

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 25, 2022

Findings Date: May 25, 2022

Project Analyst: Tanya M. Saporito

Co-Signer: Micheala Mitchell

Project ID #: G-12206-22

Facility: Miller Street Dialysis Center of Wake Forest University

FID #: 070671

County: Forsyth

Applicants: Miller Street Dialysis Center of Wake Forest University  
Wake Forest University Health Sciences

Project: Add no more than 19 in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 dialysis stations upon completion of this project and Project ID# G-12172-22 (relocate 19 stations)

### 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

Miller Street Dialysis Center of Wake Forest University and Wake Forest University Health Sciences, collectively referred to as “the applicants” propose to add no more than 19 dialysis stations pursuant to Condition 2 of the facility need methodology to Miller Street Dialysis Center of Wake Forest University (MSDC) for a total of no more than 50 stations upon completion of this project and Project ID# G-12172-22 (relocate 19 stations).

#### **Need Determination**

Chapter 9 of the 2022 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 9B, page 136, the county need methodology shows there is not a county need determination for additional dialysis stations in Forsyth County.

However, the applicants are eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2022 SMFP, if the utilization rate for the facility as reported in the 2022 SMFP is at least 75.00% or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9A, page 124, the utilization rate reported for the facility is 88.54% or 3.54 patients per station per week, based on 170 in-center dialysis patients and 48 certified dialysis stations [ $170 \text{ patients} / 48 \text{ stations} = 3.54$ ;  $3.54 / 4 = 0.8854$ ].

As shown in Table 9D, page 140, based on the facility need methodology for dialysis stations, the potential number of stations needed that can be added pursuant to Condition Number 2 of the Facility Need Methodology is up to 19 additional stations; thus, the applicants are eligible to apply to add up to 19 dialysis stations during the 2022 SMFP review cycle.

The applicants propose to add no more than 19 new stations to the facility, which is consistent with the 2022 SMFP calculated facility need determination for up to 19 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2022 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 30 of the 2022 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 applicants describe how they believe the proposed project will promote safety and quality in Section B, pages 18-21; Section N, pages 77-78; Section O, page 79-80; and referenced exhibits. The information provided by the applicants is reasonable and supports the determination that the applicants’ proposal will promote safety and quality in the delivery of dialysis services.

### **Promote Equitable Access**

The applicants describe how they believe the proposed project will promote equitable access in Section B, page 21; Section C, pages 33-34; Section L, pages 72-74; Section N, page 78; and referenced exhibits. The information provided by the applicants is reasonable and supports the determination that the applicants' proposal will promote equitable access to dialysis services.

### Maximize Healthcare Value

The applicants describe how they believe the proposed project will maximize healthcare value in Section B, page 21; Section N, pages 77-78; and referenced exhibits. The information provided by the applicants is reasonable and supports the determination that the applicants' proposal will maximize healthcare value for dialysis services.

The applicants adequately demonstrate 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 applicants. Therefore, the application is consistent with Policy GEN-3.

### Conclusion

The Agency reviewed the:

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

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

- The applicants adequately demonstrate that the application is consistent with the facility need methodology as applied from the 2022 SMFP
- The applicants adequately demonstrate how the facility's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need
- The applicants adequately demonstrate that the application is consistent with Policy GEN-3 based on how it describes the facility's policies and programs, which promote the concepts of quality, equitable access and maximum value for resources

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

C

The applicants propose to add no more than 19 dialysis stations pursuant to Condition 2 of the facility need methodology to Miller Street Dialysis Center of Wake Forest University (MSDC) for a total of no more than 50 stations upon completion of this project and Project ID# G-12172-22 (relocate 19 stations).

**Patient Origin**

On page 115, the 2022 SMFP defines the service area for the county need methodology 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 area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* MSDC is located in Forsyth County. Thus, the service area for this application is Forsyth County. Facilities may serve residents of counties not included in their service area.

