

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 19, 2025

Findings Date: September 19, 2025

Project Analyst: Yolanda W. Jackson

Co-Signer: Gloria C. Hale

Project ID #: D-12666-25

Facility: Wilkes Dialysis Center of Wake Forest University

FID #: 956103

County: Wilkes

Applicant(s): Wake Forest University Health Sciences

Wilkes Dialysis Center of Wake Forest University

Project: Add no more than three in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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 Wilkes Dialysis Center of Wake Forest University (“WDC”) (hereinafter collectively referred to as “the applicant”) propose to add no more than three in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

Need Determination (Condition 2)

Chapter 9 of 2025 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 138, the facility need methodology shows there is a facility need

determination for additional dialysis stations at Wilkes Dialysis Center of Wake Forest University in Wilkes County.

As shown in Table 9D, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to three additional stations; thus, the applicant is eligible to apply to add up to three stations during the 2025 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than three new stations to the facility, which is consistent with the 2025 SMFP calculated facility need determination for up to three stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

One policy in Chapter 4 of the 2025 SMFP is applicable to this review, *Policy GEN-5: Access to Culturally Competent Healthcare*.

Policy GEN-5, pages 30-31 of the 2025 SMFP, states:

“A certificate of need (CON) applicant applying to offer or develop 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 provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities. The delivery of culturally competent healthcare requires the implementation of systems and training to provide responsive, personalized care to individuals with diverse backgrounds, values, beliefs, customs, and languages. A certificate of need applicant shall identify the underserved populations and communities it will serve, including any disparities or unmet needs of either, document its strategies to provide culturally competent programs and services, and articulate how these strategies will reduce existing disparities as well as increase health equity.

CON applications will include the following:

The applicant shall, in its CON application, address each of the items enumerated below:

Item 1: *Describe the demographics of the relevant service area with a specific focus on the medically underserved communities within that service area. These communities shall be described in terms including, but not limited to: age, gender, racial composition; ethnicity; languages spoken; disability; education; household income; geographic location and payor type.*

Item 2: *Describe strategies it will implement to provide culturally competent services to members of the medically underserved community described in Item 1.*

Item 3: Document how the strategies described in Item 2 reflect cultural competence.

Item 4: Provide support (e.g., best-practice methodologies, evidence-based studies with similar communities) that the strategies described in Items 2 – 3 are reasonable pathways for reducing health disparities, increasing health equity and improving the health outcomes to the medically underserved communities within the relevant service area.

Item 5: Describe how the applicant will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities in underserved communities.”

Demographics

In Section L, page 59, the applicant provided the following table that reflects the patient demographics at Wilkes Dialysis Center of Wake Forest University (WDC).

Group	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served^	Percentage of the Population of the Service Area*
Female	36.08%	50.6%
Male	63.92%	49.4%
Unknown	N/A	N/A
64 and Younger	46.39%	76.3%
65 and Older	53.61%	23.7%
American Indian	0.00%	0.5%
Asian	1.03%	0.7%
Black or African American	12.37%	4.8%
Native Hawaiian or Pacific Islander	0.00%	0.2%
White or Caucasian	73.20%	91.9%
Hispanic or Latino	13.40%	7.9%
Declined / Unavailable	1.03%	0.0%

^All patients (in-center, home hemodialysis, and peritoneal dialysis)

* 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.

In Section B, page 17-19, the applicant explains why it believes its application is conforming to *Policy GEN-5*.

