

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 27, 2022

Findings Date: January 27, 2022

Project Analyst: Ena Lightbourne

Co-Signer: Gloria C. Hale

Project ID #: G-12137-21

Facility: Kernersville Dialysis Center of Wake Forest University

FID #: 210744

County: Forsyth

Applicant(s): Wake Forest University Health Sciences

Kernersville Dialysis Center of Wake Forest University

Project: Develop a new dialysis facility by relocating no more than 24 stations from Salem Kidney Center

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 and Kernersville Dialysis Center of Wake Forest University (hereinafter referred to as “the applicant” or “WFUHS”), propose to develop a new kidney disease treatment center (dialysis facility) in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

Need Determination

Chapter 9 of the 2021 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 county need methodology shows there is no county need determination for additional dialysis stations in Forsyth County. The applicant is

proposing to relocate existing dialysis stations; therefore, the facility need methodology does not apply to this proposal. Therefore, neither of the two need determination methodologies in the 2021 SMFP apply to this proposal.

Policies

There is one policy in the 2021 SMFP that is applicable to this review:

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities

Policy GEN-4 on page 29 of the 2021 SMFP states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$5 million. In Exhibit B-7, the applicant provides a letter from the project’s architect describing the plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency

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

- Neither the county nor facility need methodology is applicable to this review.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-4 by including a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(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 develop a new dialysis facility in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

On page 113, the 2021 SMFP defines the service area for dialysis stations as "*the service area is the county in which the dialysis station is located*". Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The applicant is proposing to develop a new facility by transferring stations from an existing facility, therefore, there is no historical patient origin to report. The following table illustrates projected patient origin.

Kernersville Dialysis Center of Wake Forest University Projected Patient Origin				
County	Operating Year 1 (OY1) (09/01/2023-08/31/2024)		Operating Year 1 (OY2) (09/01/2024-08/31/2025)	
	# of In-Center Patients	% of Total	# of In-Center Patients	% of Total
Forsyth-SKC Transfer In	44.51	48.75%	46.51	48.75%
Forsyth-PDC Transfer In	15.98	17.50%	16.70	17.50%
Forsyth-MSDC Transfer In	15.98	17.50%	16.70	17.50%
Forsyth-Near Kernersville	14.84	16.25%	15.50	16.25%
Total	91.29	100.00%	95.40	100.00%

Source: Section C, page 24

Note: (SKC)Salem Kidney Center, (PDC) Piedmont Kidney Center, (MSDC) Miller Street Kidney Center

In Section C, pages 24-26, the applicant provides the assumptions and methodology used to project its patient origin.

- The applicant projects Forsyth County patient growth and station needs using the Forsyth County Five-Year Average Annual Change Rate (AACR) of 4.5%, as published in the 2021 SMFP.
- The proposed facility is projected to begin offering services August 31, 2023. The applicant projects the first two full operating years of the project will be September 1, 2023-August 31, 2024 (OY1) and September 1, 2024-August 31, 2025 (OY2).
- The applicant begins with the current Forsyth County patients residing most conveniently to the proposed KVDC as of August 31, 2021 and projects forward to the end of OY2 using the Forsyth County Five-Year AACR of 4.5%, as published in the 2021 SMFP.
- The applicant projects that by the end of the OY1, 91.29 WFUHS patients will attend KVDC based on their resident proximity to the new facility.
- The applicant projects that the initial patients will transfer in from SKC, PDC, MSDC, and other WFUHS facilities in contiguous counties serving Forsyth County patients near Kernersville, assuming that the existing patients at these facilities will continue to grow at their respective SMFP change rates through the end of OY2.

Analysis of Need

In Section C, pages 27-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The applicant states that although the 2021 SMFP identifies facility need determinations for WFUHS facilities in Forsyth County, none of the facilities have the capacity to add stations. SKC does not have a facility need determination nor the capacity to add enough stations. The applicant states that a new location is needed to add stations in Forsyth County to meet future patient needs.

- Based on data from the 2021 and the proposed 2022 SMFPs and using the current Forsyth County Five-Year AACR of 4.5%, the applicant projects that by the end of OY1, Forsyth County will have a 28.46 station deficit which represents the need for services by 91.07 additional Forsyth County patients ($28.46 \times 3.2 = 91.07$). Similarly, the applicant projects that 91.29 patients will utilize KVDC by the end of OY1. The table below illustrates the applicant’s projections for Forsyth County.