The applicants provide the following historical in-center (IC) patient origin for MSDC for the last full year of operation, calendar year (CY) 2021, as shown in the table below:

**Historical Patient Origin, MSDC, CY 2021**

COUNTY	# IN-CTR. PTS.	% OF TOTAL
Davidson	6.00	3.55%
Davie	3.00	1.78%
Forsyth	154.00	91.12%
Guilford	4.00	2.37%
Randolph	1.00	0.59%
Yadkin	1.00	0.59%
<b>Total</b>	<b>169.00</b>	<b>100.00%</b>

Source: application page 23

Numbers may not sum due to rounding

The following table illustrates projected IC patient origin at MSDC in the second full fiscal year (FY) of operation, FY 2025, which the applicants measure from September 1 – August 31:

**MSDC Projected Patient Origin FY 2025 (9/1/24-8/31/25)**

COUNTY	# IN-CTR. PTS.	% OF TOTAL
Davidson	7.03	4.58%
Davie	3.64	2.37%
Forsyth	182.26	118.87%
Guilford	4.51	2.94%
Randolph	1.00	0.65%
Yadkin	1.23	0.80%
Pts to transfer to Salem Kidney Center	-29.60	-19.30%
Pts to transfer to Kernersville Dialysis Center	-16.73	-10.91%
<b>Total</b>	<b>153.33</b>	<b>100.00%</b>

Source: application page 25

Numbers may not sum due to rounding

In Section C, pages 23-29, the applicants provide the assumptions and methodology used to project its patient origin and its projected utilization. On page 23, the applicants state:

*“This CON requests to add back 19 stations via facility need in conjunction with the transfer of 19 stations from Miller Street Dialysis Center (‘MSDC’) to Salem Kidney Center (‘SKC’) – Project ID# G-12172-22 and the transfer of 24 ICH stations from SKC to Kernersville Dialysis Center (‘KVDC’) – Project ID# G-12137-21, resulting in a total of 65 ICH stations at SKC, 24 ICH stations at KVDC, and 50 ICH stations at MSDC upon project completion, Forsyth County.”*

The applicants’ assumptions are reasonable and adequately supported based on the following:

- The applicants begin with the number of patients dialyzing at the facility as of the end of the last full FY of operation and project pro-rated utilization based on 8 months of data for the remainder of 2022, since the applicants’ FY begins September 1.
- The applicants use the Average Annual Change Rate (AACR) as published in the 2022 SMFP for each county in which the facility’s patients reside to project patient growth for the future patient population.
- The applicants subtract those patients who are projected to transfer their care to a different facility when other pending projects are complete.

### **Analysis of Need**

In Section C, page 30, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services. The applicants state:

*“This project is part of the third round of three CON filings ....*

*..*

*This [CON] requests to add back 19 stations at MSDC via facility need methodology.*

*...*

*This CON is needed by ALL Forsyth County dialysis patients to ensure available services are in place to prevent any disruption in care. This CON will add back stations at MSDC in conjunction with the transfer out of stations to SKC and prevent projected utilization from exceeding 100% at MSDC. It will allow the dialysis patient population served in Forsyth County to rebalance among all WFUHS facilities. Patients will have the opportunity to move to the facility closest to their homes on a shift most convenient to their lifestyles. Patient compliance will be enhanced improving overall patient health and dialysis outcomes, reducing healthcare costs, and improving patient lives.”*

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

- The 2022 SMFP shows a facility need determination for up to 19 stations at MSDC.
- The applicants apply the appropriate Five Year AACR as provided in the 2022 SMFP to project growth in each county’s patient census according to that growth rate.
- The applicants demonstrate that the facility will need the additional stations to accommodate the existing and projected patient population.
- The applicants state that this project, Project ID# G-12172-22 and Project ID# G-12137-21 are necessary to best serve existing and projected patients who will choose to dialyze at MSDC and will also prevent a shortfall of needed dialysis stations in Forsyth County.

Projected Utilization

In Section Q Form C the applicants provide the projected utilization for the interim and project years (PY). The applicants’ project years (PY) are from September 1 – August 31. The following table illustrates the projections:

**MSDC Projected Utilization**

FORM C UTILIZATION	END PRIOR YEAR (CY 2021)	END CURRENT YEAR 2022*	INTERIM 9/1/22- 8/31/23	INTERIM 9/1/23- 8/31/24	INTERIM 9/1/24- 8/31/25
# of Patients at the Beginning of the Year	167	169	174	155	147
# of Patients at the End of the Year	169	174	155	147	153
Average # of Patients during the Year	168	172	165	151	150
# of Treatments / Patient / Year	145	145	145	145	145
<b>Total # of Treatments</b>	<b>24,360</b>	<b>24,940</b>	<b>23,925</b>	<b>21,895</b>	<b>21,750</b>

