

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 3, 2020

Findings Date: June 3, 2020

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: G-11868-20

Facility: Piedmont Dialysis Center of Wake Forest University

FID #: 944661

County: Forsyth

Applicants: Wake Forest University Health Sciences

Piedmont Dialysis Center of Wake Forest University

Project: Add no more than 10 dialysis stations pursuant to facility need for a total of no more than 64 in-center 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 Piedmont Dialysis Center of Wake Forest University (Piedmont Dialysis Center), collectively referred to as “the applicant”, proposes to add no more than 10 dialysis stations to the Piedmont Dialysis Center of Wake Forest University (Piedmont Dialysis Center) pursuant to facility need for a total of no more than 64 in-center (IC) stations upon project completion. Piedmont Dialysis Center currently offers both a peritoneal dialysis (PD) program and a home hemodialysis (HH) program.

## **Need Determination**

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. The applicant has submitted an application to add ten dialysis stations pursuant to the facility need methodology.

An applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center, as reported in Table 9B of the 2020 SMFP, is at least 75% or 3.0 patients per station per week, as stated in Condition 2.a on page 116.

The utilization rate reported for Piedmont Dialysis Center on page 155 of the 2020 SMFP, is 78.0% or 3.12 patients per station per week, based on 181 in-center dialysis patients and 58 certified dialysis stations [ $181 / 58 = 3.12$ ;  $3.12 / 4 = 0.78$  or 78.0%]. Therefore, the applicant exceeds the minimum utilization required in Condition 2.a. and is eligible to apply for additional stations based on the facility need methodology in Condition 2.b, pages 116-117.

As shown in Table 9E, page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Piedmont Dialysis Center is ten additional stations; the applicant has not applied for any additional dialysis stations for Piedmont Dialysis Center to date this year. Therefore, the applicant is eligible to apply to add up to ten stations pursuant to the facility need methodology.

The applicant proposes to add no more than ten new dialysis stations pursuant to facility need, which is consistent with the 2020 SMFP calculated facility need determination for ten dialysis stations; therefore, the application is consistent with the facility need determination for dialysis stations.

## **Policies**

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, pages 30-31 of the 2020 SMFP, states:

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

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.5, pages 14-18; Section N, pages 84-86, Section O, pages 87-88; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.5(b), pages 19-23; Section L, pages 74-81; Section N, pages 84-86, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.5(c), page 23; and Section N, pages 84-86. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant does not propose to develop more dialysis stations than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 because the applicant adequately demonstrates how Piedmont Dialysis Center’s projected volumes incorporate the concepts of safety and quality, equitable access and maximum healthcare value for resources expended in meeting the facility need.

- (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 no more than 10 dialysis stations to Piedmont Dialysis Center pursuant to a facility need for a total of no more than 64 in-center stations upon project completion.

**Patient Origin**

On page 113, the 2020 SMFP defines the service area for dialysis stations as, “*the service area is 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.*” Piedmont Dialysis Center is in Forsyth County. Thus, the service area for this facility is Forsyth County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical patient origin for the last full operating year (OY) 12/31/2018 to 12/31/2019 (CY2019), from page 27.

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Burke	0.00	0.00%	0.00	0.00%	1.00	1.33%
Catawba	0.00	0.00%	0.00	0.00%	1.00	1.33%
Cumberland	0.00	0.00%	1.00	14.29%	0.00	0.00%
Davidson	8.00	4.30%	0.00	0.00%	5.00	6.67%
Davie	1.00	0.54%	0.00	0.00%	2.00	2.67%
Forsyth	172.00	92.47%	5.00	71.43%	61.00	81.33%
Guilford	3.00	1.61%	1.00	14.29%	3.00	4.00%
Haywood	0.00	0.00%	0.00	0.00%	1.00	1.33%
Henry, VA	0.00	0.00%	0.00	0.00%	1.00	1.33%
Iredell	1.00	0.54%	0.00	0.00%	0.00	0.00%
Rockingham	1.00	0.54%	0.00	0.00%	0.00	0.00%
<b>Total</b>	<b>186.00</b>	<b>100.00%</b>	<b>7.00</b>	<b>100.00%</b>	<b>75.00</b>	<b>100.00%</b>

Totals may not sum due to rounding

The following table illustrates projected patient origin for the second full OY 1/1/2022 to 12/31/2022 (CY2022), from page 28.