SMFP Projected Date	CON Ending Prior Year Date	Difference in Months	Pro-Rated Growth Rate						
12/31/20	8/31/21	8	3.00%						
County	12/31/19 Total Patients	AACR from SMFP	12/31/20 Projected patients	8/31/21 Projected patients	8/31/22 Projected patients	8/31/23 Projected patients	8/31/24 Projected patients	8/31/25 Projected patients	
Forsyth	747.00	4.50%	780.62	804.03	840.21	878.02	917.54	958.82	
# Home Patients	13.0%		13.0%	13.0%	13.0%	13.0%	13.0%	13.0%	
Total Home Patients	97.11		101.48	104.52	109.23	114.14	119.28	124.65	
Total ICH Patients	649.89		679.14	699.51	730.99	763.88	798.26	834.18	
Projected County ICH Stations	221.00		221.00	221.00	221.00	221.00	221.00	221.00	
County Stations Surplus/Deficit 80% Utilization	17.91		8.77	2.40	(7.43)	(17.71)	(28.46)	(39.68)	

Source: Section C. page 27

- The proposed 2022 SMFP projects Forsyth County Five-Year AACR to increase to 4.7%. Based on the increase in the change rate, the applicant projects the need for more stations to serve Forsyth County dialysis patients is greater than previously anticipated. The applicant projects that by the end of OY1, Forsyth County will have a 32.23 station deficit which represents the need for services by 103.14 additional Forsyth County patients ($32.23 \times 3.2 = 103.14$), as illustrated in the table below.

SMFP Projected Date	CON Ending Prior Year Date	Difference in Months	Proposed Growth Rate					
12/31/20	12/31/21	12	4.70%					
County	12/31/19 Total Patients	AACR from SMFP	12/31/20 Projected patients	12/31/21 Projected patients	12/31/22 Projected patients	12/31/23 Projected patients	12/31/24 Projected patients	12/31/25 Projected patients
Forsyth	747.00	4.50%	776.00	812.47	850.66	890.64	932.50	976.33
# Home Patients	13.0%		13.1%	13.1%	13.1%	13.1%	13.1%	13.1%
Total Home Patients	97.11		101.66	106.43	111.44	116.67	122.16	127.90
Total ICH Patients	649.89		67.34	706.04	739.22	773.97	810.34	848.43
Projected County ICH Stations	221.00		221.00	221.00	221.00	221.00	221.00	221.00
County Stations Surplus/Deficit 80% Utilization	17.91		10.27	0.36	(10.01)	(20.86)	(32.23)	(44.13)

Source: Section C, page 28

- In Exhibit C-4, the applicant maps out the WFUHS patient populations by facility to determine the best location for a new facility within Forsyth County and determined that Kernersville was the best choice. On page 28, the applicant states:

“The Kernersville location would improve patient access to care due to alternate traffic patterns, drawing patients from multiple WFUHS locations and allowing a county-wide patient re-balance among the other dialysis facilities there.”

- The applicant states that the proposed KVDC demonstrates that the 24 stations are needed by meeting and exceeding the utilization threshold by the end of OY1. At the end of OY1 the facility is projected to serve 91.29 in-center patients on 24 dialysis stations, a utilization rate of 95.10%.

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

- The projected patient needs of WFUHS dialysis patients residing in and around the area of the proposed facility.
- The applicant adequately demonstrates the need for the proposed project by projecting a possible station deficit in Forsyth County by August 31, 2024 if no action is taken.

Projected Utilization

In Section Q, pages 85-87, the applicant provides projected utilization, as illustrated in the following table.

Kernersville Dialysis Center of Wake Forest University Projected Utilization			
		End of OY1	End of OY2
County	AACR	8/31/2024	8/31/2025
Forsyth-SKC Transfer In	4.50%	44.51	46.51
Forsyth-PDC Transfer In	4.50%	15.98	16.70
Forsyth-MSDC Transfer In	4.50%	15.98	16.70
Forsyth-Near Kernersville	4.50%	14.84	15.50
Total		91.29	95.40
Total Treatments		7,105	13,485
Utilization Rate		95.10%	99.38%

In Section Q, pages 85-87, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant determined the total number of treatments per patient per year by taking the maximum number of treatments per year and reducing it by the percentage of missed treatments. The total number of treatments were determined by multiplying the billable treatments by the average number of patients during the year for each period.