\*Prorated based on 8 months from January 1, 2022 – August 31, 2022

In Section C, pages 26-29 and in Section Q, pages 83-85, the applicants provide the assumptions and methodology used to project in-center utilization, which are summarized below:

- The applicants begin with the MSDC facility census as of December 31, 2021 of 158 patients.
- The applicants state the patients projected to dialyze at MSDC and the other WFUHS dialysis facilities in Forsyth County do so out of geographic convenience and/or physician preference.
- The applicants project station certification will be August 31, 2023. The first PY will thus be 9/1/2023-8/31/2024; the second PY will be 9/1/2024-8/31/2025.

- The applicants begin with an eight-month prorated year that begins December 31, 2021 and ends on August 31, 2022, utilizing a growth factor of 0.6603 [242 days / 365 = 0.6603] to project growth during that initial time period.
- The applicants project the Forsyth County patient population forward to 8/31/2022, using the Forsyth County Five-Year AACR of 4.7% and projects the future patient population for the interim year, OY1 and OY 2 as follows:

*Forsyth County Five-Year AACR = 4.7%*  
*154 + (154 x 0.047 x 0.6603) = 158.8 patients Ending Current Year (8/31/2022)*  
*158.5 x 1.047 = 166.26 patients end of interim (8/31/2023)*  
*166.26 x 1.047 = 174.08 patients end of OY1 (8/31/2024)*  
*174.08 x 1.047 = 182.26 patients end of OY2 (8/31/2025)*

- The applicants account for the Forsyth County patients who will transfer their care to KVDC when that project is complete as follows:

*Forsyth County Five-Year AACR = 4.7%*  
*0 Pts. + (0 x 0.047 x 0.6603) = 0.00 patients Ending Current Year (8/31/2022)*  
*0.00 Pts. x 1.047 = 0.00 end of interim (8/31/2023)*  
*-15.98 patients (projections from Project ID #G-12137-21) end of OY1 (8/31/2024)*  
*-15.98 x 1.047 = -16.73 patients end of OY2 (8/31/2025)*

- The applicants account for the Forsyth County patients who will transfer their care to SKC when that project is complete as follows:

*Forsyth County Five-Year AACR = 4.7%*  
*0 Pts. + (0 x 0.047 x 0.6603) = 0.00 patients Ending Current Year (8/31/2022)*  
*-27.00 patients end of interim (8/31/2023)*  
*-27.00 patients (projections from Project ID #G-12172-22) x 1.047 = -28.27 pts. end of OY1 (8/31/2024)*  
*-28.27 x 1.047 = -29.60 patients end of OY2 (8/31/2025)*

- The applicants project the growth of those patients who reside outside of Forsyth County using the counties' respective Five-Year AACR from the 2022 SMFP, and projects growth for this population for the 9-month period ending 8/31/2022, the interim year, OY1 and OY 2, as illustrated in Section C, pages 28-29 of the application.

At the end of OY1, MSDC is projected to serve 146.53 in-center patients and at the end of OY2 the facility is projected to serve 153.33 in-center patients on 50 stations.

The projected utilization rates for the end of first two operating years are as follows:

- OY1: 2.94 patients per station per week or 73.5% [147 patients / 50 stations = 2.94; 2.94 / 4 = 0.735 or 73.5%].
- OY2: 3.06 patients per station per week or 76.5% [153 patients / 50 stations = 3.06; 3.06 / 4 = 0.765 or 76.5%].

The projected utilization of 2.94 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported based on the following:

- The applicants project growth of the Forsyth County patient population using the Five-Year AACR for Forsyth County as published in the 2022 SMFP.
- The applicants subtract those patients projected to transfer their care to another WFUHS dialysis facility pursuant to previously approved projects.
- The applicants project growth of those patients who reside outside of Forsyth County using each county's respective Five Year-AACR as published in the 2022 SFMP.
- The applicants project utilization based on the number of SKC patients residing in Forsyth County and other counties that will transfer their services after the proposed and approved relocation of stations to and from SKC.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 IC patients per station per week required by 10A NCAC 14C .2203(b).