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Burke	0.00	0.00%	0.00	0.00%	1.06	1.24%
Catawba	0.00	0.00%	0.00	0.00%	1.25	1.46%
Cumberland	0.00	0.00%	1.00	14.29%	0.00	0.00%
Davidson	9.45	4.44%	0.00	0.00%	5.90	6.87%
Davie	1.19	0.56%	0.00	0.00%	2.38	2.76%
Forsyth	196.28	92.34%	5.00	71.43%	69.61	81.00%
Guilford	3.51	1.65%	1.00	14.29%	3.51	4.09%
Haywood	0.00	0.00%	0.00	0.00%	1.22	1.42%
Henry, VA	0.00	0.00%	0.00	0.00%	1.00	1.16%
Iredell	1.08	0.51%	0.00	0.00%	0.00	0.00%
Rockingham	1.05	0.50%	0.00	0.00%	0.00	0.00%
<b>Total</b>	<b>212.57</b>	<b>100.00%</b>	<b>7.00</b>	<b>100.00%</b>	<b>85.94</b>	<b>100.00%</b>

Totals may not sum due to rounding

In Section C, pages 28-31, the applicant provides the assumptions and methodology used to project Piedmont Dialysis Center’s patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C and supplemental information, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed additional dialysis stations. The applicant states:

- Table 9E of the 2020 SMFP, page 171, shows Piedmont Dialysis Center as having a facility need of ten dialysis stations.
- As of December 31, 2018, based on 181 IC patients and 58 certified stations, Piedmont Dialysis Center was operating at 78.02% utilization (See Table 9B of the 2020 SMFP, page 155).
- As of December 31, 2019, Piedmont Dialysis Center had 54 certified dialysis stations and 186 IC patients for a utilization of 86.0% or 3.44 patients per station per week, based on 186 in-center dialysis patients and 54 certified dialysis stations [ $186 / 54 = 3.44$ ;  $3.44 / 4 = 0.86$  or 86.0%].
- The facility’s existing 54 stations will be utilized at approximately 94.13%, as of the end of 2021 and at more than 98% by the end of 2022, if no stations are added (page 32).

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

- The applicant demonstrates the need to add stations pursuant to facility need as the facility is operating at 86.0% of capacity as of December 31, 2019.

- Each of the existing, operational Forsyth County facilities, except for NC Baptist Hospital ESRD which only has four certified dialysis stations, are operating at or above 3.1 patients per station per week or 78% capacity per the 2020 SMFP.
- The applicant bases the future need for services upon the facility’s historical patient utilization, applying the 5-year county Average Annual Change Rate (AACR) from Table 9C of the 2020 SMFP of 5.7%, 5.9%, 4.5%, 5.4%, 2.7% and 1.8% for patients from Davidson, Davie, Forsyth, Guilford, Iredell and Rockingham counties, respectively, to project growth in patient need at the facility.
- The facility need methodology in the 2020 SMFP shows a need for ten additional dialysis stations at Piedmont Dialysis Center.

*Projected Utilization*

*In-Center Patients*

In Section C.4, page 32, and supplemental information, the applicant provides the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project. The following table provides historical and projected utilization of in-center dialysis patients at Piedmont Dialysis Center.