3 treatments per week x 52 weeks per year = 156 maximum treatments
165 maximum treatments x 7% missed treatment average = 11 missed treatments
156 maximum treatments – 11 missed treatments = 145 billable treatments
145 billable treatments x 49 (average # of patients during the year) = 7,105 Treatments (OY1)
145 billable treatments x 93 (average # of patients during the year) = 13,485 Treatments (OY2)

- The applicant begins with the facility census as of 8/31/2021 (9/1/2021) sorted by modality and patient home county. KVDC will only provide in-center dialysis, therefore, home hemodialysis and peritoneal dialysis is not included in this analysis.
- The proposed facility is projected to begin offering services August 31, 2023. The applicant projects the first two full operating years of the project will be September 1, 2023-August 31, 2024 (OY1) and September 1, 2024-August 31, 2025 (OY2).
- The applicant projects the future facility census by county using the Forsyth County Five-Year AACR of 4.5%, as published in the 2021 SMFP.
- The patient volumes by county were summed by project year resulting in a projected year-end facility census.

At the end of OY1 KVDC is projected to serve 91.29 in-center patients and at the end of OY2 the facility is projected to serve 95.40 in-center patients on 24 stations.

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

- OY1: 3.804 patients per station per week or 95.10% (91.29 patients / 24 stations = $3.804/4 = 0.9510$ or 95.10%)
- OY2: 3.975 patients per station per week or 85.58% (95.40 patients / 24 stations = $3.975/4 = 0.9938$ or 99.38%)

The project utilization of 3.804 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 future utilization based on the projected number of WFUHS dialysis patients residing in and around the area of the proposed facility that will transfer their services to the new facility.
- The applicant utilized a projected annual growth rate of 4.5% for Forsyth County patients which reflects the Forsyth County Five-Year AACR, as published in the 2021 SMFP.
- 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, page 32, the applicant states:

“It is anticipated KVDC will serve patients with similar demographics to SKC.”

In Section C, page 34, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	8.34%
Racial and ethnic minorities	78.74%
Women	47.70%
Persons with Disabilities	n/a
The elderly	49.43%
Medicare beneficiaries	57.03%
Medicaid recipients	33.93%

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 applicant projects that the proposed facility will serve patients with similar demographics to SKC.
- The applicant assumes that the projected payor mix for KVDC will remain constant through the first two operating years.

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.

- (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.

C

The applicant proposes to develop a new dialysis facility in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

In Section D, page 40, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced will be adequately met following completion of the project. On page 40, the applicant states:

“This CON relocating 24 stations from SKC to KVDC is the first step in a multi-step process to increase the overall number of stations in Forsyth County while enhancing patient access to services and preventing over-utilization at existing clinics, which have no physical plant capacity to further expand.”

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

- The applicant is proposing to relocate stations from a facility that does not have a facility need determination nor the capacity to add enough stations pursuant to ESRD-2.
- The applicant’s proposal is the first step in a series of steps to be taken to increase the number of stations in Forsyth County by year 2023.

- The applicant adequately demonstrates the possible station deficit in Forsyth County by the end of year 2024 if no action is taken to add stations.

In Section D, page 41, the applicant provides projected utilization, as illustrated in the following table.

		8/31/20	8/31/21	8/31/22	8/31/23	8/31/24	8/31/25	8/31/24	8/31/25
County	AACR	Prior Year Beginning Census	Ending Prior Year	Ending Current Year	Ending Interim	Ending OY1	Ending OY2	% of total Patients Ending OY1	% of total Patients Ending OY2
Forsyth	4.50%	164.00	163.00	170.34	178.00	186.01	194.38	101%	101%
Forsyth SKC Transfer Out	4.50%	0.00	0.00	0.00	0.00	-44.61	-46.51	-24%	-24%
Forsyth Rebalance	4.50%	0.00	0.00	0.00	29.00	30.31	31.67	16%	16%
Davidson	5.30%	1.00	4.00	4.21	4.44	4.67	4.92	3%	3%
Guilford	4.00%	6.00	4.00	4.16	4.33	4.50	4.68	2%	2%
Iredell	3.70%	0.00	1.00	1.04	1.08	1.12	1.16	1%	1%
Rockingham	3.90%	1.00	1.00	1.04	1.08	1.12	1.17	1%	1%
Stokes	6.30%	0.00	1.00	1.06	1.13	1.20	1.28	1%	1%
Totals		172.00	174.00	181.85	219.05	184.41	192.73	100%	100%
Projected Utilization of 35.00 dialysis Stations		122.86%	124.29%	129.89%	156.46%	131.72%	137.67%		
Projected Utilization of 59.00 dialysis Stations			73.73%	77.05%	92.82%	78.14%	81.67%		
Projected Utilization of 65.00 dialysis Stations			66.92%	69.94%	84.25%	70.93%	74.13%		