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

In Section C.6, pages 33-34, the applicants discuss access to the facility's services, stating:

*"...At least **6.36%** of the ICH patients served by MSDC during the last OY were Medicaid Primary patients. [emphasis in original] ...*

...

*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."*

On pages 34-35, the applicants provide the estimated percentage for each medically underserved group it will serve during the second year of operation, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons*	6.36%
Racial and ethnic minorities	66.86%
Women	48.28%
Persons with disabilities**	--
Persons 65 and older	47.70%
Medicare beneficiaries	56.33%
Medicaid beneficiaries	25.80%

\*Applicants state this category includes recipients of Medicaid only

\*\*Applicants state: "Unknown/Stat unable to be tracked. Facility ADA compliant"

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

- The application and Exhibit L.4 provide information and policies that demonstrate the applicants' commitment to provide services to all patients referred for ESRD services
- The applicants demonstrate that the facility has historically provided care to all in need of ESRD services, including underserved persons

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicants adequately identify the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants describe the extent to which all residents, including underserved groups, are likely to have access to the proposed services 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 applicants do 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 applicants propose to add no more than 19 dialysis stations pursuant to Condition 2 of the facility need methodology to Miller Street Dialysis Center of Wake Forest University (MSDC) for a total of no more than 50 stations upon completion of this project and Project ID# G-12172-22 (relocate 19 stations).

In Section E, page 42, the applicants describe the alternatives they considered and explain why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicants refer to Project ID# G-12137-21 that approved development of a new dialysis facility in Forsyth County (Kernersville Dialysis Center) and Project ID# G-12172-22, that approved relocation of 19 stations from MSDC to that facility. The applicants state that the relocation of 19 stations from MSDC without backfilling those stations will leave MSDC “*severely short*” on dialysis stations and unable to effectively serve its patients. Therefore, the applicants state this alternative is less effective.
- The applicants state that without the stations requested in this application, the utilization at the facility will exceed 100%, which is detrimental to the facility patients. Therefore, the applicants determined that this was not the most effective alternative.

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

- The application is conforming or conditionally conforming to all statutory and regulatory review criteria.
- The applicants provide 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. **Miller Street Dialysis Center of Wake Forest University and Wake Forest University Health Sciences (hereinafter certificate holders) shall materially comply with all representations made in the certificate of need application.**
  2. **The certificate holders shall develop no more than 19 in-center stations for a total of no more than 50 stations at Miller Street Dialysis Center of Wake Forest University upon completion of this project and Project ID# G-12172-22 (relocate 19 stations).**
  3. **Progress Reports:**
    - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. **The certificate holders shall complete all sections of the Progress Report form.**
    - c. **The certificate holders shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. **The first progress report shall be due on September 1, 2022.**
  4. **The certificate holders shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicants propose to add no more than 19 dialysis stations pursuant to Condition 2 of the facility need methodology to Miller Street Dialysis Center of Wake Forest University (MSDC) for a total of no more than 50 stations upon completion of this project and Project ID# G-12172-22 (relocate 19 stations).

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

In Section Q, Form F.1a, the applicants project the total capital cost of the project and state the cost will be incurred by Wake Forest University Health Sciences, as shown in the table below.

Site Costs	\$0
Medical Equipment	\$275,500
Non-Medical Equipment	\$60,800
<b>Total</b>	<b>\$336,300</b>

In Section F.3, page 46, the applicants state there are no start-up costs or initial operating expenses associated with this project. In Section Q, page 86, the applicants provide the assumptions used to project the capital cost. The applicants adequately demonstrate that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The medical equipment cost is based on a price per dialysis machine.
- The non-medical equipment cost is based on a price per TV and chair.

