

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 16, 2019

Findings Date: May 16, 2019

Project Analyst: Julie M. Faenza

Team Leader: Fatimah Wilson

Project ID #: F-11673-19

Facility: Lake Norman Dialysis Center of Wake Forest University

FID #: 990439

County: Iredell

Applicants: Wake Forest University Health Sciences

Lake Norman Dialysis Center of Wake Forest University

Project: Add four stations for a total of 31 stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Wake Forest University Health Sciences (WFUHS) and Lake Norman Dialysis Center of Wake Forest University (LNDC-WFU), collectively referred to as “the applicant,” proposes to add four dialysis stations to its existing facility for a total of 31 dialysis stations upon project completion.

#### **Need Determination**

The 2019 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 D in the January 2019 Semiannual Dialysis Report (SDR), there is a surplus of 12 dialysis stations in Iredell County. Therefore, there is no county need determination for new dialysis stations in Iredell County. However, the applicant is eligible to apply for additional

dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate for LNDC-WFU in the January 2019 SDR is 3.5185 patients per station per week. This utilization rate was calculated based on 95 in-center dialysis patients and 27 certified dialysis stations as of June 30, 2018 (95 patients / 27 stations = 3.5185 patients per station per week).

Application of the facility need methodology indicates that up to a potential maximum of four additional stations are needed for this facility, as illustrated in the following table.

<b>APRIL 1 REVIEW – JANUARY 2019 SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		87.96%
Certified Stations		27
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>27</b>
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR2)		95
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		91
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.0879
(ii)	Divide the result of Step (i) by 12	0.0073
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.0440
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	99.1758
(v)	Divide the result of Step (iv) by 3.2 patients per station	30.9924
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>4</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 2019 SDR. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add four new stations and is therefore consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2019 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles* on page 31 of the 2019 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical*

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

### Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 11-16; Section K, pages 57-59; Section N, pages 74-75; Section O, pages 76-77; supplemental information requested by the Agency; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 16-21; Section C, page 27; Section L, pages 63-72; Section N, pages 74-75; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 21; Section C, pages 23-27; Section F, pages 35-38; Section K, pages 57-59; Section N, pages 74-75; supplemental information requested by the Agency; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

### Conclusion

The Agency reviewed the:

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

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

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

### C

The applicant proposes to add four dialysis stations to its existing facility for a total of 31 dialysis stations upon project completion.

LNDC-WFU currently offers both home hemodialysis (HH) and home peritoneal dialysis (PD) training, and plans to continue to offer both types of home training in the future.

In supplemental information requested by the Agency, the applicant states LNDC-WFU is a subsidiary of, and owned entirely by, WFUHS. WFUHS, in turn, is a wholly-owned subsidiary of Wake Forest University. The applicant states that Wake Forest University healthcare-related entities do business under the “brand” name Wake Forest Baptist Health.

### **Patient Origin**

On page 369, the 2019 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Iredell County. Facilities may also serve residents of counties not included in their service area.

The following table shows current and projected patient origin.

<b>LNDC-WFU Current and Projected Patients by County of Residence</b>											
<b>County</b>	<b>Current As of February 28, 2019</b>			<b>OY1 3/1/20-2/28/21</b>			<b>OY2 3/1/21-2/28/22</b>			<b>County Patients as % of Total</b>	
	<b>IC*</b> Patients	<b>PD</b> Patients	<b>HH</b> Patients	<b>IC*</b> Patients	<b>PD</b> Patients	<b>HH</b> Patients	<b>IC*</b> Patients	<b>PD</b> Patients	<b>HH</b> Patients	<b>OY1</b>	<b>OY2</b>
Cabarrus	1	0	0	1.16	0.00	0.00	1.24	0.00	0.00	1.00%	1.04%
Catawba	9	0	0	10.71	0.00	0.00	11.69	0.00	0.00	9.22%	9.79%
Iredell	70	3	0	72.26	3.10	0.00	73.41	3.15	0.00	64.88%	64.11%
Lincoln	4	0	0	4.00	0.00	0.00	4.00	0.00	0.00	3.44%	3.35%
Mecklenburg	16	6	0	17.27	6.48	0.00	17.95	6.73	0.00	20.45%	20.66%
Rowan	0	1	0	0.00	1.16	0.00	0.00	1.26	0.00	1.00%	1.05%
<b>Total</b>	<b>100</b>	<b>10</b>	<b>0</b>	<b>105.40</b>	<b>10.74</b>	<b>0.00</b>	<b>108.29</b>	<b>11.13</b>	<b>0.00</b>	<b>100.00%</b>	<b>100.00%</b>