**Piedmont Dialysis Center In-Center Dialysis Utilization**

County	5-Yr AACR	Beginning Census 12/31/2019	Ending Current Year 12/31/2020	End of OY1 12/31/2021	End of OY2 12/31/2022
Davidson	5.70%	8.00	8.46	8.94	9.45
Davie	5.90%	1.00	1.06	1.12	1.19
Forsyth	4.50%	172.00	179.74	187.83	196.28
Guilford	5.40%	3.00	3.16	3.33	3.51
Iredell	2.70%	1.00	1.03	1.05	1.08
Rockingham	1.80%	1.00	1.02	1.04	1.05
<b>Totals</b>		<b>186.00</b>	<b>194.47</b>	<b>203.31</b>	<b>212.57</b>

Totals may not sum due to rounding

Source: Table on page 32 of the application.

As the table above shows, the methodology used by the applicant shows a projection of 203.31 in-center patients by the end of the first operating year, OY1, for a utilization rate of 3.17 patients per station per week or 79.25% (203 patients / 64 stations = 3.17/ 4 = 0.7925 or 79.25%).

By the end of OY2, following the applicant’s methodology and assumptions, Piedmont Dialysis Center will have 212.57 in-center patients dialyzing at the center for a utilization rate of 82.75% (212 / 64 = 3.31/ 4 = .8275 or 82.75%).

The projected utilization of 3.17 patients per station per week for OY1 satisfies the 2.8 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

In Section C.3, pages 29-31, and Section Q, pages 92-94, the applicant provides the methodology and assumptions used to project utilization at Piedmont Dialysis Center. Based on the facility need methodology, Piedmont Dialysis Center is eligible to add ten dialysis stations.

The applicant's methodology and assumptions are summarized below:

- Existing patients are grouped by modality and county of origin, as of December 31, 2019.
- Utilization is based on current patients at Piedmont Dialysis Center, projected forward by applying the 5-year Average Annual Change Rate (AACR), by county of patient origin, to the current patient populations to project patient census through the end of Operating Year 2.
- OY1 ends December 31, 2021; OY2 ends December 31, 2022.

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

- The applicant bases the future utilization of services upon the facility's historical patient utilization,
- The applicant bases the future need for services upon the facility's historical patient utilization, applying the 5-year county AACR from Table 9C of the 2020 SMFP of 5.7%, 5.9%, 4.5%, 5.4%, 2.7% and 1.8% for patients from Davidson, Davie, Forsyth, Guilford, Iredell and Rockingham counties, respectively, to project growth in patient need at the facility.
- Based on Table 9E of the 2020 SMFP, page 171, Piedmont Dialysis Center has a Facility Station Need for ten dialysis stations.

*Peritoneal Patients*

**Piedmont Dialysis Center PD Dialysis: Historical and Projected Utilization**

	<b>Last Full Operating Year: 12/31/2019</b>	<b>End of OY2: 12/31/2022</b>
PD Patients	85.00	90.2

Source: Table on page 31 in Section C of the application and Section Q.

The applicant started with the historical number of PD patients as of 12/31/19 and applied an annual growth rate of 2.0%.

**Piedmont Dialysis Center PD Dialysis: Historical and Projected Utilization**

Historical number of PD patients at Piedmont Dialysis Center as of 12/31/2019	85
Based on a 2.0% growth rate project the number of PD patients forward one year to 12/31/2020	$1.02 \times 85 = 86.70$
Based on a 2.0% growth rate project the number of PD patients forward one year to 12/31/2021. This is the projected ending PD patient census for Operating Year One.	$1.02 \times 86.70 = 88.43$
Based on a 2.0% growth rate project the number of PD patients forward one year to 12/31/2022. This is the projected ending PD patient census for Operating Year One.	$1.02 \times 88.43 = 90.20$

*Home Hemodialysis Patients*

**Piedmont Dialysis Center HH Dialysis: Historical and Projected Utilization**

	<b>Last Full Operating Year: 12/31/2019</b>	<b>End of OY2: 12/31/2022</b>
HH Patients	11.00	11.67

Source: Table on page 30 in Section C of the application and Section Q.

The applicant started with the historical number of HH patients as of 12/31/19 and applied an annual growth rate of 2.0%.