In Section D, pages 39-41, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins with SKC’s Forsyth County facility census as of August 31, 2021 and projects forward using the Forsyth County Five-Year AACR of 4.5%, as published in the 2021 SMFP.
- The applicant subtracts the percentage of patients that will transfer their services upon completion of this project (relocate 24 stations from SKC).
- The applicant is proposing to file a CON application on January 15, 2022 to transfer 19 stations from MSDC and 11 stations from NDC to KVDC and file two CON applications on March 15, 2022, to add back the 30 stations to MSDC and NDC. These projects are anticipated to be certified by August 31, 2023. The applicant projects the facility census forward using the Forsyth County Five-Year AACR of 4.5%, assuming that the number of patients will continue to grow with the additional stations.
- The applicant projects the growth in the facility census of patients residing outside of Forsyth County using their respective Five-Year AACR, as published in the 2021 SMFP.
- The applicant projects utilization of 35 stations (59-24), 59 stations (no change to stations count), and 65 stations (35 + 19 + 11 = 65).

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

- OY1: 2.84 patients per station per week or 70.93% (184.41 patients / 65 stations = $2.8370/4 = 0.70925$ or 70.93%)
- OY2: 2.97 patients per station per week or 74.13% (192.73 patients / 65 stations = $2.9650/4 = 0.74125$ or 74.13%)

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

- The applicant utilized the appropriate annual growth rate to project growth in the facility census for patients residing in Forsyth and surrounding counties.
- The applicant is proposing to relocate and add stations within WFUHS facilities in Forsyth county to increase the number of stations in Forsyth County to prevent over-utilization while enhancing patient access to services.
- 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 D, page 41, the applicant states:

“Patients are admitted to the dialysis center based upon a diagnosis of ESRD...it is anticipated that access to services by all groups will be enhanced via the addition of stations at SKC after transfer of stations to KVDC...and is expected to remain consistent after the county patient re-balance anticipated to occur by 8/31/2023.”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services will be adequately met following completion of the project. The addition of stations at SKC, following the completion of this project will enhance access to services by 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 the following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.

- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (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 develop a new dialysis facility in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

In Section E, pages 44-45, 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:

ESRD-2 Transfer of Stations from a Contiguous County-The applicant owns facilities in the seven counties contiguous to Forsyth County. According to the 2021 SMFP, Forsyth County has a 9-station surplus. Therefore, the applicant dismissed this alternative because Forsyth County is ineligible to receive stations from a contiguous county.

ESRD-2 In-County Transfer of Stations from Miller Street Dialysis Center (MSDC), Northside Dialysis Center (NDC), and/or Piedmont Dialysis Center (PDC) to Kernersville Dialysis Center (KVDC)-The applicant owns four dialysis facilities in Forsyth County. The applicant states that of the four facilities, SKC serves the most patients from Kernersville and has next to the least current utilization rate. Transferring stations from MSDC, NDC, and PDC and transferring patients from SKC would result in an imbalance in utilization. The applicant states that it is not necessarily the most effective alternative to ensure availability of services to Forsyth County patients.

On page 45, the applicant states that its proposal is the most effective alternative because Kernersville is the most geographically underserved area in Forsyth County and SKC serves the most Kernersville-resident patients of all WFUHS locations. The applicant states that its proposal will promote the overall goal of “*re-balancing*” the Forsyth County patient population among all WFUHS facilities in the service area.

