

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 21, 2024

Findings Date: February 21, 2024

Project Analyst: Tanya M. Saporito

Co-Signer: Gloria C. Hale

Project ID #: G-12460-23

Facility: North Randolph Dialysis Center of Wake Forest University

FID #: 140089

County: Randolph

Applicants: Wake Forest University Health Sciences

North Randolph Dialysis Center of Wake Forest University

Project: Add no more than 7 dialysis stations pursuant Condition 2 of the facility need methodology for a total of no more than 17 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 and North Randolph Dialysis Center of Wake Forest University, collectively referred to as “the applicant” propose to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

Need Determination

Chapter 9 of the 2023 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 133, the county need methodology shows there is no county need determination for additional dialysis stations in Randolph 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 2023 SMFP, if the utilization rate for the facility as reported in the 2023 SMFP is at least 75% or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for NRDC is 85.0% or 3.4 patients per station per week, based on 34 in-center dialysis patients and 10 certified dialysis stations [34 patients / 10 stations = 3.4: $3.4 / 4 = 0.85$].

As shown in Table 9A on page 127 of the 2023 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at NRDC is up to seven additional stations; thus, the applicant is eligible to apply to add up to seven stations during the 2023 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than seven new stations to the facility, which is consistent with the 2023 SMFP calculated facility need determination for up to seven stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2023 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy *GEN-3*, page 30 of the 2023 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 will promote safety and quality in Section B, pages 17-21; Section N, page 71; Section O, page 72; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality in the delivery of dialysis services.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 21; Section C, pages 29-31; Section L, pages 62-66; Section N, page 71; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access to dialysis services.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 17-21; Section C, pages 29-32; Section N, page 71; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 applicant adequately demonstrates that the application is consistent with Condition 2 of the facility need methodology in the 2023 SMFP.
- The applicant adequately demonstrates how North Randolph Dialysis Center's projected volumes incorporate the concepts of safety and quality, equitable access and maximum value for resources expended in meeting the facility need and is consistent with Policy GEN-3.

- (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 applicant proposes to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

Patient Origin

On page 113, the 2023 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 is Randolph County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 23, the applicant provides the following historical in-center (IC) and peritoneal dialysis (PD) patient origin for NRDC for the last full year of operation, fiscal year (FY) 2023 (November 1, 2022-October 31, 2023), as shown in the table below:

Historical Patient Origin, NRDC, FY 2023

COUNTY	# IN-CTR. PTS.	% OF TOTAL	# PD PTS.	% OF TOTAL
Davidson	5.0	13.51%	4.0	44.44%
Guilford	5.0	13.51%	1.0	11.11%
Randolph	27.0	72.97%	4.0	44.44%
Total	37.0	100.00%	9.0	100.00%

Numbers may not sum due to rounding

The following table, from Section C page 24, illustrates projected IC and PD patient origin for NRDC in the second full fiscal year (FY) of operation, FY 2026:

Projected Patient Origin, NRDC, FY 2026

COUNTY	# IN-CTR. PTS.	% OF TOTAL	# PD PTS.	% OF TOTAL
Davidson	5.74	11.61%	4.59	46.40%
Guilford	5.51	11.15%	1.10	11.19%
Randolph	28.07	56.76%	4.16	42.21%
Randolph Transfers In	10.13	20.49%	0.00	0.00%
Total	49.45	100.00%	9.85	100.00%

Numbers may not sum due to rounding

In Section C, pages 24-25, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant states the 2023 SMFP includes a seven-station need determination for NRDC.

- The applicant states the patients projected to utilize NRDC originate from Davidson, Guilford and Randolph counties, which is consistent with its historical patient origin.
- The applicant begins with the number of patients dialyzing at the facility as of the end of the last full FY of operation.
- The applicant uses the Average Annual Change Rate (AACR) as published in the 2023 SMFP for each county in which the facility's patients reside to project patient growth for the future patient population.
- In PYs one and two, the applicant adds Randolph County patients who are projected to transfer their care to NRDC when the seven stations are developed.