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 does not propose to develop more dialysis stations than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-5* based on the following:
 - The applicant provided patient demographics for Wilkes County.
 - Health Systems Management, Inc. (“HSM”) is the manager of WFUHS dialysis centers. HSM described the strategies that it would implement on behalf of WFUHS at WDC including identifying populations facing the greatest health inequities, setting clear goals and taking decisive action steps to eliminate barriers to health and well-being.
 - The applicant describes how the strategies reflect cultural competence by setting the following goals: reduce disparities, improve access, promote health literacy, enhance policy advocacy, and foster collaboration.
 - The applicant provides support that its strategies are reasonable pathways for reducing health disparities, increasing health equity and improving health outcomes by providing a statement that it will take the following action steps:
 - Conduct Need Assessments
 - Develop Targeted Interventions
 - Provide Culturally Competent Care
 - Monitor Progress and Outcomes
 - Advocate for Policy Change
 - The applicant described how it will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities by employing the following specific resources:
 - HMS will collect and analyze data on health outcomes, disparities and social determinants of health to inform their interventions and advocate for change.
 - HMS will invest in training and education for staff to enhance cultural competency and promote health literacy.
 - HMS will collaborate with community organizations, academic institutions, healthcare providers and government agencies to leverage resources and expertise.

- HMS will collaborate with community-based resources, local organizations, healthcare providers, and local government agencies and advocate for health equity in the community.
 - HMS will develop culturally tailored outreach materials and communication strategies.
 - HMS will empower individuals and communities to advocate for their own health needs.
- (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion. Wilkes Dialysis Center of Wake Forest University currently has 24 in-center stations and is approved to provide home peritoneal dialysis (PD) training and support and home hemodialysis (HHD) support services.

On page 113, the 2025 SMFP defines the service area for dialysis stations as *“the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.”* WDC is located in Wilkes County. Thus, the service area for this facility consists of Wilkes County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrates historical and projected patient origin.

County	Wilkes Dialysis Center Historical 06/01/2024 to 05/31/2025					
	# of In-Center Patients	% of Total	# of Home Hemodialysis Patients	% of Total	# of Peritoneal Dialysis Patients	% of Total
Alexander	0.00	0.00%	0.00	0.00%	0.00	0.00%
Ashe	4.00	4.71%	0.00	0.00%	2.00	13.33%
Burke	1.00	1.18%	0.00	0.00%	0.00	0.00%
Caldwell	1.00	1.18%	0.00	0.00%	0.00	0.00%
Wilkes	79.00	92.94%	1.00	100.00%	13.00	86.67%
Total	85.00	100.00%	1.00	100.00%	15.00	100.00%

Source: Section C, page 20.

County	Wilkes Dialysis Center First FY of Operation following Project Completion 06/01/2026 to 05/31/2027					
	# of In-Center Patients	% of Total	# of Home Hemodialysis Patients	% of Total	# of Peritoneal Dialysis Patients	% of Total
Alexander	0.00	0.00%	0.00	0.00%	0.00	0.00%
Ashe	4.29	4.84%	0.00	0.00%	2.15	13.67%
Burke	1.01	1.14%	0.00	0.00%	0.00	0.00%
Caldwell	1.04	1.18%	0.00	0.00%	0.00	0.00%
Wilkes	82.35	92.84%	1.04	100.00%	13.55	86.33%
Total	88.70	100.00%	1.04	100.00%	15.70	100.00%

Source: Section C, page 21.

County	Wilkes Dialysis Center Second Full FY of Operation following Project Completion 06/01/2027 to 05/31/2028					
	# of In-Center Patients	% of Total	# of Home Hemodialysis Patients	% of Total	# of Peritoneal Dialysis Patients	% of Total
Alexander	0.00	0.00%	0.00	0.00%	0.00	0.00%
Ashe	4.45	4.91%	0.00	0.00%	2.22	13.85%
Burke	1.02	1.12%	0.00	0.00%	0.00	0.00%
Caldwell	1.07	1.18%	0.00	0.00%	0.00	0.00%
Wilkes	84.08	92.79%	1.06	100.00%	13.84	86.15%
Total	90.62	100.00%	1.06	100.00%	16.06	100.00%

Source: Section C, page 21.