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’s proposal will ensure availability of services in a largely underserved area and avoid possible capacity constraints at other Forsyth County facilities.
- 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 Kernersville Dialysis Center of Wake Forest University (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new kidney disease treatment center by relocating no more than 24 in-center stations from Salem Kidney Center for a total of no more than 24 in-center dialysis stations at Kernersville Dialysis Center of Wake Forest University upon project completion.**
- 3. The certificate holder shall install plumbing and electrical wiring through the walls for no more than 24 in-center dialysis (and home hemodialysis) stations.**
- 4. Upon completion of this project, the certificate holder shall take the necessary steps to decertify 24 in-center (and home hemodialysis) stations at Salem Kidney Center for a total of no more than 35 in-center and home hemodialysis stations at Salem Kidney Center.**
- 5. 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. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on August 1, 2022. The second progress report shall be due on December 1, 2022 and so forth.**

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 develop a new dialysis facility in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

Capital and Working Capital Costs

In Section Q, page 91, the applicant projects the total capital cost of the project, as shown in the table below.

Site Preparation	\$427,000
Construction/Renovation Contract(s)	\$4,533,000
Architect/Engineering Fees	\$169,950
Non-Medical Equipment	\$164,761
Furniture	\$166,064
Other (Emergency Generator)	\$68,100
Total	\$5,528,875

In Section Q, page 91, 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 applicant's estimated costs for site prep, construction, architecture and engineering fees, non-medical equipment and furniture.
- The applicant provides supporting documentation in Exhibit F-1(b).

In Section F, page 48, the applicant states that the start-up costs will be funded by patient service revenues generated from operations of existing WFUHS facilities from which initial patient populations will transfer. Initial operating expenses will be \$100,000 for a total working capital of \$100,000. On page 49, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant projects that the initial operating period will be a 10-month period for which the facility will obtain Medicare and Medicaid certification and secure

participation in commercial networks which is anticipated to occur at the beginning of OY1.

- The applicant will advance the initial operating expenses during OY1 and projects that the initial operating costs will be recouped by the end OY1 as the patient volume increases, driving down the operating costs per treatment.

Availability of Funds

In Section F, page 46, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	WFUHS	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$5,528,875	\$5,528,875
Bonds	\$0	\$0
Other	\$0	\$0
Total Financing	\$5,528,875	\$5,528,875

* OE = Owner's Equity

In Section F, page 49, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

WFUHS	
Sources of Financing for Working Capital	Amount
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$100,000
Lines of credit	\$0
Bonds	\$0
Total	\$100,000

Exhibit F-2(c)(2) contains a letter dated September 15, 2021, from the Chief Executive Officer of Wake Forest Baptist System stating their commitment to fund the project. Exhibit F-2(c)(3) contains Consolidated Financial Statements for Wake Forest University for the fiscal year ended June 30, 2020, showing Wake Forest University with over \$150 million in cash and cash equivalents and over \$3 billion in total assets to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based the information provided in Section F and Exhibits F-2(c)(2) and F-2(c)(3) of the application.

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, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

Kernersville Dialysis Center of Wake Forest University	OY1 FY2024	OY2 FY 2025
Total Treatments	7,105	13,485
Total Gross Revenues (Charges)	\$16,090,196	\$30,538,536
Total Net Revenue	\$2,253,733	\$4,277,494
Average Net Revenue per Treatment	\$317	\$317
Total Operating Expenses (Costs)	\$2,090,906	\$3,767,544
Average Operating Expense per Treatment	\$294	\$279
Net Income	\$162,827	\$509,950

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

- 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.
- (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 develop a new dialysis facility in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

On page 113, the 2021 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located.”* Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Forsyth County as of December 31, 2019. There are four kidney disease treatment centers providing dialysis services in Forsyth County. The applicant is the only provider of dialysis services in Forsyth County.

Facility Name	Certified Stations as of 12/31/2019	# IC Patients as of 12/31/2019	Utilization by Percent as of 12/31/2019	Patients Per Station Per Week
Miller Street Dialysis Center	48	149	77.60%	3.10
Northside Dialysis Center	45	152	84.44%	3.37
Piedmont Dialysis Center	54	186	86.11%	3.44
Salem Kidney Center	47	158	84.04%	3.36
Total	194	645		

Source: 2021 SMFP, Table 9A, page 123

In Section G, pages 53-54, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Forsyth County. The applicant states:

“This project will not increase the total number of stations in Forsyth County. Though, it will allow the county to eventually add stations where it currently may not due to the lack of physical plant capacity at existing facilities with published facility need determinations.

