

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 17, 2020

Findings Date: November 17, 2020

Project Analyst: Celia C. Inman

Co-Signer: Gloria C. Hale

Project ID #: G-11921-20

Facility: Miller Street Dialysis Center of Wake Forest University

FID #: 070671

County: Forsyth

Applicant: Wake Forest University Health Sciences

Miller Street Dialysis Center of Wake Forest University

Project: Add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 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 Miller Street Dialysis Center of Wake Forest University, collectively referred to as “the applicant”, proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations upon project completion.

Need Determination

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

However, the 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 the 2020 SMFP, is at least 75% or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Miller Street Dialysis Center of Wake Forest University (MSDC) on page 155 of the 2020 SMFP, is 80.11% or 3.2 patients per station per week, based on 141 in-center dialysis patients and 44 certified dialysis stations [$141 / 44 = 3.20$; $3.20 / 4 = 0.8011$].

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 MSDC is five additional stations; thus, the applicant is eligible to apply to add up to five stations pursuant to the facility need methodology.

The applicant proposes to add no more than two new stations pursuant to facility need, which is consistent with the 2020 SMFP calculated facility need determination for up to five 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: Basic Principles, 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(a), pages 13-17, referencing other application sections and exhibits with specific details. 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 18-22, referencing other application sections and exhibits; Section L, pages 64-72; and Section N, pages 74-76. 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 22, referencing Sections F and K; and in Section N, pages 74-76. 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. 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 the application is conforming to this criterion based on the following:

- The applicant adequately demonstrates that the application is consistent with the facility need determination as applied from the 2020 SMFP.
- The applicant adequately demonstrates how MSDC's projected volumes incorporate the concepts of safety and quality, equitable access, and maximizing healthcare value for resources expended in meeting the facility need.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 because the proposal demonstrates 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; documents its plans for providing access to services for patients with limited financial resources; and demonstrates the availability of capacity to provide these services.

(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 two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations upon project completion.

The following table, summarized from data on page 8 of the application and page 155 of the 2020 SMFP, shows the projected number of stations at MSDC upon project completion.

Stations	Description	Project ID #
44	Total existing certified stations in the SMFP in effect on the day the review will begin	
+4	Add four stations for a total of 48 stations	G-11675-19
+2	Stations to be added as part of this project (add two stations pursuant to facility need)	G-11921-20
50	Total stations upon completion of proposed project and previously approved projects	

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-Graham counties and Avery-Mitchell-Yancey counties.*” The facility referred to in this application is 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.

In Section C.2, page 25, the applicant provides the historical in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for MSDC during the last full operating year, July 1, 2019-June 30, 2020, as summarized in the following table:

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Davidson	4.00	2.48%	0.00	0.00%	0.00	0.00%
Davie	2.00	1.24%	0.00	0.00%	0.00	0.00%
Forsyth	149.00	92.55%	0.00	0.00%	0.00	0.00%
Guilford	1.00	0.62%	0.00	0.00%	0.00	0.00%
Iredell	1.00	0.62%	0.00	0.00%	0.00	0.00%
Randolph	1.00	0.62%	0.00	0.00%	0.00	0.00%
Surry	3.00	1.86%	0.00	0.00%	0.00	0.00%
Total	161.00	100.00%	0.00	0.00%	0.00	0.00%

Totals may not sum due to rounding

As shown in the table above and stated on page 26 of the application, MSDC currently serves only in-center patients and projects to serve in-center patients only.