**Availability of Funds**

In Section F.2, page 44, the applicants state that the capital cost will be funded as shown in the following table:

**Sources of Capital Cost Financing**

TYPE	WAKE FOREST UNIVERSITY HEALTH SCIENCES	TOTAL
Loans	\$0	\$0
Accumulated reserves or OE *	\$336,300	\$336,300
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$336,300</b>	<b>\$336,300</b>

\* OE = Owner's Equity

In Exhibit F-2(c)(2), the applicants provide a March 1, 2022 letter signed by the Chief Executive Officer of Atrium Health Wake Forest Baptist, the ultimate parent company of Wake Forest University Health Sciences, confirming the proposed capital cost of the project and committing the funds to the development of the project. In Exhibit F-(2)(c)(3), the applicants provide the consolidated balance sheets for Wake Forest University for year ending June 30, 2020, which show total assets in the amount of \$2 billion, and cash and cash equivalents in the amount of \$177,688,000.

The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project based on the letter of commitment and consolidated balance sheets provided in Exhibits F-2(c)(2) and F-(2)(c)(3) of the application.

**Financial Feasibility**

In Section Q, the applicants provide pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicants project that revenues will exceed operating expenses in each of the first two full fiscal years of operation following completion of the proposed project, as shown in the following table:

MILLER STREET DIALYSIS CENTER	1 <sup>ST</sup> FULL OY FY 2024	2 <sup>ND</sup> FULL OY FY 2025
Total Treatments, including HH and PD Treatments and Training Days	21,895	21,750
Total Gross Revenue (charges)	\$50,443,672	\$50,109,608
Total Net Revenue	\$8,242,131	\$8,187,547
Average Net Revenue per Treatment	\$376	\$376
Total Operating Expenses (costs)	\$5,587,541	\$5,551,676
Average Operating Expense per Treatment	\$255	\$255
Net Income	\$2,654,590	\$2,635,871

The assumptions used by the applicants in preparation of the pro forma financial statements are provided in Section Q of the application. The applicants adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Charges and expenses are based on historical facility operations projected forward.
- Payor percentages are based on historical facility operations.
- The applicants provide reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicants adequately demonstrate that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicants adequately demonstrate availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicants adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicants propose to add no more than 19 dialysis stations pursuant to Condition 2 of the facility need methodology to Miller Street Dialysis Center of Wake Forest University (MSDC) for a total of no more than 50 stations upon completion of this project and Project ID# G-12172-22 (relocate 19 stations).

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Forsyth County as of December 31, 2020. There are four kidney disease treatment centers providing dialysis services and one approved but not yet operational in Forsyth County. The applicants are the only providers of dialysis services in Forsyth County.

FACILITY NAME	CERTIFIED STATIONS AS OF 12/31/2020	# IC PATIENTS AS OF 12/31/2020	UTILIZATION BY PERCENT AS OF 12/31/2020	PATIENTS PER STATION PER WEEK
Miller Street Dialysis Center	48	170	88.54%	3.40
Northside Dialysis Center	45	159	88.33%	3.31
Piedmont Dialysis Center	64	180	70.31%	2.81
Salem Kidney Center	51	169	82.84%	2.86
Kernersville Dialysis Center	0	0		
<b>Total</b>	<b>208</b>	<b>678</b>		

Source: 2022 SMFP, Table 9A, page 124

In Section G, page 52, the applicants explain why they believe the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Forsyth County. The applicants state:

*“This proposal is filed as one part of three CON filings proposed by WFUHS to meet the growing demand for dialysis services within Forsyth County.*

...

*The culmination of these CON filings will provide an additional treatment location in an area of Forsyth County currently underserved. ...*

...

*The addition of these resources will allow WFUHS to rebalance its county-wide patient population to ensure that patients are able to attend the facility closest to their homes, reducing overall patient travel times, increasing patient compliance with their care plans, and alleviating a strain on community resources.”*

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

- The applicants adequately demonstrate that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.
- The applicants propose in this application to backfill 19 stations previously approved to relocate from MSDC to develop a new ESRD facility.
- The applicants are the only providers of dialysis services in Forsyth County.

**Conclusion**

The Agency reviewed the:

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

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

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

C

The applicants propose to add no more than 19 dialysis stations pursuant to Condition 2 of the facility need methodology to Miller Street Dialysis Center of Wake Forest University (MSDC) for a total of no more than 50 stations upon completion of this project and Project ID# G-12172-22 (relocate 19 stations).