Analysis of Need

In Section C, pages 25-26, the applicant explains why they believe the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- The 2023 SMFP identified a facility need determination for NRDC for seven additional stations.
- Based on historical utilization at NRDC and information contained in the 2023 SMFP, the applicant calculates a projected potential deficit of dialysis stations in Randolph County by FY 2026.
- Based on historical utilization at NRDC and on an 80% utilization rate, the applicant projects a two-station deficit in Randolph County by the end of the applicant's first FY of operation, FY 2025.
- Based on the projected deficit of dialysis stations in the county, the applicant states it is reasonable to assume the proposed seven stations will be utilized by existing and projected Randolph County dialysis patients.
- The applicant (WFUHS) currently serves 58 Randolph County residents, 50 of whom are in-center patients. Of those patients, the applicant states 27 currently utilize NRDC. Additionally, the applicant states NRDC's current utilization rate is 92.50%, which is resulting in patient dissatisfaction, particularly regarding dialysis shift time choices.
- Even with the addition of the stations as proposed in this application, the facility utilization will be over 70% by the end of the first operating year, which substantiates the need for the additional dialysis stations at NFDC.

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

- The 2023 SMFP shows a facility need determination for up to seven stations at NRDC.

- The applicant applies the appropriate Five Year AACR as published in the 2023 SMFP to project growth in each county’s patient census according to that growth rate.
- The applicant demonstrates that the facility will need the additional stations to accommodate the existing and projected patient population.
- The applicant states that this project is necessary to best serve existing and projected patients who will choose to dialyze at NRDC and will also prevent a shortfall of needed dialysis stations in Randolph County.

Projected Utilization

In Section Q Form C, the applicant provides projected utilization for the interim and project years, as illustrated in the following table:

NRDC Projected Utilization				
FORM C UTILIZATION	END PRIOR YEAR (FY 2023)	END CURRENT YEAR (FY 2024)	END PY 1 (FY 2025)	END PY 2 (FY 2026)
# of In-Ctr. Patients at the Beginning of the Year	34	37	38	49
# of In-Ctr. Patients at the End of the Year	37	38	49	49
Average # of In-Ctr. Patients during the Year	36	37	43	49
# of Treatments / Patient / Year	144	144	144	144
Total In-Ctr. Treatments	5,184	5,328	6,192	7,056
# of PD Patients at the Beginning of the Year	9	9	9	10
# of PD Patients at the End of the Year	9	9	10	10
Average # of PD Patients during the Year	9	9	9	10
# of Treatments / Patient / Year	144	144	144	144
Total PD Treatments	1,296	1,296	1,296	1,440
Total # of Treatments	6,480	6,624	7,488	8,496

In Section C, pages 24-26, and in Section Q, pages 76-78, the applicant provides the assumptions and methodology used to project in-center utilization, as summarized below:

- The applicant begins with the NRDC facility patient census as of the end of FY 2023.
- The applicant uses each of the applicant’s service area counties’ Five Year AACR as published in the 2023 SMFP to project future volume for the facility.
- The applicant projects utilization by applying the projected county growth rate from the 2023 SMFP to each county’s patient census at NRDC, beginning with facility census as of the end of FY 2023, sorted by dialysis modality and patient home county.
- The applicant calculated an average number of patients per year by taking the mean of the beginning and ending facility census by year and by modality.