In Section C.3, page 26, the applicant provides the projected IC, HH, and PD patient origin for MSDC for the second full operating year following project completion, July 1, 2022 – June 30, 2023 (OY2), as summarized in the following table:

**Projected Patient Origin
 July 1, 2022 – June 30, 2023**

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Davidson	4.72	2.57%	0.00	0.00%	0.00	0.00%
Davie	2.38	1.29%	0.00	0.00%	0.00	0.00%
Forsyth	170.03	92.42%	0.00	0.00%	0.00	0.00%
Guilford	1.17	0.64%	0.00	0.00%	0.00	0.00%
Iredell	1.08	0.59%	0.00	0.00%	0.00	0.00%
Randolph	1.04	0.57%	0.00	0.00%	0.00	0.00%
Surry	3.55	1.93%	0.00	0.00%	0.00	0.00%
Total	183.98	100.00%	0.00	0.00%	0.00	0.00%

Totals may not sum due to rounding

In Section C, pages 26-27, the applicant provides the assumptions and methodology used to project MSDC's patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 27-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant discusses the need based on MSDC's and Forsyth County's patient growth rates over the last year. The applicant states:

- MSDC’s patient population is expected to increase from 161 patients on June 30, 2020 to 183.98 patients by the end of the second operating year, June 30, 2023. (page 28)
- MSDC is at 83.85% utilization, as of June 30, 2020. (page 28)
- The facility’s existing 48 stations will be utilized at approximately 95.82%, as of the end of the second operating year, if no stations are added. (page 28)
- The additional two stations are needed to prevent facility utilization from rising above 91.99% and to preserve viable availability of services in Forsyth and surrounding counties. (pages 28-29)

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

- The applicant adequately demonstrates the need to add two dialysis stations pursuant to facility need.
- The applicant provides supporting documentation in Exhibit C-4.

Projected Utilization

In Section Q Form C Utilization, page 82, the applicant provides its projected utilization for in-center patients, as summarized below.

Form C Utilization	Last Full OY 07/01/2019- 06/30/2020	Interim Year 07/01/2020- 06/30/2021	First Full OY 07/01/2021- 06/30/2022	Second Full OY 07/01/2022- 06/30/2023
In-Center Patients*				
# of Patients at the Beginning of the Year	145	161	168	176
# of Patients at the End of the Year	161	168	176	184
Average # of Patients during the Year	153	165	172	180
# of Treatments / Patient / Year	150	150	150	150
Total # of Treatments	22,950	24,750	25,800	27,000

*The applicant does not propose to serve home hemodialysis or peritoneal dialysis patients.

In Section Q, pages 82-83, the applicant provides the following assumptions and methodology.

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

The applicant provides the calculation table for its projected utilization In Section C, page 28, with the results summarized in the table below.

County	AACR	June 30, 2020	June 30, 2021	June 30, 2022	June 30, 2023
Davidson	5.7%	4.00	4.23	4.47	4.72
Davie	5.9%	2.00	2.12	2.24	2.38
Forsyth	4.5%	149.00	155.71	162.71	170.03
Guilford	5.4%	1.00	1.05	1.11	1.17
Iredell	2.7%	1.00	1.03	1.05	1.08
Randolph	1.3%	1.00	1.01	1.03	1.04
Surry	5.8%	3.00	3.17	3.36	3.55
Totals		161.00	168.32	175.97	183.98

Totals may not sum due to rounding.

As the table above shows, using conventional rounding, the methodology used by the applicant achieves a projection of 176 in-center patients by the end of the first operating year, OY1 (June 30, 2022), for a utilization rate of 3.5 patients per station per week or 87.99% ($176 \text{ patients} / 50 \text{ stations} = 3.52 \text{ patients per station} / 4 = 0.8799$). By the end of OY2 (June 30, 2023), following the applicant’s methodology and assumptions, MSDC will have 184 in-center patients dialyzing at the center for a utilization rate of 91.99% ($184 / 50 = 3.68 / 4 = .9199$). The projected utilization of 3.5 patients per station per week for OY1 satisfies the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on existing MSDC patients.
- The applicant projects the growth of the patient census using each county’s five-year AACR, as reported in the 2020 SMFP.

Access

In Section C.7, pages 30-32, the applicant discusses access to services at MSDC. On page 31, 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.”

On pages 31-32, the applicant provides the following estimated percentages for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	25.00%
Racial and ethnic minorities	62.73%
Women	49.69%
Persons with Disabilities	Facility does not track
The elderly	47.20%
Medicare beneficiaries	79.00%
Medicaid recipients	25.00%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

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

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

- The 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 proposes to add dialysis stations pursuant to facility need. The project does not involve a reduction or elimination of a services or a relocation of a service.