In Section Q, Form H, page 103, the applicants provide current and projected full-time equivalent (FTE) positions for MSDC as shown in the following table:

POSITION	CURRENT FTE POSITIONS*	FTE POSITIONS OY1	FTE POSITIONS OY2
RN	8.00	5.75	5.50
Licensed Practical Nurse	3.00	2.25	2.00
Patient Care Technician (PCT)	19.50	14.50	13.75
Director of Nursing	1.00	1.00	1.00
Dietician	1.00	1.00	1.00
Social Worker	2.00	2.00	2.00
Dialysis Technician	2.00	2.00	2.00
Biomedical Technician	1.00	1.00	1.00
Clerical	2.00	2.00	2.00
<b>Total</b>	<b>39.50</b>	<b>31.50</b>	<b>30.25</b>

\*As of December 31, 2021  
 Source: Section Q Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicants are budgeted in Form F.4. In Section H.3, pages 55-56, the applicants describe the methods used to recruit or fill new positions and their existing training and continuing education programs.

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

- The facility is an existing facility and the applicants base projected staffing on existing staff and historical experience in providing dialysis services at the facility.
- The applicants have existing policies in place regarding recruitment, training and continuing education, and will continue to abide by those policies.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicants propose to add no more than 19 dialysis stations pursuant to Condition 2 of the facility need methodology to Miller Street Dialysis Center of Wake Forest University (MSDC) for a total of no more than 50 stations upon completion of this project and Project ID# G-12172-22 (relocate 19 stations).

### **Ancillary and Support Services**

In Section I, page 58, the applicants identify each ancillary and support service listed in the application as necessary for the existing and proposed dialysis services. On pages 59-62, the applicants explain how each ancillary and support service is made available.

The applicants adequately demonstrate that the necessary ancillary and support services will be made available based on the following:

- The applicants currently provide dialysis services at MSDC.
- The applicants explain how they provide each necessary ancillary and support service at the facility and how they will continue to provide the same services following the addition of 19 stations.

### **Coordination**

In Section I, pages 62-63, the applicants describe existing relationships with other local health care and social service providers.

The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system based on the following:

- The applicants discuss existing relationships with local health care providers.
- The applicants discuss existing relationships with local social service providers.
- The applicants state the same relationships will be in place following the proposed addition of stations.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO.

In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

(11) Repealed effective January 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

In Section K, page 65, the applicants state there is no construction or renovation associated with the proposed project, since the proposed stations will replace stations relocated from this facility. Therefore, Criterion (12) is not applicable to this review.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 68, the applicants provide the historical payor mix during CY 2021 for MSDC, as illustrated in the table below:

**Historical Payor Mix (CY 2021), MSDC**

PAYOR SOURCE AT ADMISSION	IN-CENTER PATIENTS	
	# PTS.	% OF TOTAL
Self-Pay	2	1.12%
Commercial Insurance	27	16.11%
Medicare*	95	56.33%
Medicaid*	43	25.80%
Other (VA)	1	0.64%
<b>Total</b>	<b>168</b>	<b>100.0%</b>

\*Includes any managed care plans

In Section L, page 69, the applicants provide the following comparison of facility patients and the service area population for the last full FY before application submission:

MSDC	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY, CY2021	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	48.28%	52.70%
Male	51.72%	47.30%
Unknown	--	--
64 and Younger	52.30%	83.60%
65 and Older	47.70%	16.40%
American Indian	0.00%	0.90%
Asian	2.37%	2.60%
Black or African-American	57.99%	27.50%
Native Hawaiian or Pacific Islander	1.18%	0.10%
White or Caucasian	33.14%	56.30%
Other Race	6.51%	15.60%
Declined / Unavailable	0.0%	--

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities 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, pages 69-71, the applicants state that MSDC is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities. However, as a Medicare provider, it must and does abide by Medicare regulations regarding equal access/non-discrimination.

In Section L, page 71, the applicants state that during the last 18 months no patient civil rights access complaints have been filed against the facility identified in Section A, Question 4.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.3(a), page 72, the applicants project payor mix for the proposed services during the second full fiscal year of operation following project completion, as summarized in the table below:

**MSDC Projected Payor Mix (FY 2025)**

PAYOR SOURCE AT ADMISSION	IN-CENTER PATIENTS	
	# PTS.	% OF TOTAL
Self-Pay	2	1.12%
Commercial Insurance	24	16.11%
Medicare*	84	56.33%
Medicaid*	39	25.80%
Other (VA)	1	0.64%
<b>Total</b>	<b>150</b>	<b>100.0%</b>

\*Includes any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicants projects that 1.12% of dialysis services will be provided to self-pay patients, 56.33% to Medicare recipients and 25.80% to Medicaid recipients.