**Piedmont Dialysis Center HH Dialysis: Historical and Projected Utilization**

Historical number of HH patients at Piedmont Dialysis Center as of 12/31/2019	11
Based on a 2.0% growth rate project the number of HH patients forward one year to 12/31/2020	$1.02 \times 11 = 11.22$
Based on a 2.0% growth rate project the number of HH patients forward one year to 12/31/2021. This is the projected ending HH patient census for Operating Year One.	$1.02 \times 11.22 = 11.44$
Based on a 2.0% growth rate project the number of HH patients forward one year to 12/31/2022. This is the projected ending HH patient census for Operating Year One.	$1.02 \times 11.44 = 11.67$

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

- the applicant bases the future utilization of services upon the facility’s historical patient utilization, and
- the applicant bases the future need for services upon the facility’s historical patient utilization, applying a 2% annual growth rate to project utilization.

**Access**

In Section C, page 39, the applicant states,



*“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.”*

Further, on page 40 the applicant states,

*“The facility 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 78, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**Projected Payor Mix: CY2022**

<b>Payor Source</b>	<b>Percent Total Patients</b>	<b>Percent of IC Patients</b>	<b>Percent of PD &amp; HH Patients</b>
VA	6%	6%	4%
Medicare	10%	10%	8%
Medicaid	7%	7%	4%
Medicare / Medicaid	24%	26%	16%
Medicare Advantage	21%	22%	16%
Medicare / Commercial	24%	22%	32%
Commercial Insurance	9%	7%	20%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Application page 78

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

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 reduce a service, eliminate a service or relocate 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 no more than 10 dialysis stations to Piedmont Dialysis Center pursuant to a facility need for a total of no more than 64 in-center stations upon project completion.

In Section E, pages 49-51, the applicant describes the alternatives 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:

- *Transfer Stations from a Contiguous County per Policy ESRD-2-* The applicant states that WFUHS, the parent of Piedmont Dialysis Center has dialysis facilities in the counties of Davie, Davidson, Guilford, Stokes, Surry and Yadkin which are all contiguous to Forsyth County. However, the 2020 SMFP indicates that Forsyth has a one-station surplus which prevents a transfer of stations from a contiguous county. Therefore, this is not the least costly or most effective alternative.
- *Add Less than 8 Stations and no dedicated HH Training Stations-* The facility need methodology identifies a need for eight [sic] additional stations at Piedmont Dialysis Center. The applicant states that adding less than 8 additional stations will not meet the projected patient needs. In addition, not adding the dedicated HH training stations would

ultimately interfere with the facility's ability to meet IC patient needs as some stations would then need to be used for HH training. Therefore, this is not the least costly or most effective alternative.

On page 50, the applicant states that its proposal is the most effective alternative because the proposed project meets the projected patient population need of eight dialysis stations using the facility need methodology and the addition of two dedicated HH training stations alleviates HH training from interfering with Piedmont Dialysis Center's ability to utilize its full complement of stations to deliver IC dialysis services. The Project Analyst notes that the proposed project meets the projected population need for ten dialysis stations using the facility need methodology.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Wake Forest University Health Sciences and Piedmont 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 Piedmont Dialysis Center of Wake Forest University shall materially comply with the last made representation.**
- 2. Pursuant to the facility need determination in the 2020 SMFP, Wake Forest University Health Sciences and Piedmont Dialysis Center of Wake Forest University shall develop no more than ten additional dialysis stations for a total of no more than sixty-four certified stations at Piedmont Dialysis Center which shall include any home hemodialysis training or isolation stations.**
- 3. Wake Forest University Health Sciences and Piedmont 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 no more than 10 dialysis stations to Piedmont Dialysis Center pursuant to a facility need for a total of no more than 64 in-center stations upon project completion.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, page 96, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$168,000
<b>Total</b>	<b>\$168,000</b>

In Section Q, Form F-1(b), page 96, the applicant provides the assumptions used to project the capital cost.

In Section F, page 54, the applicant states that Piedmont Dialysis Center is an existing operational facility; therefore, there are no start-up or initial operating expenses.