In Section C, pages 21-22, 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 used the 5-Year Average Annual Change Rate (AACR) by patient county of origin for projecting patient growth.
 - The 5-Year AACR for Alexander County in the 2025 SMFP=0.0010 or 0.10% (The applicant included Alexander County because WDC had one Alexander County patient at the beginning of the prior year. WDC currently does not have any patients from Alexander County and is not predicting any in the future.)
 - The 5-Year AACR for Ashe County in the 2025 SMFP = 0.036 or 3.6%
 - The 5-Year AACR for Burke County in the 2025 SMFP =0.006 or 0.6%
 - The 5-Year AACR for Caldwell County in the 2025 SMFP = 0.022 or 2.20%
 - The 5-Year AACR for Wilkes County in the 2025 SMFP = 0.021 or 2.10%
- The 05/31/2025 WDC patient population was increased for each operating year (OY) through the projected end of OY2 and totaled to arrive at the projected patient volumes.

Analysis of Need

In Section C, pages 22-23, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 22, the applicant states:

“The WDC facility is well utilized and based upon its current utilization rate as of 5/31/2025 of 86.46% for 24 stations, additional stations are needed at that location.”

The information is reasonable and adequately supported because the applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2025 SMFP. The discussion regarding the need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section Q, Form C Utilization, page 83, the applicant provides historical and projected utilization, as illustrated in the following table.

Form C Utilization	Ending Prior Year 06/01/2024 to 05/31/2025	Ending Current Year 06/01/2025 to 05/31/2026	Ending OY1 06/01/2026 to 05/31/2027	Ending OY2 06/01/2027 to 05/31/2028
In-Center Patients				
# of Patients at Beginning of Year	83	85	87	89
# of Patients at the End of the Year	85	87	89	91
Avg. # of Patients During the Year	84	86	88	90
# of Treatments / Patient / Year	145	145	145	145
Total # of Treatments	12,180	12,470	12,760	13,050
Home Hemodialysis Patients				
# of Patients at Beginning of Year	0	1	1	1
# of Patients at the End of the Year	1	1	1	1
Avg. # of Patients During the Year	1	1	1	1
# of Hemo-Equivalent Treatments / Patient / Year	145	145	145	145
Total # of Treatments	145	145	145	145
Peritoneal Dialysis Patients				
# of Patients at Beginning of Year	12	15	15	16
# of Patients at the End of the Year	15	15	16	16
Avg. # of Patients During the Year	14	15	16	16
# of Hemo-Equivalent Treatments / Patient / Year	145	145	145	145
Total # of Treatments	2,030	2,175	2,320	2,320
Total Hemo-Equivalent Patients				
# of Patients at Beginning of Year	95	101	103	105
# of Patients at the End of the Year	101	103	105	108
Avg. # of Patients During the Year	99	102	105	107
# of Hemo-Equivalent Treatments / Patient / Year	145	145	145	145
Total # of Hemo-Equivalent Treatments	14,335	14,790	15,225	15,515
Total Home Training Billable Days Per OY				
Total HH Training Days	0	0	0	0
Total PD Training Days	48	56	64	74
Total Billable Treatments (All Sources)	14,403	14,846	15,289	15,589

In Section C, pages 24-25, and Section Q, pages 83-85, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

In-Center Patients

- The applicant began with the patient census at WDC as of 05/31/2025.
- The applicant used the 5-Year AACR by county published in the 2025 SMFP and the beginning patient populations were increased respectively, resulting in the number of patients projected by the end of OY1 and OY2.

County	5-Year AACR	05/31/2025	Ending Current Yr 5/31/2026	Ending OY1 5/31/2027	Ending OY2 5/31/2028
Alexander	0.10%	0.00	0.00	0.00	0.00
Ashe	3.60%	4.00	4.14	4.29	4.45
Burke	0.60%	1.00	1.01	1.01	1.02
Caldwell	2.20%	1.00	1.02	1.04	1.07
Wilkes	2.10%	79.00	80.66	82.35	84.08
Totals		85.00	86.83	88.70	90.62

Source: Section C, page 24.

