2020 SMFP does not provide a need methodology for determining the need for kidney disease treatment centers dedicated to providing home PD services.
- acquire any medical equipment for which there is a need determination in the 2020 SMFP.
- offer a new institutional health service for which there are any applicable policies in the 2020 SMFP. Policy GEN-3 is not applicable to this review because the applicant does not propose to develop or offer a new institutional health service for which there is a need determination in the 2020 SMFP. Policy GEN-4 is not applicable to this review because the proposed capital cost for the project is \$388,000 which is less than the \$2 million dollars required for Policy GEN-4 to be applicable.

Therefore, Criterion (1) is not applicable to this review.

- (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 develop a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

### **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 Forsyth County. Facilities may serve residents of counties not included in their service area.

In Section C, page 18, the applicants state that they propose “*to develop a new home peritoneal dialysis training facility*”; therefore, there is no historical patient origin information to report. In Section C, page 18, the applicants state there are two (2) distinct patient populations to be served at Highland Oaks: 1) PD patients already dialyzing at home who will transfer their monthly follow-up care to the new facility due to convenience and 2) new patients who will

train to perform their PD dialysis treatments at home. The following table illustrates projected patient origin for operating year (OY) 1 and OY 2.

<b>Highland Oaks Projected Patient Origin</b>				
<b>COUNTY</b>	<b>FIRST FULL OY 11/1/2021-10/31/2022</b>		<b>SECOND FULL OY 11/1/2022-10/31/2023</b>	
	<b># PD Pts.</b>	<b>% OF TOTAL</b>	<b># PD Pts.</b>	<b>% OF TOTAL</b>
Forsyth	16.72	100.00%	17.47	100.00%
<b>Total</b>	<b>16.72</b>	<b>100.00%</b>	<b>17.47</b>	<b>100.00%</b>

Source: Application pages 19-20

In Section C, pages 19-21 and Section Q, Form C, the applicants provide the assumptions and methodology used to project PD patient origin. The applicants’ assumptions are reasonable and adequately supported based on the following:

- The applicants project 16 PD patients already dialyzing at home will transfer their services to the new facility based upon greater geographic convenience, which is the number used for the initial PD patient population. The Project Analyst notes that Wake Forest University Health Sciences is currently the only provider of dialysis services in Forsyth County.
- New patients who will train to perform their PD services at home will increase based upon increased referrals to the training program.
- Since July 10, 2019, there has been a shift in referral patterns to increase capacity for PD training services due to President Trump’s Executive Order on Advancing American Kidney Health.
- The applicants project future PD growth by using the 5-Year Average Annual Change Rate (AACR) for Forsyth County (4.5%) as published in the 2020 SMFP.

**Analysis of Need**

In Section C, pages 22-24, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services. On pages 23-24, the applicants state:

- The development of the proposed facility supports the expansion of PD services in Forsyth County in conjunction with the Executive Order to expand home training services, recent referral patterns, and patients’ preference to dialyze at home during COVID-19.
- Additional availability of PD training rooms in Forsyth County will eliminate wait times for access to the service resulting in better patient outcomes and quality of life.
- The proposed facility’s location will relieve geographic access burdens for many patients.
- The proposed facility will have a “Sister Facility Agreement” in place to provide in-center services, if necessary.

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

- Home dialysis provides patient flexibility, convenience, and avoids possible missed treatments.
- The proposed project will enable more patients to dialyze at home in Forsyth County which supports the mission of the Executive Order, recent referral patterns and patients’ preference to dialyze at home during COVID-19.

*Projected Utilization - Peritoneal Dialysis Patients*

In Section Q, Form C Utilization, page 72, the applicants provide a table to illustrate their methodology used to project PD utilization, as shown below:

Form C Utilization	First Full OY* 11/01/2021- 10/31/2022	Second Full OY 11/01/2022- 10/31/2023
<b>PD Patients</b>		
# of Patients at the Beginning of the Year	16	17
# of Patients at the End of the Year	17	17
Average # of Patients during the Year	16	17
# of Treatments / Patient / Year	150	150
Total # of Treatments	2,400	2,550

\*OY = Operating Year

In Section C, pages 19-21 and Section Q, pages 72-74, the applicants provide the following assumptions and methodology for PD patients:

- The applicants project 16 PD patients will transfer their services to the new facility based upon greater geographic convenience.
- The applicants’ experience show an average of 7 days per projected PD training per patient; therefore, the applicants use 7 days for each projected PD training per patient for OY 1 and OY 2.
- The applicants state given the increased PD training capacity that will be made available in Forsyth County by development of this project, they project to train about 40% more patients year over year, resulting in 14 new PD patients training an average of 7 days with a total of 98 training days in OY 1, and 19.60 PD patients training an average of 7 days with a total of 137.20 training days in OY 2.
- The applicants project growth by using the 5-Year Average Annual Change Rate (AACR) for Forsyth County (4.5%) as published in the 2020 SMFP.