**Availability of Funds**

In Section F, page 52, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	Wake Forest University Health Sciences	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$168,000	\$ 168,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$168,000</b>	<b>\$168,000</b>

\* OE = Owner's Equity

In Exhibit F-2(c)(ii), the applicant provides a letter dated March 15, 2020, from the Chief Executive Officer of Wake Forest Baptist Health, authorizing the project and committing \$168,000 from WFUHS for the development of the project. Exhibit F-2(c)(iii) contains Consolidated Financial Statements for Wake Forest University for the fiscal year ended June 30, 2019, showing WFUHS with \$19,175,000 in cash and cash equivalents, \$1.37 billion in total assets and \$807,739,000 in net assets.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, 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>1<sup>st</sup> Full Fiscal Year</b>	<b>2<sup>nd</sup> Full Fiscal Year</b>
Total Treatments	43,392	45,502
Total Gross Revenues (Charges)	\$97,182,270	\$101,907,535
Total Net Revenue	\$15,265,023	\$16,017,403
Average Net Revenue per Treatment	\$352	\$352
Total Operating Expenses (Costs)	\$11,647,311	\$12,157,096
Average Operating Expense per Treatment	\$268	\$267
Net Income	\$3,617,712	\$3,860,307

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

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

- 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 no more than 10 dialysis stations to Piedmont Dialysis Center pursuant to a facility need for a total of no more than 64 in-center stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as, “*the service area is 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.*” Piedmont Dialysis Center is in Forsyth County. Thus, the service area for this facility is Forsyth County. Facilities may also serve residents of counties not included in their service area.

According to Table 9B: *Inventory of Dialysis Stations and Calculation of Utilization Rates* on page 155 of the 2020 SMFP, there are five existing dialysis facilities in Forsyth County as shown in the following table:

<b>Forsyth County Dialysis Facilities: Certified Stations/Utilization as of December 31, 2018</b>			
<b>Dialysis Facility</b>	<b># of Certified Stations</b>	<b>Percent Utilization</b>	<b>Facility Station Need Determination</b>
Miller Street Dialysis Center of Wake Forest University	44	80.11%	5
NC Baptist Hospital ESRD	4	12.50%	0
Piedmont Dialysis Center of Wake Forest University	58	78.02%	10
Salem Kidney Center of Wake Forest University	45	85.00%	8
Northside Dialysis Center of Wake Forest University	45	80.56%	13

Source: 2020 SMFP, page 155.

In Section G, page 57, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Forsyth County. The applicant states:

*“This application projects the need for the requested stations in line with the Performance Standards, which require 70% utilization by the end of OY1 of the proposed project (12/31/2021.)”*

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

- There is a facility need determination in the 2020 SMFP for the proposed ten in-center dialysis stations.

- The applicant adequately demonstrates that the proposed IC dialysis stations, including HH training stations, are needed in addition to the existing or approved IC dialysis stations and dedicated HH training stations.

**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 based on the reasons stated above.

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

**C**

In Section Q, Form H, page 109, and supplemental information, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

<b>POSITION</b>	<b>Current FTE Positions as of 12/31/19</b>	<b>PROJECTED FTE POSITIONS OY2 (1/1/2022 TO 12/31/2022)</b>
RN	9.25	8.75
LPN	1.00	1.00
Patient Care Tech	19.25	18.50
Clinical Nurse Manager (DON)	2.00	2.00
Dietician	3.25	3.25
Social Worker	3.00	3.00
Home Training Nurse	5.50	5.50
Dialysis Tech	2.00	2.00
Bio-med Technician	2.00	2.00
Clerical	6.94	6.94
<b>Total</b>	<b>54.19</b>	<b>52.94</b>

Source: Sections Q, Form H, page 109 of the application.

The assumptions and methodology used to project staffing are provided in Section Q, Form H, and in supplemental information. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q.

In Sections H.2 and H.3, pages 59-61, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H,

page 62, the applicant identifies the current medical director. In Exhibit H-4(b), the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-3, H-4(a)(i) and H-4(a)(ii), the applicant provides supporting documentation.