- (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 two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations upon project completion.

In Section E, pages 39-40, 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 identified need. The alternatives considered were:

- Policy ESRD-2, Contiguous County Station Relocation – the applicant states that WFUHS has dialysis facilities in contiguous counties from which stations might be relocated pursuant to Policy ESRD-2. However, the 2020 SMFP shows Forsyth County with a station surplus, which prevents a contiguous county relocation of stations. Thus, this alternative is not an effective alternative.
- Add less than two stations – the applicant states that a request for less than two stations cannot meet the needs of the proposed project. Thus, this alternative is not an effective alternative.
- The project as proposed – the applicant states that the proposed project will optimize MSDC’s ability to treat its existing and projected dialysis patients. Thus, the applicant states that this is the most effective alternative for meeting the needs of MSDC’s projected patients.

The applicant adequately demonstrates that the alternative proposed in this application is the more 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 they believe 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 Miller Street Dialysis Center of Wake Forest University (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall add no more than two additional in-center dialysis stations for a total of no more than 50 in-center stations at Miller Street Dialysis Center of Wake Forest University upon completion of this project.**
 - 3. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations upon project completion.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 84, the applicant projects the total capital cost for the project as summarized below.

Projected Capital Costs	
	Total Costs
Medical Equipment	\$29,000
Non-Medical Equipment/Furniture	\$4,600
Total Capital Costs	\$33,600

The applicant provides the assumptions used to project the capital cost in Section Q, page 84.

In Section F, page 43, the applicant shows that there will be no start-up or initial operating expenses because MSDC is an existing facility.

Availability of Funds

In Section F, page 41, the applicant states that the capital cost will be funded through owner's equity, as shown in the table below.

Sources of Capital Financing	
Type	Wake Forest University Health Sciences
Loans	
Accumulated reserves or OE *	\$33,600
Bonds	
Other (Specify)	
Total Financing	\$33,600

In Exhibit F-2, the applicant provides a letter dated August 15, 2020, from Wake Forest Baptist Health, authorizing the project and committing to cover the development cost of the project.

Exhibit F-2 also contains pertinent pages from the 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 equity.

The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Section Q Form F-2 Income Statement, the applicant projects that revenues will exceed operating expenses in the first two operating years of this project, as summarized in the table below.

**Miller Street Dialysis Center
 Revenue and Expenses**

	OY1 Ending June 30, 2022	OY2 Ending June 30, 2023
In-Center Patients*	172	180
In-Center Treatments	25,800	27,000
Gross Patient Revenue	\$47,462,454	\$49,670,010
Other Revenue	\$10,320,000	\$10,800,000
Adjustment from Gross**	\$47,594,927	\$49,808,645
Net Revenue	\$10,187,527	\$10,661,365
Average Net Revenue per Treatment	\$395	\$395
Total Operating Expenses	\$6,854,372	\$7,161,176
Average Operating Expense per Treatment	\$266	\$265
Net Income	\$3,333,155	\$3,500,190

*Average patients per year = beginning + ending census / 2

**Includes charity care and bad debt

Totals may not sum due to rounding

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 because the applicant adequately demonstrates sufficient funds for the capital and 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 two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 stations upon project completion.

On page 113, the 2020 SMFP defines the service area 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-Graham counties and Avery-Mitchell-Yancey counties.*” The facility referred to in this application is 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.