In Section C, page 77, the applicant provides the following table to illustrate the assumptions and projected utilization at NRDC:

COUNTY	AACR	11/1/22	PRIOR YR.	10/31/23	END PRIOR YEAR	10/31/24	END CURRENT YEAR	10/31/25	END OY 1	10/31/26	END OY 2
		IN-CTR.	PD	IN-CTR.	PD	IN-CTR.	PD	IN-CTR.	PD	IN-CTR.	PD
Davidson	4.7%	5.00	2.00	5.00	4.00	5.24	4.19	5.48	4.38	5.74	4.59
Guilford	3.3%	4.00	3.00	5.00	1.00	5.17	1.03	5.34	1.07	5.51	1.10
Randolph	1.3%	25.00	4.00	27.00	4.00	27.35	4.05	27.71	4.10	28.07	4.16
Randolph Transfers In.	1.3%	0.00	0.00	0.00	0.00	0.00	0.00	10.00	0.00	10.13	1.00
Total		34.00	9.00	37.00	9.00	37.75	9.27	48.52	9.56	49.45	9.85

At the end of PY1, NRDC is projected to serve 48.52 in-center patients and at the end of PY2 the facility is projected to serve 49.45 in-center patients on 17 stations.

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

- OY1: 48.52 patients per station per week or 71.4% [48.52 patients / 17 stations = 2.85; 2.85 / 4 = 0.7135 or 71.4%].
- OY2: 49.45 patients per station per week or 72.7% [49.45 patients / 17 stations = 2.90; 2.90 / 4 = 0.7272 or 72.7%].

The projected utilization of 2.85 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 applicant projects growth of each county’s patient population using the Five-Year AACR for each county as published in the 2023 SMFP.
- The applicant projects utilization based on the number of NRDC patients residing in Randolph County who indicated they will transfer their services after the proposed addition of stations at NRDC.
- 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 29-30, the applicant discusses access to the facility’s dialysis services, stating:

“...At least 2.61% of the ICH patients projected to be served by NRDC will be 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 page 31, the applicant provides 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*	2.61%
Racial and ethnic minorities	35.71%
Women	38.10%
Persons with disabilities**	--
Persons 65 and older	59.52%
Medicare beneficiaries	69.02%
Medicaid beneficiaries	13.27%

*The applicant states this category includes recipients of Medicaid only

**The applicant states: “Unknown/Stat unable to be tracked. Facility ADA compliant”

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 based on the following:

- The application and Exhibit L.4 provide information and policies that demonstrate the applicant's commitment to provide services to all patients referred for ESRD services.
- The applicant demonstrates 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 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 describes 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 applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

In Section E, pages 38-39, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Transfer existing dialysis stations from a contiguous county – The applicant determined that transferring existing dialysis stations from a contiguous county would be inconsistent with Policy ESRD-2 in the 2023 SMFP. Randolph County does not currently have a station surplus nor deficit as reported in the 2023 SMFP and thus relocating existing dialysis stations is not an effective alternative.
- Transfer existing dialysis stations from within Randolph County – The applicant states it does not own any other ESRD facilities in Randolph County and thus it is not possible to transfer existing dialysis stations from another facility. Therefore, this was not an effective alternative.

- Add fewer than the seven dialysis stations as proposed – The applicant considered adding fewer than seven stations as proposed in this application, but determined that is not a feasible alternative, because there are a large number of dialysis patients currently served by the applicant who are leaving the county for dialysis and who would be better served in a facility within their home county. The seven stations determined to be needed in the 2023 SMFP and applied for in this application are a sufficient number to effectively and efficiently serve current and projected dialysis patients. Therefore, adding fewer than seven stations is not the most effective alternative.

On page 38, the applicant states adding seven stations as proposed in this application is the most effective alternative to meet the current and future needs of dialysis patients in Randolph County, because it will obviate the need for many Randolph County patients to travel out of the county to receive dialysis.