**Source:** Section C, pages 23 and 29

\*IC = In-center

In Section C, pages 23-27, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 24-26, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 24, the applicant states:

*“LNDC has experienced net patient growth of 10 patients over the last 12 months. Its utilization rate is currently 92.59%. Without additional stations, the facility’s access to service for new ESRD patients will begin to be limited.”*

The information is reasonable and adequately supported for the following reasons:

- The applicant’s utilization in the January 2019 SDR was 87.96 percent.
- Application of the facility need methodology shows a need for up to four additional stations based on historical utilization.

**Projected Utilization – In-Center Patients**

In Section C, page 25, the applicant provides historical and projected utilization, as shown in the table below.

<b>LNDC-WFU Historical and Projected Utilization – In-Center Patients</b>						
		<b>Prior Year</b>	<b>Current Year</b>	<b>As of Certification</b>	<b>End of OY1</b>	<b>End of OY2</b>
<b>County</b>	<b>AACR*</b>	<b>2/28/18</b>	<b>2/28/19</b>	<b>2/29/20</b>	<b>2/28/21</b>	<b>2/28/22</b>
Cabarrus	7.5%	1.00	1.00	1.08	1.16	1.24
Catawba	9.1%	8.00	9.00	9.82	10.71	11.69
Iredell	1.6%	62.00	70.00	71.12	72.26	73.41
Lincoln	0.0%	2.00	4.00	4.00	4.00	4.00
Mecklenburg	3.9%	16.00	16.00	16.62	17.27	17.95
Rowan	7.9%	1.00	0.00	0.00	0.00	0.00
<b>Total</b>		<b>90.00</b>	<b>100.00</b>	<b>102.64</b>	<b>105.40</b>	<b>108.29</b>

\*AACR = Five Year Average Annual Change Rate from the January 2019 SDR

In Section C, pages 23-26, and in supplemental information requested by the Agency, the applicant provides the assumptions and methodology it uses to project in-center patient utilization, which are summarized below.

- Existing patient population for LNDC-WFU as of February 28, 2018 is grouped by county of patient origin.
- The existing patient population for every county except Lincoln County is increased each year by the Five Year AACR for that county as published in the January 2019 SDR, beginning with the current patient census as of February 28, 2019.
- The existing patient population for Lincoln County, which has a Five Year AACR of -4.5 percent as published in the January 2019 SDR, is held constant. In supplemental information requested by the Agency, the applicant states the existing patient population is not expected to decline simply because the Five Year AACR is negative.
- The project is scheduled for certification on February 29, 2020. Operating Year One is March 1, 2020 through February 28, 2021. Operating Year Two is March 1, 2021 through February 28, 2022.

The applicant projects to serve 105 patients on 31 stations, which is 3.39 patients per station per week (105 patients / 31 stations = 3.39), by the end of OY1 and 108 patients on 31 stations, which is 3.48 patients per station per week (108 patients / 31 stations = 3.48), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

*Projected Utilization – Home Peritoneal Dialysis Patients*

In Section C, pages 23 and 29, the applicant provides historical and projected utilization, as shown in the table below.

<b>LNDC-WFU Historical and Projected Utilization – PD Patients</b>					
		<b>Current Year</b>	<b>As of Certification</b>	<b>End of OY1</b>	<b>End of OY2</b>
<b>County</b>	<b>AACR</b>	<b>2/28/19</b>	<b>2/29/20</b>	<b>2/28/21</b>	<b>2/28/22</b>
Cabarrus	7.5%	0.00	0.00	0.00	0.00
Catawba	9.1%	0.00	0.00	0.00	0.00
Iredell	1.6%	3.00	3.05	3.10	3.15
Lincoln	0.0%	0.00	0.00	0.00	0.00
Mecklenburg	3.9%	6.00	6.23	6.48	6.73
Rowan	7.9%	1.00	1.08	1.16	1.26
<b>Total</b>		<b>10.00</b>	<b>10.36</b>	<b>10.74</b>	<b>11.13</b>

In supplemental information requested by the Agency, the applicant states that it applied the same assumptions about in-center patient growth to the historical PD patient population.

*Projected Utilization – Home Hemodialysis Patients*

In Section C, page 27, the applicant states that, as of February 28, 2019, it did not have any home hemodialysis patients at its facility. In supplemental information requested by the Agency, the applicant states that, despite not having any current patients, it plans to continue to offer HH patient training and support as long as the service is needed.