	IC Stations	IC Patients
Begin with the station count and patient census at the facility as of 5/31/2025.	24	Ashe: 4 Burke: 1 Caldwell: 1 Wilkes: 79
The facility's patient census is projected forward to 5/31/2026. This is the ending census for the current year.		Ashe: $4 \times 1.036 = 4.14$ Burke: $1 \times 1.006 = 1.01$ Caldwell: $1 \times 1.022 = 1.02$ Wilkes: $79 \times 1.021 = 80.66$ Total: 86.83
The proposed project is projected to be certified on 5/31/2026. This is the station count at the beginning of the project's first operating year (OY1).	$24 + 3 = 27$	
The facility's patient census is projected forward a year to 5/31/2027. This is the ending census for OY1.		Ashe: $4.14 \times 1.036 = 4.29$ Burke: $1.01 \times 1.006 = 1.01$ Caldwell: $1.02 \times 1.022 = 1.04$ Wilkes: $80.66 \times 1.021 = 82.35$ Total: 88.70
The facility's patient census is projected forward a year to 5/31/2028. This is the ending census for OY2.		Ashe: $4.29 \times 1.036 = 4.45$ Burke: $1.01 \times 1.006 = 1.02$ Caldwell: $1.04 \times 1.022 = 1.07$ Wilkes: $82.35 \times 1.021 = 84.08$ Total: 90.62

Source: Section C, page 24.

- At the end of OY1, WDC is projected to serve 88.70 in-center patients and at the end of OY2, the facility is projected to serve 90.62 in-center patients.
- The applicant projects to serve 88.70 patients on 27 stations, which is 3.29 patients per station per week (88 patients / 27 stations = 3.29), by the end of OY1.
- This meets the minimum requirements of 2.8 patients per station per week as of the end of the first full fiscal year as required by 10A NCAC 14C .2203(b).

Home Peritoneal Dialysis (PD) Patients

- The applicant began with the current number of PD patients trained as of the last OY ending 05/31/2025 and compared the current number of patients to prior numbers of patients trained by year.

- The applicant states that historical data shows an average increase in the total number of patients trained year-over-year of about 15%.
- The applicant began with the most recent number of patients trained for the last OY and increased those numbers by 15% resulting in the total number of patients trained for each subsequent year.
- WDC is not certified to provide Home Hemodialysis (HH) Training (HH support only). Therefore, there are no projected HH training days.

	# of PD Patients Trained
5/31/2025	11.00
5/31/2026	12.65
5/31/2027	14.55
5/31/2028	16.73

Source: Section C, page 24.

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

- The applicant projects future utilization for in-center patients by increasing the current patient population by the applicable county-specific 5-Year AACRs in the 2025 SMFP.
- Projected utilization at the end of FY1 meets the minimum of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).
- The applicant projects future utilization for peritoneal dialysis patients based on historical data of patients trained by year.

Access to Medically Underserved Groups

In Section C, page 26, the applicant states:

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

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Group	Percentage of Total Patients during the Second Full Fiscal Year
Low income persons (Medicaid Only)	11.40% ICH / 6.70% Home
Racial and ethnic minorities	26.8%
Women	36.08%
Persons with Disabilities	Unknown / Stat Unable to be Tracked Facility ADA Compliant
Persons 65 and older	53.60%
Medicare beneficiaries	68% (combined ICH & Home)
Medicaid recipients	19.51% (combined ICH & Home)

Source: Section C, page 27.

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 applicant's history of providing services to medically underserved groups.

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.

- (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, ... persons [with disabilities], 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 three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

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

- **Transfer stations from Iredell County (19 station surplus) or Surry County (23 station surplus) or Yadkin County (0 station surplus) to Wilkes County (2 station deficit) via ESRD-2.** The applicant states that while Table B in the SMFP demonstrates surpluses in contiguous counties to Wilkes, those surpluses do not take into account the patients who are not residents of those counties who utilize the facilities there. The applicant states that the “surplus” stations in those contiguous counties are utilized in the facilities where they are located and moving them would only result in having to add them back at a later date which is a more costly alternative.
- **Add less than three stations via facility need methodology.** The applicant states that adding less than three stations would not resolve the utilization issues at WDC and only result in the need to add more stations in a separate CON sooner rather than later. Therefore, this is a less effective alternative.
- **Do nothing.** The applicant states that while this alternative would be less costly, it does not resolve the utilization issues at WDC and is the least effective alternative.