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

- The applicants project future utilization based on historical utilization of all end stage renal disease (ESRD) patients who are residents of Forsyth County and would benefit from the geographic location of the new facility.
- Future growth of all Forsyth County ESRD patients is based on the 5-Year AACR for Forsyth County (4.5%).

- The Executive Order on Advancing American Kidney Health issued on July 10, 2019, by President Trump promotes home training over in-center dialyzing.
- The applicants' representation that they have experienced a significant shift in referral numbers for home dialysis.
- The physician letters of support from Nephrology Associates, PLLC and Wake Forest Baptist Health in Exhibit H-4.

### **Access to Medically Underserved Groups**

In Section C.7, pages 25-27, the applicants discuss access to services at Highland Oaks. On page 25, 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 25-27, the applicants provide the following estimated percentages for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	18.00%
Racial and ethnic minorities	60.00%
Women	44.00%
Persons with Disabilities	Applicants do not track
The elderly	29.33%
Medicare beneficiaries	75.00%
Medicaid recipients*	18.00%

\*Includes dual eligible recipients

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 for Forsyth 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 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 develop a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

In Section E, page 32, the applicants state that no other alternatives were considered and that the only option was to apply or not to apply. The applicants state that the purpose of developing the facility is to better serve the ESRD population in Forsyth County choosing home peritoneal dialysis. The applicants further state that there is a lack of physical plant capacity to offer or expand the availability of PD training services at existing facilities owned, operated or managed by the applicants in Forsyth County.

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

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

- The proposed project will result in more patients having the ability to choose home dialysis in Forsyth County.
- The proposed project will accommodate the lack of physical plant capacity to offer or expand PD training services in Forsyth County.

### **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 Highland Oaks Dialysis Center of Wake Forest University of Wake Forest University (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
  - 2. The certificate holder shall establish a freestanding home dialysis training and support program with five (5) peritoneal training rooms to provide only peritoneal dialysis training and support services.**
  - 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 July 1, 2021. The second progress report shall be due on November 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 develop a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

**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
Construction/Renovation Contract(s)	\$287,890
Furniture	\$100,100
<b>Total</b>	<b>\$388,000</b>

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 submitted supporting documentation from Shelco, a general contracting company, illustrating the cost to upfit the property would be \$287,890.00 in Exhibit K-3.
- The applicants project the PD training rooms will not require the purchase of a fixed dialysis machine since the PD training rooms will not be used for in-center services.

In Section F.3, page 35, the applicants state there will be no start-up or initial operating expenses associated with the proposed project because billing associated with the transferred patients receiving follow-up services will generate sufficient revenue from the date of opening. Additionally, the applicants state existing staff from other Wake Forest University Health Sciences' dialysis facilities will participate in start-up of the proposed dialysis center with some staff eventually transferring to the new proposed location.

**Availability of Funds**

In Section F, page 33, 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 *	\$388,000	\$388,000
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$388,000</b>	<b>\$388,000</b>

\* OE = Owner's Equity

Exhibit F-2(c)(iii) contains the Consolidated Financial Statements for year ending June 30, 2020, which shows Wake Forest University, parent company to the applicants, currently has over \$166 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(c)(ii) provides a letter dated November 15, 2020 and signed by Wake Forest Baptist Health 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 (2) 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.

**Highland Oaks  
 Projected Revenue and Operating Expenses**

	OY 1 11/1/2021- 10/31/2022	OY 2 11/1/2022- 10/31/2023
Total Treatments	2,400	2,550
Total Gross Revenue**/**	\$5,652,050	\$6,080,139
Total Net Revenue	\$1,113,832	\$1,198,194
Average Net Revenue per Treatment	\$446	\$446
Total Operating Expenses (costs)	\$861,578	\$904,725
Average Operating Expense per Treatment	\$359	\$354
<b>Net Income</b>	<b>\$252,254</b>	<b>\$293,469</b>

\*Rounded

\*\* Includes drug administration revenue

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 develop a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

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 Forsyth County. Facilities may serve residents of counties not included in their service area.