On page 72, the applicants provide 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 based on the following:

- The applicants base payor mix on treatment volumes at the facility.
- The applicants base future payor mix percentages on CY 2020 payor mix percentages for treatment volumes.

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 reasons stated above.

- (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.5, page 74, the applicants adequately describe 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

The applicants propose to add no more than 19 dialysis stations pursuant to Condition 2 of the facility need methodology to Miller Street Dialysis Center of Wake Forest University (MSDC) for a total of no more than 50 stations upon completion of this project and Project ID# G-12172-22 (relocate 19 stations).

In Section M, page 76, the applicants describe the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1(a). The applicants adequately demonstrate that health professional training programs in the area have access to the facility for training purposes based on the following:

- MSDC has an existing agreement with Forsyth Technical Community College Nursing Program.
- WFUHS facilities provide onsite educational experiences to local training programs in the area and will continue to do so following addition of 19 stations.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants 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 applicants propose to add no more than 19 dialysis stations pursuant to Condition 2 of the facility need methodology to Miller Street Dialysis Center of Wake Forest University (MSDC) for a total of no more than 50 stations upon completion of this project and Project ID# G-12172-22 (relocate 19 stations).

On page 115, the 2022 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located.”* Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Forsyth County as of December 31, 2020. There are four kidney disease treatment centers providing dialysis services and one approved but not yet operational in Forsyth County. The applicants are the only providers of dialysis services in Forsyth County.

FACILITY NAME	CERTIFIED STATIONS AS OF 12/31/2020	# IC PATIENTS AS OF 12/31/2020	UTILIZATION BY PERCENT AS OF 12/31/2020	PATIENTS PER STATION PER WEEK
Miller Street Dialysis Center	48	170	88.54%	3.40
Northside Dialysis Center	45	159	88.33%	3.31
Piedmont Dialysis Center	64	180	70.31%	2.81
Salem Kidney Center	51	169	82.84%	2.86
Kernersville Dialysis Center	0	0		
<b>Total</b>	<b>208</b>	<b>678</b>		

Source: 2022 SMFP, Table 9A, page 124

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

*“The project will have no effect on competition in the proposed service area of Forsyth County because no other provider exists and because the need for these stations at MSDC is not applicable to any other dialysis provider.”*

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

*“The proposal will replenish stations at MSDC as described throughout this CON. This project along with the KVDC project, the SKC project, and the project for Northside Dialysis Center to add back 11 stations, also filed during this review period will allow for a full county rebalance of patients among the WFUHS dialysis centers. This is necessary to ensure patients will have optimal geographic access to care, reduce patient travel time, and improve overall patient outcomes.”*

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

Regarding the impact of the proposal on quality, in Section N, page 77, the applicants state:

*“Service quality will remain of the highest standard. The proponent WFUHS has over 40 years’ experience providing ESRD care to North Carolinians.”*

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

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

*“This proposal will improve geographic access to service by all persons with ESRD, including the medically underserved, reducing their need to travel outside of their home county for dialysis care, now, and in the future.” [emphasis in original]*

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

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (19) Repealed effective January 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, page 105, the applicants identify the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicants or a related entity. The applicants identify a total of 20 of this type of facility located in North Carolina.

In Section O, page 80, the applicants state that, during the 18 months immediately preceding the submittal of the application, 10 facilities were cited for deficiencies, however, all facilities are currently back in compliance. After reviewing and considering information provided by the applicants, the Agency determined that the applicants provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective January 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.

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

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

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

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

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

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

-C- In Section C and Section Q, Form C, the applicants document the need for the 19 stations as proposed. The applicants projects to serve 146 patients at the end of the first 12 months of operation following certification of the proposed additional stations, which is 2.92 patients per station per week [ $146 / 50 = 2.92$ ].

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

-C- In Section C, pages 26-29, and in the Assumptions following Form C in Section Q, pages 83-85, the applicants provide the assumptions and methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.