...

*...existing facilities in Forsyth County have all reached their physical plant capacity, except SKC, which is incapable of housing enough additional stations to head off an impending county stations deficit, even if it **could** add them. SKC does not have a facility need determination in the SMFP.*

...

KVDC proves the need the existing and projected patient population has for the proposed service in compliance with ESRD Performance Standards.”

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 proposal would not result in an increase in dialysis stations in Forsyth County.
- The existing dialysis facilities in Forsyth County are operating at more than 70% capacity. This project will allow the county to add stations based on future need.

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 develop a new dialysis facility in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

In Section Q, page 106, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff	
	2 nd Full Fiscal Year FY 2024	3 rd Full Fiscal Year FY 2025
RN	2.50	4.75
LPN	0.00	0.00
Patient Care Tech	4.00	9.00
DON	0.50	1.00
Diet	0.50	1.00
Social Work	0.50	1.00
Dialysis Tech	1.00	2.00
Biomed	0.25	0.25
Clerical	1.00	1.00
TOTAL	10.25	20.00

The assumptions and methodology used to project staffing are provided in Section Q, page 107. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 55-57, 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 applicant is an existing provider of dialysis services which demonstrates WFUHS' experience in attracting qualified staff.
- Each new employee is required to complete an intensive training program and routinely participate in continuing education provided onsite.
- The minimum requirements for each staffing position, as stated on pages 56-57.

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 develop a new dialysis facility in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

Ancillary and Support Services

In Section I, page 59, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 60-62, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits A-4 (c), H-3, I-1, and I-2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the applicant's history of providing the stated ancillary and support services through their existing providers.

Coordination

In Section I, pages 63-64, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1 and I-2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant's established relationship with Wake Forest Baptist Medical Center and their agreement to provide services such as transplantation, blood bank and emergency services and an extensive range of services including a full renal care unit capable of providing acute dialysis and chronic dialysis care.
- WFUHS has relationships with many local physicians to coordinate patient care.

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 develop a new dialysis facility in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

In Section K, page 66, the applicant states that the project involves constructing 14,000 square feet of new space. Line drawings are provided in Exhibit K-1.

On pages 68-69, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K-4. The site appears to be suitable for the proposed kidney disease treatment center based on the applicant's representations and supporting documentation.

On pages 66-67, 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 proposed project will allow the county to add stations, therefore, ensuring that current and future ESRD patients will have access to dialysis services.
- The project will include energy saving features that will help minimize physical plant operating costs.
- The facility will be developed on property owned by the applicant, thus, saving costs on purchasing a new site.

On page 67-68, 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:

- The applicant states that the proposed project will lower costs of providing dialysis services over time and the cost of healthcare by enhancing the underserved patients' convenience to care resulting in overall improvement in total patient health.
- The applicant adequately demonstrates that the charge per dialysis treatment is not projected to increase by the end of OY2 based on the information provided in the pro forma financial statements in Section Q.

In Exhibit B-7, the applicant provides a letter from the project's architect describing the plan to improve energy efficiency and conserve water.

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

The applicant's proposal includes the development of a new facility by transferring 24 dialysis stations from SKC. Therefore, there is no historical payor mix to report. However, in Section L, page 70, the applicant provides the historical payor mix for SKC during the last full fiscal year, as shown in the table below.

Salem Kidney Center Historical Payor Mix 09/01/2020-08/31/2021		
Payor Category	Average In-Center Patients	% of In-Center Patients
Self-Pay	2	1%
Commercial Insurance Only	11	6%
Medicare*	103	60%
Medicaid*	54	31%
VA	2	1%
Total*	173	100.0%

*Including managed care plans.
 May not foot due to rounding.

In Section L, page 71, the applicant provides the following comparison.

Salem Kidney Center	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area*
Female	47.70%	52.7%
Male	52.30%	47.3%
Unknown	N/A	N/A
64 and Younger	50.57%	83.6%
65 and Older	49.43%	16.4%
American Indian	0.00%	0.9%
Asian	0.57%	2.6%
Black or African-American	70.69%	27.6%
Native Hawaiian or Pacific Islander	0.00%	0.1%
White or Caucasian	21.26%	56.3%
Other Race	6.90%	12.6%
Declined / Unavailable	0.57%	N/A

*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>.