There are five (5) dialysis centers in Forsyth County. The applicants operate all five (5) dialysis centers in Forsyth County. According to the most recent ESRD Data Collection Forms submitted to the Agency, home PD services are currently available at Northside Dialysis Center of Wake Forest University (27 patients) and Piedmont Dialysis Center of Wake Forest

University (75 patients) facilities. Utilization of each dialysis center located in Forsyth County is shown in the following table from the 2020 SMFP and page 38 of the application:

**Forsyth County Dialysis Facilities**

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CENTER PTS.	% UTILIZATION	# PTS. / STATION PER WEEK
Miller Street Dialysis Center of Wake Forest University	44	141	80.11%	3.2
NC Baptist Hospital ESRD	4	2	12.50%	0.5
Northside Dialysis Center of Wake Forest University	45	145	80.56%	3.2
Piedmont Dialysis Center of Wake Forest University	58	181	78.02%	3.1
Salem Kidney Center of Wake Forest University	45	153	85.00%	3.4
<b>Total</b>	<b>196</b>	<b>622</b>		

Source: 2020 SMFP, Table 9B and application, page 38.

In Section G.2, page 38, the applicants explain why they believe their proposal would not result in the unnecessary duplication of existing or approved dialysis services in Forsyth County. The applicants list a series of statements regarding the data found in the 2020 SMFP prior to stating:

*“This application does not propose to add ICH (in-center) stations for which utilization and need is reflected in the SMFP. This application is for the development of a new PD home dialysis training facility and is based upon current patient data and referral patterns not reflected in the 2020 SMFP.”*

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 proposed project does not involve adding dialysis stations.
- The project involves the development of a new facility that will exclusively serve home PD patients.
- The applicants adequately demonstrate that the five (5) proposed PD training stations are needed to support a shift in referral patterns since the issuance of the Executive Order which promotes home training over in-center dialyzing.
- The most recent ESRD Data Collection Forms submitted to the Agency by the applicants or their affiliates illustrate the demand for home PD training services in Forsyth 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 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 develop a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

In Section Q, Form H Staffing, page 90, the applicants provide a table showing projected staffing in full time equivalent (FTE) positions for Highland Oaks, as summarized below. There are no current staffing needs as the facility is new and not established.

<b>POSITION</b>	<b>PROJECTED FTE POSITIONS October 31, 2022</b>	<b>PROJECTED FTE POSITIONS October 31, 2023</b>
Patient Care Tech	0.50	0.50
Clinical Nurse Manager (DON)	1.00	1.00
Dietician	0.25	0.25
Social Worker	0.25	0.25
HT Nurse	0.50	0.50
Bio-Med Technician	0.25	0.25
Clerical	0.50	0.50
<b>Total</b>	<b>3.25</b>	<b>3.25</b>

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 40, the applicants describe the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibits H-4(a)(i), H-4(a)(ii) and H-4(b) 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.

**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 develop a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

#### **Ancillary and Support Services**

In Section I, page 44, the applicants identify the necessary ancillary and support services for the proposed services as shown in the table below:

**Highland Oaks Dialysis Center of Wake Forest University**

<b>ANCILLARY AND SUPPORT SERVICES</b>	
<b>SERVICES</b>	<b>PROVIDER</b>
(a) In-center dialysis/maintenance	Piedmont Dialysis Center (PDC)
(b) Self-care training (performed in-center)	PDC
(c) Home training	Highland Oaks Dialysis Center (HODC)/PDC
(1) Hemodialysis	PDC
(2) Peritoneal dialysis	HODC
(3) Accessible follow-up program	HODC
(4) Sister-Facility Agreement	PDC
(d) Psychological counseling	HODC
(e) Isolation-hepatitis	HODC
(f) Nutritional counseling	HODC
(g) Social work services	HODC
(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	Wake Forest Baptist Hospital
(l) X-ray services	Wake Forest Baptist Hospital
(m) Laboratory services	Wake Forest Baptist Hospital/Meridian Lab
(n) Pediatric nephrology	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	Various community resources*

\*Community resources noted in Exhibit I-1(b)(xviii)

On pages 44-47, the applicants explain how each ancillary and support service is or will be made available and provide supporting documentation in Exhibit I. 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 Forsyth County and how these will be made available.

**Coordination**

In Section I, pages 47-48, the applicants describe their existing and proposed relationships with other local health care and social service providers and provide supporting documentation in Exhibits I-2(a), (b) and (c)(i-iv). 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 proposed 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.

### C

The applicants propose to develop a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

In Section K, page 51, the applicants state that the project involves up fitting 3,400 square feet of leased space. Line drawings are provided in Exhibit K-2(b).

On pages 53-54, the applicants identify the proposed site and provide information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K-3 and Exhibit K-4(b). The site appears to be suitable for the proposed dialysis facility based on the applicants' representations and supporting documentation.

