

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 6, 2022

Findings Date: April 6, 2022

Project Analyst: Ena Lightbourne

Co-Signer: Gloria C. Hale

Project ID #: G-12172-22

Facility: Salem Kidney Center

FID #: 944758

County: Forsyth

Applicant(s): Wake Forest University Health Sciences

Salem Kidney Center of Wake Forest University

Project: Relocate 19 dialysis stations from Miller Street Dialysis Center and 11 dialysis stations from Northside Dialysis Center for a total of no more than 65 dialysis stations upon completion of this project and Project ID #G-12137-21

### 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.

NA

Wake Forest University Health Sciences and Salem Kidney Center of Wake Forest University (hereinafter referred to as “the applicant” or “WFUHS”), propose to relocate 19 in-center dialysis stations from Miller Street Dialysis Center (MSDC) and 11 in-center dialysis stations from Northside Dialysis Center (NDC) to Salem Kidney Center (SKC) for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to the new Kernersville Dialysis Center of Wake Forest University (KVDC)).

Chapter 9 of the 2022 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis

stations. According to Table 9D, page 136, 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, neither of the two need determination methodologies in the 2022 SMFP apply to this proposal.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP)
- Acquire any medical equipment for which there is a need determination in the 2022 SMFP
- Offer a new institutional health service for which there are any applicable policies in the 2022 SMFP

Therefore, Criterion (1) is not applicable to this review.

- (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 relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC to SKC for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to KVDC).

The following table, summarized from data on pages 12-13 of the application, shows the projected number of stations at SKC upon project completion.

<b>Salem Kidney Center</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
59	Total existing certified stations as reported in the most recent ESRD Data Collection Forms.	
+30	Stations to be added as part of this project (relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC)	G-12172-22
-24	Total # of dialysis stations proposed to be deleted in applications still under review as of the application deadline	G-12137-21
65	Total # of dialysis stations upon completion of all proposals involving the dialysis facility identified in Section A, Question 4 of the application	

**Patient Origin**

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

The following tables illustrate historical and projected patient origin.

<b>Historical Patient Origin Last Operating Year (OY) 01/01/2021-12/31/2021</b>								
<b>County</b>	<b>Salem Kidney Center</b>		<b>Miller Street Dialysis Center</b>		<b>Northside Dialysis Center</b>			
	<b># of In-Center Patients</b>	<b>% of Total</b>	<b># of In-Center Patients</b>	<b>% of Total</b>	<b># of In-Center Patients</b>	<b>% of Total</b>	<b># of Peritoneal Dialysis Patients</b>	<b>% of Total</b>
Forsyth	168	94.38%	154	91.12%	149	96.75%	23	100.00%
Davidson	4	2.25%	6	3.55%	0	0.00%	0	0.00%
Guilford	3	1.69%	4	2.37%	1	0.65%	0	0.00%
Iredell	1	0.56%	0	0.00%	0	0.00%	0	0.00%
Rockingham	1	0.56%	0	0.00%	0	0.00%	0	0.00%
Stokes	1	0.56%	0	0.00%	3	1.95%	0	0.00%
Davie	0	0.00%	3	1.78%	0	0.00%	0	0.00%
Randolph	0	0.00%	1	0.59%	0	0.00%	0	0.00%
Yadkin	0	0.00%	1	0.59%	1	0.65%	0	0.00%
<b>Total</b>	<b>178</b>	<b>100.00%</b>	<b>169</b>	<b>100.00%</b>	<b>154</b>	<b>100.00%</b>	<b>23</b>	<b>100.00%</b>

Source: Section C, pages 23-24

Salem Kidney Center Projected Patient Origin				
County	Ending OY1 9/1/2023-8/31/2024		Ending OY2 9/1/2024-8/31/2025	
	# of In-Center Patients	% of Total	# of In-Center Patients	% of Total
Forsyth	189.90	92.34%	198.83	92.38%
SKC Transfers to KVDC	-44.51	-21.64%	-46.60	-21.65%
Forsyth Rebalance Transfers	49.21	23.93%	51.52	23.94%
Davidson	4.49	2.18%	4.68	2.18%
Guilford	3.27	1.59%	3.38	1.57%
Iredell	1.08	0.53%	1.12	0.52%
Rockingham	1.10	0.54%	1.15	0.53%
Stokes	1.11	0.54%	1.15	0.53%
<b>Total</b>	<b>205.66</b>	<b>100.00%</b>	<b>215.23</b>	<b>100.00%</b>