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
- Supplemental information requested by the Agency

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 63, the applicant states that the following ancillary and support services are necessary for the proposed services:



<b>PIEDMONT DIALYSIS CENTER Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	On Premises
Self-care training (in-center)	On Premises
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	On Premises On Premises On Premises
Psychological counseling	On Premises with appropriate referral after evaluation by MSW
Isolation – hepatitis	On Premises
Nutritional counseling	On Premises
Social Work services	On Premises
Acute dialysis in an acute care setting	Wake Forest Baptist Hospital
Emergency care	Wake Forest Baptist Hospital
Blood bank services	Wake Forest Baptist Hospital
Diagnostic and evaluation services	Wake Forest Baptist Hospital
X-ray services	Wake Forest Baptist Hospital
Laboratory services	Wake Forest Baptist Hospital and Meridian Laboratory Corp
Pediatric nephrology	Wake Forest Baptist Hospital
Vascular surgery	Wake Forest Baptist Hospital
Transplantation services	Wake Forest Baptist Hospital
Vocational rehabilitation & counseling	On Premises with appropriate referral after evaluation by MSW
Transportation	Social Workers, Department of Social Services, Grant Agencies, Individual Transport Agencies

On page 63-67, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1(b)(xiii), 1(b)(v), 1(b)(xviii); Exhibits I-2(a), 2(b), 2(c)(i) and Exhibits H-4(a)(i) and 4(a)(ii).

In Section I.2, pages 66-67, the applicant describes Piedmont Dialysis Center’s existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-2(a), 2(b), 2(c)(i), 2(c)(ii), 2(c)(iii), 2c(iv) and Exhibit M-1.

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.

C

In Section K, page 70, the applicant states that the project involves renovating 1,500 square feet of existing space. Line drawings are provided in Exhibit K-2(b).

On pages 70-71, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. and provides supporting documentation in Exhibit K-2(b).

On page 71, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 71-72, the applicant identifies 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

In Section L, page 75, the applicant provides the historical payor mix for Piedmont Dialysis Center's patients during CY2019 for the proposed services, as shown in the table below.

**Historical Payor Mix: Last Full OY (12/31/2018 to 12/31/2019)**

<b>Payor Source</b>	<b>Percent Total Patients</b>	<b>Percent of IC Patients</b>	<b>Percent of PD &amp; HH Patients</b>
VA	6%	6%	4%
Medicare	10%	10%	8%
Medicaid	6%	7%	4%
Medicare / Medicaid	24%	26%	16%
Medicare Advantage	21%	22%	16%
Medicare / Commercial	24%	22%	32%
Commercial Insurance	9%	7%	20%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Application page 75

In Section L, page 74, the applicant provides the following comparison.

	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY</b>	<b>Percentage of the Population of the Service Area</b>
Female	46.00%	52.60%
Male	54.00%	47.40%
Unknown	n/a	n/a
64 and Younger	52.00%	84.00%
65 and Older	48.00%	16.00%
American Indian	0.37%	0.90%
Asian	1.87%	2.60%
Black or African-American	63.43%	27.50%
Native Hawaiian or Pacific Islander	0.37%	0.10%
White or Caucasian	25.00%	56.50%
Other Race	8.21%	13.00%
Declined / Unavailable	0.37%	2.30%

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.2(a), page 75, the applicant states that while the facility is not required or obligated to provide uncompensated care or community service, as a Medicare Participating Provider, it is at a minimum subject to Federal laws and regulations regarding equal access and non-discrimination.

On page 77, the applicant states there have been no civil rights access complaints filed against the facility within the last five years.

The Agency reviewed the:

- application, and
- 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 78, 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.