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

- The applicant begins with the existing patient populations as of February 28, 2019.
- The growth of the patient population for most counties is consistent with the Five Year AACR for those counties as published in the January 2019 SDR.
- The growth of the patient population for Lincoln County, which is not consistent with the Five Year AACR for Lincoln County as published in the January 2019 SDR, is adequately explained.

**Access**

In Section C, page 27, the applicant states:

*“LNDC accepts patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents with ESRD. Further, the facility also accepts the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need.”*

In Section L, page 64, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

<b>LNDC-WFU Projected Payor Mix – OY 2</b>			
<b>Payor Category</b>	<b>% of Total Patients</b>	<b>% In-Center Patients</b>	<b>% Home (HH &amp; PD) Patients</b>
Private Pay	1%	1%	0%
Medicare	9%	10%	3%
Medicaid	3%	3%	1%
Medicare/Medicaid	19%	20%	14%
Commercial Insurance	10%	8%	21%
Medicare/Commercial	38%	36%	45%
VA	5%	6%	1%
Medicare Advantage	16%	16%	15%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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



NA

The applicant does not propose to relocate, reduce, or eliminate 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 applicant proposes to add four dialysis stations to its existing facility for a total of 31 dialysis stations upon project completion.

In Section E, pages 33-34, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – the applicant states it currently has 100 patients being served on 27 stations, which is a utilization rate of 92.59 percent. The applicant states applying the Five Year AACR for each county population being served at LNDC-WFU results in a utilization close to 100 percent by the end of the first operating year if additional stations are not added. Therefore, this was not considered an effective alternative.
- Add Fewer than Four Stations – the applicant states it calculated the resulting utilization for every potential new station, from zero new stations to four new stations, in Section C, page 26. The applicant states since adding the maximum four stations permitted under the facility need methodology results in a utilization rate greater than 80 percent in the first operating year, adding fewer than four stations is not considered an effective option.
- Relocate Existing Stations from Another Facility in Iredell County – the applicant considered relocating stations from its other facilities in Iredell County, since the other facilities have utilization rates close to or below 80 percent. The applicant states that transferring stations from other facilities would result in increased utilization and need for additional stations at those facilities at a later date; therefore, this was not considered an effective alternative.
- Relocate Existing Stations from a Contiguous County – the applicant states that, since Iredell County has a surplus of 12 dialysis stations, relocating existing stations from a contiguous county is not permitted and therefore is not an effective alternative.

On page 34, the applicant states:

*“Facility need methodology allows LNDC to gain the 4 stations it is projected to need. LNDC’s application meets the requirements for an expansion via facility need methodology. The project cost is estimated at \$67,200. Because no other option is compatible with LNDC’s need, an addition of 4 stations via facility need methodology*

*is the most-effective alternative to meet the current and projected needs at LNDC irrespective of the cost.”*

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 above stated reasons. Therefore, the application is approved subject to the following conditions:

- 1. Wake Forest University Health Sciences and Lake Norman Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Wake Forest University Health Sciences and Lake Norman Dialysis Center of Wake Forest University shall materially comply with the last made representation.**
  - 2. Pursuant to the facility need determination in the January 2019 SDR, Wake Forest University Health Sciences and Lake Norman Dialysis Center of Wake Forest University shall develop no more than four additional dialysis stations for a total of no more than 31 certified stations at Lake Norman Dialysis Center of Wake Forest University upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
  - 3. Wake Forest University Health Sciences and Lake Norman Dialysis Center of Wake Forest University shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add four dialysis stations to its existing facility for a total of 31 dialysis stations upon project completion.

### **Capital and Working Capital Costs**

In Section F, page 35, the applicant states that the proposed capital cost of the project is \$67,200 – \$58,000 for dialysis machines and \$9,200 for other equipment. In Section F, pages 38-39, the applicant states there are no projected start-up or initial operating expenses, since LNDC-WFU is an existing facility.

### **Availability of Funds**

In Section F, page 36, the applicant states it will fund the capital costs via accumulated reserves. Exhibit F-5 contains a letter from the president of Wake Forest Baptist Health system, committing \$67,200 in accumulated reserves toward the proposed project. Exhibit F-7(a) contains the audited financial statements of Wake Forest University for the years ending June 30, 2017 and 2018. As of June 30, 2018, Wake Forest University had adequate assets and cash equivalents to fund the proposed project. See the discussion at the beginning of Criterion (3) for more details about the relationship between the applicant and the entities providing and demonstrating the availability of funding for the proposed project.