The applicant adequately demonstrates 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 applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. North Randolph 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. Pursuant to Condition 2 of the facility need determination in the 2023 SMFP, the certificate holders shall develop no more than seven in-center stations for a total of no more than 17 stations at North Randolph Dialysis Center of Wake Forest University upon project completion.**
- 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, 2024.**

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 applicant proposes to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects 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	\$106,400
Non-Medical Equipment	\$8,400
Furniture	\$17,500
Total	\$132,300

In Section F.3, page 42, the applicant states there are no start-up costs or initial operating expenses associated with this project because it is an existing facility. In Section Q, page 79, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates 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 40, the applicant states 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 *	\$132,300	\$132,300
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$132,300	\$132,300

* OE = Owner's Equity

In Exhibit F-2(c)(2), the applicant provides an October 30, 2023 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, the availability of sufficient funds and committing the funds to project development. In Exhibit F-(2)(c)(3), the applicant provides the consolidated balance sheets for Wake Forest University for year ending June 30, 2022, which confirm sufficient funds for project development.

The applicant adequately demonstrates 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 applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in each of the first two full fiscal years of operation following project completion, as shown in the following table:

NORTH RANDOLPH DIALYSIS CENTER	1 ST FULL PY (11/1/24- 10/31/25)	2 ND FULL PY (11/1/25- 10/31/26)
Total Treatments, including HH and PD Treatments and Training Days	7,524	8,536
Total Gross Revenue (charges)	\$18,507,078	\$20,995,350
Total Net Revenue	\$2,483,424	\$2,816,077
Average Net Revenue per Treatment	\$330	\$330
Total Operating Expenses (costs)	\$1,986,129	\$2,253,730
Average Operating Expense per Treatment	\$264	\$264
Net Income	\$497,295	\$562,347

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The applicant adequately demonstrates 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 applicant provides 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 applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of 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 applicant proposes to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

On page 113, the 2023 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 is Randolph County. Facilities may also serve residents of counties not included in their service area.

The following table lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Randolph County as of December 31, 2021, from Table 9A, page 127 of the 2023 SMFP. There are two kidney disease treatment centers providing dialysis services in Randolph County:

FACILITY NAME	CERTIFIED STATIONS AS OF 12/31/2021	# IC PATIENTS AS OF 12/31/2021	% UTILIZATION AS OF 12/31/2021	PATIENTS / STATION / WEEK
BMA of Asheboro	45	121	67.2%	2.68
North Randolph Dialysis Ctr.	10	34	85.0%	3.40
Total	55	155		

In Section G, page 46, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Randolph County. The applicant states:

“This project is based on Condition 2 of the facility need methodology, which provides a means by which a facility experiencing high utilization may add stations to meet patient demand.

...

Currently, NRDC is experiencing utilization greater than or equal to 92.50%, and has experienced utilization nearing 100% during 2023.”

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

- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.
- The applicant adequately demonstrates that North Randolph Dialysis Center of Wake Forest University needs additional stations to serve its existing and projected patient population.

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 applicant proposes to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

In Section Q, Form H, page 92, the applicant provides current and projected full-time equivalent (FTE) positions for NRDC as shown in the following table:

POSITION	CURRENT FTE POSITIONS*	FTE POSITIONS OY1	FTE POSITIONS OY2
RN	0.75	0.75	1.25
Patient Care Technician (PCT)	5.00	5.50	5.75
Director of Nursing	1.00	1.00	1.00
Dietician	0.25	0.25	0.50
Social Worker	0.25	0.25	0.50
Home Training Nurse	0.75	1.00	1.00
Dialysis Technician	0.25	0.50	0.50
Biomedical Technician	0.25	0.25	0.25
Clerical	1.00	1.00	1.00
Total	9.50	10.50	11.75

*As of October 31, 2023

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Section H.2 and Section H.3, pages 48-50, the applicant describes the methods used to recruit or fill new positions and their existing training and continuing education programs.

The applicant adequately demonstrates 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 applicant bases projected staffing on existing staff and historical experience in providing dialysis services at the facility.
- The applicant has existing policies in place regarding recruitment, training and continuing education, and will continue to abide by those policies following the station additions.

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 applicant proposes to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

Ancillary and Support Services

In Section I, page 52, the applicant identifies each ancillary and support service listed in the application as necessary for the existing and proposed dialysis services. On pages 53-55, the applicant explains how each ancillary and support service is made available.