According to Table B, page 155 of the 2020 SMFP, there are five existing or approved dialysis facilities in Forsyth County, four of which are owned and operated by WFUHS. Information on these dialysis facilities, from Table B of the 2020 SMFP, is provided below:

**Forsyth County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2018**

Dialysis Facility	Owner	# of Certified Stations	# of In-Center Patients	Patients per Station per Week	Utilization
Miller Street Dialysis Center of Wake Forest University	WFUHS	44	141	3.2	80.11%
NC Baptist Hospital ESRD	NCBH	4	2	0.5	12.50%
Northside Dialysis Center of Wake Forest University	WFUHS	45	145	3.2	80.56%
Piedmont Dialysis Center of Wake Forest University	WFUHS	58	181	3.1	78.02%
Salem Kidney Dialysis Center of Wake Forest University	WFUHS	45	153	3.4	85.00%
Total Forsyth County		196	622	3.2	79.34%

Source: 2020 SMFP, Table B

In Section G, pages 46-47, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Forsyth County. The applicant lists a series of statements regarding Forsyth County dialysis patients and the proposed addition of the stations prior to stating:

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

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

- All four WFUHS Forsyth County dialysis facilities are currently operating above the ESRD performance standard of 2.8 patients per station per week.
- Forsyth County facilities, as a whole, are operating above the ESRD performance standard of 2.8 patients per station.
- The applicant adequately demonstrates that MSDC will be operating above 2.8 patients per station per week in its projected utilization, which is based on historical patient utilization increased annually at the individual county annual growth rate.
- The applicant adequately demonstrates that the proposed addition of two stations is needed in addition to the existing and approved 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 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 Staffing, page 98, the applicant provides the current and projected staffing in full-time equivalent (FTE) positions, as summarized in the following table.

POSITION	CURRENT FTE POSITIONS JUNE 30, 2020	PROJECTED FTE POSITIONS June 30, 2021	PROJECTED FTE POSITIONS June 30, 2022	PROJECTED FTE POSITIONS June 30, 2023
RN	7.00	7.75	8.00	8.25
LPN	3.00	3.00	3.00	3.00
Patient Care Tech	20.00	21.25	21.75	22.25
Clinical Nurse Manager (DON)	1.00	1.00	1.00	1.00
Dietician	1.00	1.25	1.25	1.25
Social Worker	2.00	2.00	2.00	2.00
Dialysis Tech	2.00	2.00	2.00	2.00
Bio-med Technician	1.00	1.00	1.00	1.00
Clerical	2.00	2.00	2.00	2.00
Total	39.00	41.25	42.00	42.75

Source: Section Q Form H of the application.

The Medical Director and administrative services are contract and regional administration services, respectively, not FTE positions.

The assumptions and methodology used to project staffing are provided in Section Q, page 99. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, pages 49-50, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. On page 52, the applicant states that Shariar Moossavi, M. D. will serve as the Medical Director for the facility. In Exhibit H, 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

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.1, pages 53-56, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 53, as summarized below.

**Miller Street Dialysis Center
 Ancillary and Support Services**

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

In Section I, pages 56-57, the applicant describes MSDC's relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and 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 60, the applicant states that the project involves renovating 300 square feet of existing space. Line drawings are provided in Exhibit K-2(b).

On pages 60-61, 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 Section C and Exhibit K.

On page 61, 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 61-62, 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

The applicant proposes to add no more than two dialysis stations pursuant to facility need for a total of no more than 50 stations upon project completion.

In Section L.1, page 65, the applicant provides the facility’s historical payor mix for the last full fiscal year ended June 30, 2020, as summarized in the table below.

Payor Source	Percent of Total Patients	Percent of In-center Patients	Percent of PD & HH Patients
Private Pay	0.0%	0.0%	0.0%
Medicare	9.0%	9.0%	0.0%
Medicaid	4.0%	4.0%	0.0%
Medicare / Medicaid	21.0%	21.0%	0.0%
Commercial Insurance	17.0%	17.0%	0.0%
Medicare / Commercial	23.0%	23.0%	0.0%
Medicare Advantage	26.0%	26.0%	0.0%
Total	100.0%	100.0%	0.0%

Totals may not sum due to rounding

In Section L.1(a), page 64, the applicant provides comparison of the demographical information on MSDC patients and the Forsyth County service area population during the last full operating year, as summarized below.