In Section C, page 22, the applicant determined that its proposal is the most effective alternative because the WDC facility is well utilized and based upon its current utilization rate additional stations are needed.

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 applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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 Wilkes Dialysis Center of Wake Forest University (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. Prior to issuance of the Certificate of Need, the certificate holder shall provide the Agency with documentation that an effort has been made to accommodate the clinical needs of health professional training programs in the area at Wilkes Dialysis Center of Wake Forest University.**
 - 3. Pursuant to Condition 2 of the facility need determination in the 2025 SMFP, the certificate holder shall develop no more than 3 additional in-center dialysis stations for a total of no more than 27 in-center stations at Wilkes Dialysis Center of Wake Forest University upon completion of this project.**
 - 4. 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 holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder 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 April 1, 2026.**
 - 5. The certificate holder shall develop and implement strategies to provide culturally competent services to members of its defined medically underserved community that are consistent with representations made in the certificate of need application.**
 - 6. 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 three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

Capital and Working Capital Costs

On Form F.1a, in Section Q, page 86, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contract(s)	\$182,500
Medical Equipment	\$52,500
Furniture	\$15,000
Total	\$250,000

In Section Q, page 86, 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:

- Exhibit F - 1(b) contains a letter dated July 11, 2025, from the Project Manager at Omega Construction estimating the construction cost to remodel the facility to allow for the addition of the proposed stations.
- Medical Equipment and Furniture Costs are based upon recent estimates.

In Section F, page 37, the applicant states that there will be no start-up costs or initial operating costs because WDC is an existing facility that is fully operational and fully staffed to man the existing and additional stations.

Availability of Funds

In Section F, pages 35-36, the applicant states that the capital cost will be funded with the accumulated reserves of Wake Forest University Health Sciences. WFUHS is the whole-owner of WDC. WDC is a tax-exempt subordinate of WFUHS.

Exhibit F - 2(c)(2) contains a letter dated July 10, 2025, from the Chief Executive Officer and Chief Academic Officer at Atrium Health Wake Forest Baptist. The letter confirms that WFUHS is willing to commit cash reserves for the capital cost of the proposed project.

Exhibit F - 2(c)(3) contains Wake Forest University's Consolidated Financial Statements for the year ending June 30, 2024. According to the Consolidated Balance Sheet, as of June 30, 2024, Wake Forest University had adequate cash and assets to fund all the capital needs of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate WFUHS official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, in Section Q, page 87, the applicant projects that revenues will exceed operating expenses in the two full fiscal years following completion of the project, as shown in the table below.

	1st Full Fiscal Year 06/01/2026 to 05/31/2027	2nd Full Fiscal Year 06/01/2027 to 05/31/2028
Total # of Hemo-Equivalent Treatments (from Form C)	15,225	15,515
Total HH Training Days	0	0
Total PD Training Days	64	74
Total Billable Treatments (All Sources)	15,289	15,589
Total Gross Revenues (Charges)	\$45,560,635	\$46,453,435
Total Net Revenue	\$4,664,909	\$4,754,778
Average Net Revenue per Treatment (All Sources)	\$305	\$305
Total Operating Expenses (Costs)	\$4,191,527	\$4,304,921
Average Operating Expense per Treatment (All Sources)	\$275	\$276
Net Income	\$473,382	\$449,856

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 87-88. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue and operating expenses including projected reimbursement rates by payor source and operating cost such as salaries.
- 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 needs 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 three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

On page 113, the 2025 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” WDC is in Wilkes County. Thus, the service area for this facility is Wilkes County. Facilities may serve residents of counties not included in their service area.

According to the 2025 SMFP, Table 9A, page 130, WDC is the only existing dialysis facility in Wilkes County, as shown in the following table:

Wilkes County			
	# of Certified Stations as of 12/31/2023	# of In-Center Patients as of 12/31/2023	Utilization Rate as of 12/31/2023
Wilkes Dialysis Center of Wake Forest University	24	72	75.00%

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

“WDC is the sole provider of dialysis services in Wilkes County. The facility is currently utilized at 86.46% utilization and projects that by the end of OY1 of the proposed project the current plus additional three stations will be utilized at a rate of 83.90%.