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

- The applicant currently provides dialysis services at NRDC.
- The applicant explains how it provides each necessary ancillary and support service at the facility and how it will continue to provide the same services following the addition of the dialysis stations proposed in this application.

Coordination

In Section I, page 56, the applicant describes existing relationships with other local health care and social service providers and provides documentation in Exhibits I.1-1(b) and I-2(a).

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

- The applicant discusses existing relationships with local health care providers.
- The applicant discusses existing relationships with local social service providers.
- The applicant states 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 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 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.

C

The applicant proposes to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

In Section K, page 59, the applicant states the project involves renovation of approximately 840 square feet of existing space. Line drawing are provided in Exhibit K.2.

On page 59, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the existing facility houses two 12-station bays, only one of which is in use; therefore, space exists for developing the proposed additional stations.
- The proposed new stations will only require that existing hookups in the wall be uncovered and plumbed.

On pages 59-60, 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 based the information provided on pages 59-60 and on the following:

- The applicant states the proposed new stations can be housed in the existing facility without the need for costly construction.
- The applicant states the development of the new stations is a cost of doing business and is necessary to adequately serve existing and projected dialysis patients.
- The applicant states that, while the project will require an additional cost to develop, it will actually lower the cost of providing dialysis services over time by enhancing underserved patients' access to care. The result is an overall improvement in total patient health and a reduction in hospitalizations related to non-compliance.

With regard to applicable energy saving features that will be incorporated into the construction plans, on page 60, the applicant refers to Exhibit B-7, which contains a letter from a professional engineer confirming the inclusion of energy saving features that were included when the facility was constructed.

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 all the reasons described above.

(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 62, the applicant provides the historical payor mix during FY 2023 (November 1, 2022-October 31, 2023) for NRDC, as illustrated in the following table:

Historical Payor Mix (FY 2023), NRDC

PAYOR SOURCE AT ADMISSION	IN-CENTER PATIENTS		HOME PATIENTS	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Self-Pay	0.3	0.8%	0.0	0.0%
Commercial Insurance	2.9	8.1%	1.2	13.0%
Medicare*	24.8	69.0%	7.7	86.0%
Medicaid*	4.8	13.3%	0.0	0.0%
Other (VA)	3.2	8.8%	0.1	1.0%
State Kidney Program	0.0	0.0%	0.0	0.0%
Total	36.0	100.0%	9.0	100.0%

*Includes any managed care plans

In Section L, page 63, the applicant provides the following comparison:

NRDC	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	38.10%	50.40%
Male	61.90%	49.60%
Unknown	--	--
64 and Younger	40.48%	81.40%
65 and Older	59.52%	18.60%
American Indian	0.00%	1.20%
Asian	2.38%	1.70%
Black or African-American	19.05%	7.10%
Native Hawaiian or Pacific Islander	0.00%	0.10%
White or Caucasian	71.43%	87.80%
Other Race	4.76%	2.10%
Declined / Unavailable	2.38%	0.00

The Agency reviewed the:

- Application
- Exhibits to the application

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 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 63-65, the applicant states that NRDC 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 65, the applicant states that during the last 18 months preceding the application deadline, 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 65, the applicant projects payor mix for the proposed services during the second full fiscal year of operation following project completion, as summarized in the table below:

NRDC Projected Payor Mix (FY 2026)

PAYOR SOURCE AT ADMISSION	IN-CENTER PATIENTS		HOME PATIENTS	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Self-Pay	0.4	0.8%	0.0	0.0%
Commercial Insurance	4.0	8.1%	1.3	13.0%
Medicare*	33.8	69.0%	8.6	86.0%
Medicaid*	6.5	13.3%	0.0	0.0%
Other (VA)	4.3	8.8%	0.1	1.0%
State Kidney Program	0.0	0.0%	0.0	0.0%
Total	49.0	100.0%	10.0	100.0%

*Includes any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.8% of in-center dialysis services will be provided to self-pay patients, 69.0% to Medicare recipients and 13.3% to Medicaid recipients. Additionally, the applicant projects that 86.0% of home dialysis services will be provided to Medicare recipients and 0.0% to Medicaid recipients and to self-pay patients.