### **Financial Feasibility**

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

<b>LNDC-WFU Revenue and Operating Expenses – OYs 1-2</b>		
	<b>OY 1</b>	<b>OY 2</b>
	<b>(3/1/20-2/28/21)</b>	<b>(3/1/21-2/28/22)</b>
Total Treatments	19,208	19,658
Total Gross Revenues (Charges)	\$31,535,018	\$32,362,852
Total Net Revenue	\$5,176,742	\$5,355,243
Average Net Revenue per Treatment	\$270	\$272
Total Operating Expenses (Costs)	\$3,982,336	\$4,075,985
Average Operating Expense per Treatment	\$207	\$207
Net Income	\$1,194,406	\$1,279,258

The assumptions used by the applicant 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 discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- Supplemental information requested by the Agency

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add four dialysis stations to its existing facility for a total of 31 dialysis stations upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Iredell County. Facilities may also serve residents of counties not included in their service area.

Currently, there are three existing and approved dialysis facilities in Iredell County, all of which are owned by WFUHS. Current patient utilization for each of the three facilities in Iredell County is shown in the table below.

<b>Iredell County Dialysis Facilities</b>			
<b>Facility</b>	<b>Location</b>	<b># Certified Stations as of 6/30/18</b>	<b>Utilization as of 6/30/18</b>
LDNC-WFU	Mooresville	27	87.96%
Statesville Dialysis Center of Wake Forest University	Statesville	27	69.44%
West Iredell Dialysis of Wake Forest University	Statesville	20	81.25%

Source: Table B, January 2019 SDR

In Section G, page 42, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Iredell County. The applicant states:

*“The facility need projected and proven for LNDC is based upon facility need methodology that allows for an addition of stations at a facility based upon that location’s utilization. LNDC is well utilized. By adding four stations to LNDC for a total of 31 stations, a manageable utilization rate of 85.00% can be obtained by the end of OY1 of the project versus the projected utilization of 97.59% that would result by doing nothing. As described, above, LNDC’s sister facilities in Iredell County either need additional stations or transferring stations from them would create a need at their locations. Additional stations at LNDC will enhance access to services to the ESRD patients of Iredell and surrounding counties without duplicating services.”*

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

- The applicant demonstrates the need for the additional four stations based on the facility need methodology.
- The applicant demonstrates that the proposed stations are needed in addition to the existing or approved stations in Iredell County.

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

In Section H, page 43, the applicant provides the current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

<b>LNDC-WFU Current and Projected FTE Staffing</b>			
<b>Position</b>	<b>Current Positions</b>	<b>To be Added</b>	<b>Positions OY 2</b>
Registered Nurse	4.75	0.25	5.00
Licensed Practical Nurse	0.75	0.00	0.75
Patient Care Technician	8.75	1.50	10.25
Director of Nursing	1.00	0.00	1.00
Dietician	1.00	0.00	1.00
Social Worker	0.75	0.00	0.75
Home Training Nurse	1.00	0.00	1.00
Dialysis Technician	1.00	0.00	1.00
Biomed	1.25	0.00	1.25
Clerical	2.00	0.00	2.00
<b>Total</b>	<b>22.25</b>	<b>1.75</b>	<b>24.00</b>

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 47-48, the applicant describes the methods used to recruit personnel or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibit H-4. In Section I, page 53, the applicant identifies the current medical director. In Exhibit I-3(a), the applicant provides a letter from the medical director expressing support for the proposed project and expressing an interest in continuing to serve as medical director.

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 51, the applicant identifies the ancillary and support services necessary for the proposed services, as shown in the table below.

<b>LNDC-WFU Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training Hemodialysis Peritoneal Dialysis Accessible follow-up program	On site On site On site
Psychological counseling	On site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social work services	On site
Acute dialysis in an acute care setting	Wake Forest Baptist University
Emergency care	Wake Forest Baptist University
Blood bank services	Wake Forest Baptist University
Diagnostic and evaluation services	On site
X-ray services	Wake Forest Baptist University
Laboratory services	On site via contract, Wake Forest Baptist University
Pediatric nephrology	On site
Vascular surgery	Wake Forest Baptist University
Transplantation services	Wake Forest Baptist University
Vocational rehabilitation & counseling	On site, referral if necessary
Transportation	Autumn Care of Cornelius, Genesis Health Care

The applicant provides supporting documentation in Exhibits I-1(l), I-1(q), I-2(a), and I-2(b).