Since the proposed project meets utilization requirements to demonstrate need and there are no other dialysis providers in Wilkes County, by definition the proposed services will not be duplicative in the proposed service area, which is Wilkes County.”

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:

- WDC is the only dialysis facility in Wilkes County.
- There is a facility need determination in the 2025 SMFP for up to three dialysis stations at WDC.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Wilkes County.

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.

- (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 three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

In Section Q, Form H, page 98, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	<i>As of 05/31/2025</i>	2nd Full Fiscal Year 06/01/2027 to 05/31/2028
RN	4.75	4.75
PATIENT CARE TECH	7.50	7.50
DON	1.00	1.00
DIET	1.00	1.00
SOCIAL WORKER	1.00	1.00
HT NURSE	1.00	1.00
DIALYSIS TECH	2.00	2.00
BIOMED	1.00	1.00
CLERICAL	3.00	3.00
TOTAL	22.25	22.25

The assumptions and methodology used to project staffing are provided in Section Q, page 98. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.4. In Section H, pages 44-46, the applicant

describes the methods used to recruit or fill new positions and its 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 its staffing on meeting or exceeding a ratio of (3:1) 3 patients to 1 direct care staff member.
- The applicant has existing resources to recruit or fill vacant or new positions, train staff, and provide continuing education.

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.

- (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 three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

Ancillary and Support Services

In Section I, page 48, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 49-51, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit A - 4(c) (Contract with Health Systems Management, Inc.) and Exhibit I - 2(a)(i) (Agreement with North Carolina Baptist Hospital). The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, pages 52-53, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibit I - (2)(a)(iii) and Exhibit I - 2(a)(iv). The applicant adequately demonstrates that the proposed

services will be coordinated with the existing health care system based on its established relationships with other healthcare providers and social service agencies in Wilkes County.

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.

- (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

The applicant proposes to add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

In Section K, page 55, the applicant states that the project involves renovating 450 square feet of existing space. Line drawings are provided in Exhibit K - 2.

On page 55, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal because the additional stations can be housed in the existing facility with minor renovations.

On pages 55-56, 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 on the following:

- There will be no start-up period and no initial operating costs since this is an existing facility that is already Medicare and Medicaid certified and participating with commercial insurance carriers and VA.
- The applicant states that the additional stations will allow for better shift scheduling, which can better balance employee scheduling and potentially reduce costs.
- The applicant states that the cost for services rendered are projected to remain constant through all operating years, while net income is projected to increase due to the increased projected patient volumes.

On page 56, the applicant states that any applicable energy saving features were incorporated during the facility's original construction and the projected renovation will be consistent with and not compromise the existing energy saving features.

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 ... persons [with disabilities], 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 58, the applicant provides the historical payor mix during 06/01/2024 to 05/31/2025 for the proposed services, as shown in the table below.

Wilkes Dialysis Center 06/01/2024 to 05/31/2025						
Payor Source	Total Patients		In-Center Patients		Home Patients	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0	0.08%	0	0%	0	0%
Insurance	8	7.99%	6	7%	2	11%
Medicare	67	68.00%	56	67%	11	75%
Medicaid	19	19.51%	18	22%	1	7%
VA	4	4.41%	3	4%	1	7%
Total	99	100.00%	84	100%	15	100%

Source: Section L, page 58.

In Section L, page 59, the applicant provides the following comparison.

Wilkes Dialysis Center of Wake Forest University	Last Full FY before Submission of the Application	
	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	36.08%	50.6%
Male	63.92%	49.4%
Unknown	N/A	N/A
64 and Younger	46.39%	76.3%
65 and Older	53.61%	23.7%
American Indian	0.0%	0.5%
Asian	1.03%	0.7%
Black or African-American	12.37%	4.8%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	73.20%	91.9%
Hispanic or Latino	13.40%	7.9%
Declined/ Unavailable	1.03%	0.0%

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

In Section L, page 59, the applicant states that the facility is not obligated to provide uncompensated care or community service. However, the applicant states it is subject to federal laws/regulations regarding equal access and non-discrimination and it has programs and policies in place to operate in compliance with all of these requirements.