	Percentage of Total MSDC Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	49.69%	52.6%
Male	50.31%	47.4%
Unknown	N/A	N/A
64 and Younger	52.8%	84.0%
65 and Older	47.2%	16.0%
American Indian	0%	0.9%
Asian	1.24%	2.6%
Black or African-American	56.52%	27.5%
Native Hawaiian or Pacific Islander	0.62%	0.1%
White or Caucasian	37.27%	56.5%
Other Race	3.73%	13.0%
Declined / Unavailable	0.62%	2.3%

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

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 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), pages 65-67, 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 67, 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
- 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 68, 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 summarized in the table below.

**Projected Payor Mix
OY2 ending June 30, 2023**

Payor Source	Percent of Total Patients	Percent of IC Patients	Percent of PD & HH Patients
Private Pay	0.0%	0.0%	0.0%
Medicare	9.0%	9.0%	0.0%
Medicaid	4.0%	4.0%	0.0%
Medicare / Medicaid	21.0%	21.0%	0.0%
Commercial Insurance	17.0%	17.0%	0.0%
Medicare / Commercial	23.0%	23.0%	0.0%
Medicare Advantage	26.0%	26.0%	0.0%
Total	100.0%	100.0%	0.0%

Source: Application page 68

As shown in the table above, during the second full year of operation, the applicant projects that 83% of the facility patients will have all or part of their services paid for by Medicare and/or Medicaid.

On page 68, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant's proposed payor mix is based on the historical MSDC payor mix, and
- the monthly ending payor mix percentage by payor type for the last 12 months is averaged to obtain the average annual payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.5, pages 71-72, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

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 two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 50 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-Graham counties and Avery-Mitchell-Yancey counties.*” The facility referred to in this application is 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.

According to Table B, page 155 of the 2020 SMFP, there are five existing or approved dialysis facilities in Forsyth County, four of which are owned and operated by WFUHS. Information on these dialysis facilities, from Table B of the 2020 SMFP, is provided below:

**Forsyth County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2018**

Dialysis Facility	Owner	# of Certified Stations	# of In-center Patients	Patients per Station per Week	Utilization
Miller Street Dialysis Center of Wake Forest University	WFUHS	44	141	3.2	80.11%
NC Baptist Hospital ESRD	NCBH	4	2	0.5	12.50%
Northside Dialysis Center of Wake Forest University	WFUHS	45	145	3.2	80.56%
Piedmont Dialysis Center of Wake Forest University	WFUHS	58	181	3.1	78.02%
Salem Kidney Dialysis Center of Wake Forest University	WFUHS	45	153	3.4	85.00%

Source: 2020 SMFP, Table B

Regarding the expected effects of the proposal on competition in the service area, in Section N, pages 74-76, the applicant states that it does not expect the addition of stations to have any effect on the competitive climate in Forsyth County. The applicant does not project to serve dialysis patients currently being served by another provider. On page 74, the applicant further states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 74, the applicant states:

“As demonstrated in the pro forma [sic] 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 75, 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 75, 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 MSDC 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 also Sections B, C, F, and Q of the application and any exhibits).
- Quality (see also Sections B, C, and O of the application and any exhibits).
- Access to medically underserved groups (see also Sections B, C, and L 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 Facilities, page 81, 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 existing and/or approved dialysis facilities located in North Carolina.

In Section O, page 78, 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 table on page 78 shows that the facilities that were back in compliance at the time of application submittal, with the exception of the report pending on Salem Kidney Center. 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 application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new 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 ESRD 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 Q Form C Utilization, page 82, the utilization methodology proposed by the applicant achieves a projection of 176 in-center patients by the end of the first operating year, June 30, 2022, for a utilization rate of 3.5 in-center patients per station per week or 87.99% ($176 \text{ patients} / 50 \text{ stations} = 3.52 \text{ patients per station} / 4 = 0.8799$). The projected utilization of 3.5 patients per station per week exceeds the 2.8 in-center patients per station per week threshold in the first full year following project completion, as required by 10A NCAC 14C .2203(a).
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- C- In Section Q Assumptions and Methodology, pages 82-83, the applicant provides the assumptions and methodology used to project utilization of the facility.