In Section I, pages 53-55, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-3(a), I-3(b), and I-4(a).

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space, renovate existing space, or upfit 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 71, the applicant provides the historical payor mix during during the last full fiscal year, as shown in the table below.

<b>LNDC-WFU Historical Payor Mix – 2/28/18-2/28/19</b>			
<b>Payor Category</b>	<b>% of Total Patients</b>	<b>% In-Center Patients</b>	<b>% Home (HH &amp; PD) Patients</b>
Private Pay	0%	0%	0%
Medicare	7%	8%	2%
Medicaid	2%	2%	0%
Medicare/Medicaid	17%	18%	14%
Commercial Insurance	15%	13%	24%
Medicare/Commercial	37%	34%	49%
VA	4%	5%	0%
Medicare Advantage	18%	20%	11%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

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

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial and Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>	<b>2017 Estimate</b>
Iredell	16%	51%	24%	11%	10%	12%
Statewide	16%	51%	37%	15%	10%	12%

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

\*Excludes "White alone, not Hispanic or Latino"

\*\*"Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

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

The IPRO SA Network 6 2016 Annual Report (pages 25-26<sup>1</sup>) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

### C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 69, the applicant states that it has no such obligation.

In Section L, page 70, the applicant states that, during the last five years, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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

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

C

In Section L, page 64, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

<b>LNDC-WFU Projected Payor Mix – OY 2</b>			
<b>Payor Category</b>	<b>% of Total Patients</b>	<b>% In-Center Patients</b>	<b>% Home (HH &amp; PD) Patients</b>
Private Pay	1%	1%	0%
Medicare	9%	10%	3%
Medicaid	3%	3%	1%
Medicare/Medicaid	19%	20%	14%
Commercial Insurance	10%	8%	21%
Medicare/Commercial	38%	36%	45%
VA	5%	6%	1%
Medicare Advantage	16%	16%	15%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

As shown in the table above, during the second full fiscal year of operation, the applicant projects that one percent of total services will be provided to private pay patients, 82 percent to patients having some or all of their care paid for by Medicare, and 22 percent to patients having some or all of their care paid for by Medicaid.

On pages 64-65, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant relies on historical payor mix to project future payor mix.
- The applicant uses a five year historical payor mix average to ensure more accuracy in its projections.

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, page 69, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 73, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add four dialysis stations to its existing facility for a total of 31 dialysis stations upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Iredell County. Facilities may also serve residents of counties not included in their service area.

Currently, there are three existing and approved dialysis facilities in Iredell County, all of which are owned by WFUHS. Current patient utilization for each of the three facilities in Iredell County is shown in the table below.

<b>Iredell County Dialysis Facilities</b>			
<b>Facility</b>	<b>Location</b>	<b># Certified Stations as of 6/30/18</b>	<b>Utilization as of 6/30/18</b>
LDNC-WFU	Mooreville	27	87.96%
Statesville Dialysis Center of Wake Forest University	Statesville	27	69.44%
West Iredell Dialysis of Wake Forest University	Statesville	20	81.25%

Source: Table B, January 2019 SDR

In Section N, pages 74-75, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 74, the applicant states:

*“This project shall have no impact on competition in Iredell County. Patients utilize a facility based upon physician preference, geographical location, or other reasons of convenience. An addition of stations at LNDC is necessary to serve the facility’s existing and projected patients and stave off excessive utilization. By approval of this project, LNDC will have the ability to continue serving its patient base during current operating hours keeping competition at its current level.”*

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

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

## **Conclusion**

The Agency reviewed the:

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

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

- (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 supplemental information requested by the Agency, the applicant identifies the number of dialysis facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 18 of this type of facility located in North Carolina.

In Section O, pages 76-77, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that resulted in an Immediate Jeopardy in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 18 facilities, the applicant provided 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

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

**10A NCAC 14C .2203 PERFORMANCE STANDARDS**

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- LNDC-WFU is an existing facility. Therefore, this Rule is not applicable to this review.

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

-C- In Section C, page 23, the applicant projects to serve 105 in-center patients on 31 stations by the end of OY1 for a utilization rate of 3.39 patients per station per week (105 patients / 31 stations = 3.39). The discussion regarding projected utilization found in Criterion (3) 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, pages 23-27, and in supplemental information requested by the Agency, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.