In Section L, page 73, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against Wilkes Dialysis Center.

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, page 73, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Wilkes Dialysis Center Projected Payor Mix during the 2nd Full FY 06/01/2027 to 05/31/2028						
Payor Source	Total Patients		In-Center Patients		Home Patients (PD & HHD)	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0	0.08%	0	0%	0	0%
Insurance	9	8.02%	7	7%	2	11%
Medicare	73	68.07%	60	67%	13	75%
Medicaid	21	19.40%	20	22%	1	7%
VA	5	4.43%	4	4%	1	7%
Total	107	100.00%	90	100%	17	100%

Source: Section L, page 73.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.08% of total services will be provided to self-pay patients, 68.07% to Medicare patients and 19.40% to Medicaid patients.

On page 73, 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 the most recent annual average payor mix by payor that was used for all periods.

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, pages 75-76, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit I - 2(b)(i) and Exhibit L - 5.

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.

CA

The applicant proposes to add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion. In Section M, page 77, the applicant states:

“WFUHS dialysis units make every attempt to provide onsite educational experiences to local training programs in the area where applicable.

...

... all WFUHS dialysis facilities near training centers will provide these experiences to not only health professional training programs in the area, but other applicable training programs as well.”

As conditioned in Criterion (4), the applicant shall provide the Agency with documentation that an effort has been made to accommodate the clinical needs of health professional training programs in the area at Wilkes Dialysis Center of Wake Forest University prior to being issued a Certificate of Need for this proposed project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conditionally 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 three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon project completion.

On page 113, the 2025 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” WDC is in Wilkes County. Thus, the service area for this facility is Wilkes County. Facilities may serve residents of counties not included in their service area.

According to the 2025 SMFP, Table 9A, page 130, WDC is the only existing dialysis facility in Wilkes County, as shown in the following table:

Wilkes County			
	# of Certified Stations as of 12/31/2023	# of In-Center Patients as of 12/31/2023	Utilization Rate as of 12/31/2023
Wilkes Dialysis Center of Wake Forest University	24	72	75.00%

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 78, the applicant states:

“WFUHS is the whole owner of the WDC, the only ESRD facility in Wilkes County. Therefore, expansion of WDC will have no impact on competition in the service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 78, the applicant states:

“Adding stations to the existing facility will enhance access to services to all Wilkes County residents and expand treatment availability on all shifts at the least cost to the provider. The existing location is already a Medicare and Medicaid participating provider meaning there will be no start up period or initial operating expenses. The pro forma demonstrates costs to patients for services will not increase while the availability of services and access to care will increase.”

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

Regarding the impact of the proposal on quality, in Section N, page 78, 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 and O of the application and any exhibits.

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

“Increased availability of services equates increased availability to all patients who suffer with ESRD and require dialysis. The proposed additional stations will alleviate the need for many who are currently traveling outside of Wilkes County for dialysis care, now, and in the future. This will reduce the financial burden on the patient and community resources, overall.”

See also Section 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 adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the 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 all the reasons described 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, on Form O, page 99, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 21 of this type of facility located in North Carolina.

In Section O, page 80, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy violation that occurred in any of these facilities. After reviewing and considering the information provided by the applicant and considering the quality of care provided at all 21 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for 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- Wilkes Dialysis Center is an existing facility. Therefore, this Rule is not applicable to this review.
- (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, page 28, the applicant projects to serve 88.70 in-center patients on 27 stations, or a rate of 3.29 in-center patients per station per week ($88.70 \text{ patients} / 27 \text{ stations} = 3.29$), by the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (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. Therefore, this Rule does not apply.
- (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. Therefore, this Rule does not apply.
- (e) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*

- C- In Section C, pages 21-22, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.