On pages 51-52, the applicants adequately explain how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On pages 52-53, the applicants adequately explain why the proposal will not unduly increase the costs to the applicant providing the proposed services or the costs and charges to the public for the proposed services.

On pages 53, the applicants identify any applicable energy saving features that will be incorporated into the construction plans.

### **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.

- (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

The applicants state on page 55 that this is an application for a new facility. Therefore, there is no historical payor mix data to report. In Section L.1(a), page 55, the applicants provide the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED **	PERCENTAGE OF THE POPULATION OF FORSYTH COUNTY
Female	44.0%	52.7%
Male	56.0%	47.3%
Unknown	N/A	N/A
64 and Younger	71.0%	83.6%
65 and Older	29.0%	16.4%
American Indian	1.0%	0.9%
Asian	4.0%	2.6%
Black or African-American	51.0%	27.5%
Native Hawaiian or Pacific Islander	1.0%	0.1%
White or Caucasian	40.0%	56.3%
Other Race	3.0%	13.3%
Declined / Unavailable	0.0%	2.3%

\*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.

\*\*Percentage of Total Patients Served by Wake Forest University Health Sciences in Forsyth County, NC. The application is for a proposed new facility, and, thus, there is no current data for the facility.

**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' (Wake Forest University Health Sciences) 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 56-58, 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 58, 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 58, 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.

**Highland Oaks Projected Payor Mix  
11/1/2022 – 10/31/2023 (OY2)**

<b>Payment Source</b>	<b># of Patients*</b>	<b>% of Total</b>
Medicare	2	12%
Medicaid	0	1% [0%]*
Medicare / Medicaid	3	17%
Commercial Insurance	4	24%
Medicare / Commercial	5	29%
Medicare Advantage	3	17%
<b>Total</b>	<b>17</b>	<b>100%</b>

\* Analyst's calculations

**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 75% of services will be provided to Medicare patients including Medicare/Medicaid, Medicare/Commercial and Medicare Advantage patients.

On pages 58-59, 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 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.
- The total average number of patients is the total average patients per month for the operating period used to calculate revenue and expenses from the pro forma and not the total number of patients ending 10/31/2023.
- The applicants use the last operating year's PD payor mix for all Wake Forest University Health Sciences dialysis facilities in Forsyth County for the period ending 10/31/2020, and for all periods beginning 11/1/2020 through the end of OY 2.

**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 61-63, 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 develop a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

In Section M, page 64, 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 applicants submit documentation showing interest in partnering with Forsyth Technical Community College (FTCC) to extend their services as a clinical training site at the proposed dialysis center to FTCC 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 develop a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

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.”* Highland Oaks is located in Forsyth County. Thus, the service area for this facility is Forsyth County. Facilities may serve residents of counties not included in their service area.

There are five (5) dialysis centers in Forsyth County. The applicants operate all five (5) dialysis centers in Forsyth County. According to the most recent ESRD Data Collection Forms submitted to the Agency, home PD services are currently available at Northside Dialysis Center of Wake Forest University (27 patients) and Piedmont Dialysis Center of Wake Forest University (75 patients) facilities. Utilization of each dialysis center located in Forsyth County is shown in the following table from the 2020 SMFP and page 38 of the application:

**Forsyth County Dialysis Facilities**

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CENTER PTS.	% UTILIZATION	# PTS. / STATION PER WEEK
Miller Street Dialysis Center of Wake Forest University	44	141	80.11%	3.2
NC Baptist Hospital ESRD	4	2	12.50%	0.5
Northside Dialysis Center of Wake Forest University	45	145	80.56%	3.2
Piedmont Dialysis Center of Wake Forest University	58	181	78.02%	3.1
Salem Kidney Center of Wake Forest University	45	153	85.00%	3.4
<b>Total</b>	<b>196</b>	<b>622</b>		

Source: 2020 SMFP, Table 9B and application, page 38.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 65, the applicants state:

*“The proposed project is for a new PD training facility in a county where WFUHS (Wake Forest University Health Sciences) is the sole provider of dialysis services. The new facility will offer PD training in a location with greater geographic accessibility to the projected patient population.”*

Regarding the impact of the proposal on cost effectiveness, in Section N.2, page 66, 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 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 68, 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 HODC will expand access of services to all ESRD patients.”*

See also Sections 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 they 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 20 existing and/or approved dialysis facilities located in North Carolina.

In Section O.2, page 68, the applicants provide a table showing that 11 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 (1) or more incidents related to quality of care occurred in 9 of the 11 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. 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.

NA

The applicant proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for PD patients. The applicant does not propose to include any certified in-center stations or home hemodialysis stations as a part of the proposed project. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued to another provider by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving PD patients.