The Agency reviewed the:

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... 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, page 72, the applicant states:

“While the facility is not required nor obligated to provide uncompensated care nor community service. The facility, as a Medicare Participating Provider, is at minimum subject to the following Federal Laws/Regulations regarding equal access and non-discrimination: Section 1557 of the Patient Protection and Affordable Care Act.”

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 the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

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

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

- (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 74, 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.

Kernersville Dialysis Center of Wake Forest University Projected Payor Mix FY 2025		
Payor Category	Average In-Center Patients	% of In-Center Patients
Self-Pay	1	1%
Commercial Insurance Only	7	8%
Medicare*	53	57%
Medicaid*	32	34%
Total	93	100.0%

*Including managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1% of total services will be provided to self-pay patients, 57% to Medicare patients and 34% to Medicaid patients.

On page 74, 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 based on the following:

- The applicant based projected mix on the percentage of patients by payor category.
- Due to daily changes to payor mix, the projected payor mix is calculated based on the patient census as of the last day of each month of operation.
- The projected average numbers are based on the average of a 12-month interval.
- The most recent last operating payor mix for SKC was averaged with the most recent operating year's payor mix for all WFUHS overall dialysis facilities in the service area.

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 76-77, 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 develop a new dialysis facility in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

In Section M, page 78, 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:

- WFUHS has a history of allowing third year medical students and students of local high schools an opportunity to tour the facilities and learn about dialysis services.
- The applicant provides a copy of a letter sent to Forsyth Technical Community College requesting an agreement of affiliation between their nursing program and KVDC to provide education experiences for students.

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.

- (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 develop a new dialysis facility in the city of Kernersville in Forsyth County, by relocating no more than 24 stations from Salem Kidney Center (SKC) to the new Kernersville Dialysis Center of Wake Forest University (KVDC).

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Forsyth County as of December 31, 2019. There are four kidney disease treatment centers providing dialysis services in Forsyth County. The applicant is the only provider of dialysis services in Forsyth County.

Facility Name	Certified Stations as of 12/31/2019	# IC Patients as of 12/31/2019	Utilization by Percent as of 12/31/2019	Patients Per Station Per Week
Miller Street Dialysis Center	48	149	77.60%	3.10
Northside Dialysis Center	45	152	84.44%	3.37
Piedmont Dialysis Center	54	186	86.11%	3.44
Salem Kidney Center	47	158	84.04%	3.36
Total	194	645		

Source: 2021 SMFP, Table 9A, page 123

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 79, the applicant states:

“WFUHS is the whole owner of the sole providers of dialysis services within Forsyth County. This application requests to transfer existing stations from SKC to a new location, KVDC, in Kernersville, Forsyth County. The project will have no effect on competition in the proposed service area of Forsyth County because it neither increased nor decreased the number of dialysis stations within the county. It will expand 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 79, the applicant states:

“The additional stations will mean Forsyth 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.”

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

Regarding the impact of the proposal on quality, in Section N, page 79, 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 80, the applicant states:

“This project is the first step in increasing the total number of available stations within Forsyth County and in-turn increase treatment slots to serve current and future patients who will utilize the facility.”

See also Section L and C 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.
- 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
- 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 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, page 108, 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 20 of this type of facility located in North Carolina.

In Section O, page 82, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of these facilities. On page 81, the applicant identifies “*Condition Level Deficiencies*”

cited at SKC. However, the applicant states that the facility is currently back in compliance. After reviewing and considering information provided by the applicant, 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.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) *An applicant proposing to establish a new dialysis facility for in-center hemodialysis services 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.*

-C- The applicant is proposing to establish a new dialysis facility for in-center hemodialysis services by relocating 24 stations from Salem Kidney Center. In Section C, page 29 and Section Q, page 86, the applicant projects that Kernersville Dialysis Center will serve 91.29 in-center patients on 24 stations, or a rate of 3.8 patients per station per week, as of the end of the first full fiscal year of operation following certification of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(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.

- NA- The applicant is not proposing to increase the number of in-center dialysis stations in an existing dialysis facility or 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.

- (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 is not proposing 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 is not proposing 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 23-29, and Section Q, pages 85-87, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.