On page 65, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on historical treatment volumes at the facility.

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, pages 67-68 and in referenced exhibits, 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

The applicant proposes to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

In Section M, page 69, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1(b). The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- NRDC provides a copy of a November 2, 2023 letter sent to Randolph Community College requesting to participate in an affiliation agreement with its Nursing Program for clinical education and training.
- WFUHS facilities provide onsite educational experiences to local training programs in the area and will continue to do so following addition of seven stations as proposed in this application.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

The applicant proposes to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

On page 113, the 2023 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 is Randolph County. Facilities may also serve residents of counties not included in their service area.

The following table lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Randolph County as of December 31, 2021, from Table 9A, page 127 of the 2023 SMFP. There are two kidney disease treatment centers providing dialysis services in Randolph County:

FACILITY NAME	CERTIFIED STATIONS AS OF 12/31/2021	# IC PATIENTS AS OF 12/31/2021	% UTILIZATION AS OF 12/31/2021	PATIENTS / STATION / WEEK
BMA of Asheboro	45	121	67.2%	2.68
North Randolph Dialysis Ctr.	10	34	85.0%	3.40
Total	55	155		

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 70, the applicant states:

“Because this project is solely focused on meeting patient needs at NRDC without interfering in the referral patterns of patients to the BMA facility in Asheboro, this project will have no effect on competition in the proposed service area of Randolph County. Services available at NRDC will be expanded to accommodate existing WFUHS Randolph County patients traveling out of county for care due to high utilization at NRDC. The expanded facility will provide dialysis services to an underserved area of the county providing greater convenience to existing and future patients and improving ease of access.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 71, the applicant states:

“The additional stations will mean Randolph County will not suffer a persistent station shortfall that will strain existing healthcare services. This proposal will not increase the cost of services for patients and ensure the existing and projected patient volumes will have access to care on two daily shifts. Since it is the only proposal that will sufficiently address the need of the projected NRDC patients, it the most cost-effective method for ensuring continuity of care for the ESRD patients served by WFUHS in Randolph County.”

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

Regarding the impact of the proposal on quality, in Section N, page 71, the applicant states:

“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, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 71, the applicant states:

“The new stations requested in this proposal will represent improved 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. Reductions in travel time, increased convenience of care, and enhanced access to care will reduce a financial burden on the patient and community resources, overall.”

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

The applicant adequately describes 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 applicant demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrates: 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 applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
 - 3) Medically underserved groups will have access to the proposed services based on the applicant's 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

The applicant proposes to add no more than seven dialysis stations pursuant to Condition 2 of the facility need methodology to North Randolph Dialysis Center of Wake Forest University (NRDC) for a total of no more than 17 stations upon project completion. The applicant proposes to offer in-center dialysis services and peritoneal home dialysis training and support.

In Section O, page 73, the applicant states that, during the 18 months immediately preceding the submittal of the application, six facilities were cited for deficiencies, however, all facilities are currently back in compliance. After reviewing and considering information provided by the applicant, the Agency determined that 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 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 full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.*
- NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility.
- (b) *An applicant proposing to increase the number of in-center 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 full fiscal year of operation following certification of the additional stations.*
- C- In Section C and Section Q, Form C, the applicant documents the need for the seven additional dialysis stations as proposed. The applicant projects to serve 48 patients at the end of the first 12 months of operation following certification of the proposed additional stations, which is 2.9 patients per station per week [48 / 17 = 2.85].
- (c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*
- NA- The applicant does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.
- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*

- NA- The applicant does not propose to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.
- (e) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*
- C- In Section C, pages 25-26, 28-29; and in the Assumptions following Form C in Section Q, pages 76-77, the applicant provides the assumptions and methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.