**Projected Payor Mix: CY2022**

<b>Payor Source</b>	<b>Percent Total Patients</b>	<b>Percent of IC Patients</b>	<b>Percent of PD &amp; HH Patients</b>
VA	6%	6%	4%
Medicare	10%	10%	8%
Medicaid	7%	7%	4%
Medicare / Medicaid	24%	26%	16%
Medicare Advantage	21%	22%	16%
Medicare / Commercial	24%	22%	32%
Commercial Insurance	9%	7%	20%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Application page 78

As shown in the table above, during the second full calendar year of operation, the applicant projects that 6% of the dialysis patients will be VA patients and 86% will have all or part of their services paid for by Medicare and/or Medicaid.

On page 78, the applicant provides the assumptions and methodology used to project payor mix during the first two full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient origin is comparable to the historical Piedmont Dialysis Center's payor mix.

The Agency reviewed the:

- application, and
- 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 81-82, 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 83, the applicant describes the extent to which health professional training programs in the area will 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 no more than 10 dialysis stations to Piedmont Dialysis Center pursuant to a facility need for a total of no more than 64 in-center stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as, “*the service area is 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.*” Piedmont Dialysis Center is in Forsyth County. Thus, the service area for this facility is Forsyth County. Facilities may also serve residents of counties not included in their service area.

According to Table 9B: *Inventory of Dialysis Stations and Calculation of Utilization Rates* on page 155 of the 2020 SMFP, there are five existing dialysis facilities in Forsyth County as shown in the following table:

<b>Forsyth County Dialysis Facilities: Certified Stations/Utilization as of December 31, 2018</b>			
<b>Dialysis Facility</b>	<b># of Certified Stations</b>	<b>Percent Utilization</b>	<b>Facility Station Need Determination</b>
Miller Street Dialysis Center of Wake Forest University	44	80.11%	5
NC Baptist Hospital ESRD	4	12.50%	0
Piedmont Dialysis Center of Wake Forest University	58	78.02%	10
Salem Kidney Center of Wake Forest University	47	85.00%	8
Northside Dialysis Center of Wake Forest University	45	80.56%	13

Source: 2020 SMFP, page 155.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, the applicant states that it does not project to serve dialysis patients currently being served by another provider. The applicant further states:

*“Additional availability of dialysis services at PDC will not impact competition in the proposed service area, but will enhance the ability of persons suffering from ESRD who will be underserved by at least 12/31/2020 and beyond (who otherwise may be going out of county for their care) to receive ESRD care within their home county.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 84, the applicant states:

*“As demonstrated in the pro forma 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.”*

Regarding the impact of the proposal on quality, in Section N, page 85, the applicant states:

*“Service quality will remain of the highest standard.”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 85, the applicant states:

*“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 PDC will expand access of services to all ESRD patients.”*

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would be a positive impact on:

- Cost-effectiveness (see Sections B, C, F, N and Q of the application and any exhibits).
- Quality (see Sections B, C, N and O of the application and any exhibits).



- Access to medically underserved groups (see Sections B, C, D, L and N of the application and any exhibits).

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

In Section Q, Form A, page 91, the applicant identifies the dialysis facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 19 WFUHS dialysis facilities located in North Carolina.

In Section O, pages 87-88, the applicant provides a table showing that 13 of the 18 operational WFUHS dialysis facilities were surveyed within the last 18-month look-back period. During the 18 months immediately preceding the submittal of the application, one or more incidents related to quality of care occurred in 11 of the 13 facilities surveyed. These incidents were issued standard level deficiencies (not resulting in immediate jeopardy) and the list on page 88 shows that the facilities that were back in compliance at the time of application submittal, except for the one on which the report was pending. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 18 operational facilities, the applicant provides sufficient evidence that quality care has been provided in the past.

Therefore, the application is conforming to this criterion.

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

order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2203 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

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

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

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

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

(1) an existing dialysis facility; or

(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- Piedmont Dialysis Center is an existing facility. In Section C, page 42, and supplemental information, the applicant projects that the Piedmont Dialysis Center facility will serve 203 in-center patients on 64 stations, or a rate of 3.17 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

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

-C- In Section C, pages 29-31, and in Section Q, pages 92-95, the applicant provides the assumptions and methodology it used to project utilization of the facility.