Source: Section C, page 26

In Section C, pages 24-30, 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 begins its projections with a 9-month prorated year (01/01/2022-8/31/2022) for SKC to match the timeline for Project ID# G-12137-21(develop a new dialysis facility by relocating 24 stations from SKC to the KVDC) and projects growth for this period using the following calculation:  $242 \text{ days} / 365 = 0.6603$ .
- The applicant projects that the transfer of patients from SKC to KVDC will occur in phases by the end of OY1 and subtracts these patients at the appropriate time.
- The applicant projects the growth of Forsyth County patients who will transfer their care from MSDC and NDC to SKC upon project completion through 8/31/2023, based on their proximity to SKC.
- The applicant projects growth using the Five-Year Average Annual Change Rate (AACR) of 4.7% for Forsyth County, as published in the 2022 SMFP.
- The applicant projects growth for patients dialyzing at SKC and residing outside of Forsyth County, using their respective Five-Year AACR, as published in the 2022 SMFP.

### Analysis of Need

In Section C, pages 30-31, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

The applicant is proposing to transfer 30 stations from two dialysis facilities in Forsyth County and proposes to submit a CON application in March 2022 to add the 30 stations back to the facilities. The applicant was approved to develop a new dialysis facility by transferring 24 stations from SKC. The applicant states that these proposals will replenish WFUHS’s total Forsyth patient population while avoiding a shortfall of dialysis stations in the county.

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

- The applicant adequately demonstrates the need for the proposed project by projecting a possible station deficit in Forsyth County by August 31, 2023, August 31, 2024 and August 31, 2025, if no action is taken.
- The proposed project will enhance geographical access to services by allowing patients who reside closer to SKC, to receive dialysis services at a convenient location.

Projected Utilization

In Section C, page 28, the applicant provides historical and projected utilization, as illustrated in the following table.

Salem Kidney Center Projected Utilization							
		1/1/2021	12/31/2021	8/31/2022	8/31/2023	8/31/2024	8/31/2025
County	AACR	Prior year beginning Census	Ending Prior Year	Ending Current year	Ending Interim	Ending OY1	Ending OY2
Forsyth	4.70%	164.00	168.00	173.24	181.38	189.90	198.83
SKC Transfer to KVDC	4.70%	0.00	0.00	0.00	0.00	-44.51	-46.60
Forsyth Rebalance	4.70%	0.00	0.00	0.00	47.00	49.21	51.52
Davidson	4.40%	1.00	4.00	4.12	4.30	4.49	4.68
Guilford	3.30%	0.00	3.00	3.07	3.17	3.27	3.38
Iredell	3.10%	0.00	1.00	1.02	1.05	1.08	1.12
Rockingham	3.80%	0.00	1.00	1.03	1.06	1.10	1.15
Stokes	3.90%	0.00	1.00	1.03	1.07	1.11	1.15
<b>Total</b>		<b>165.00</b>	<b>178.00</b>	<b>183.51</b>	<b>239.03</b>	<b>205.66</b>	<b>215.23</b>
<b>Stations</b>							
<b>59</b>		69.92%	75.42%	77.75%	101.28%	87.14%	91.20%
<b>65</b>			68.46%	70.57%	91.93%	79.10%	82.78%

In Section C, pages 27-30, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins with the facility census as of 12/31/2021.
- The applicant begins its projections with a 9-month prorated year (01/01/2022-8/31/2022) for SKC to match the timeline for Project ID# G-12137-21(develop a new dialysis facility by relocating 24 stations from SKC to the KVDC and projects growth for this period using the following calculation:  $242 \text{ days} / 365 = 0.6603$ ).

- The applicant projects the Forsyth County patient population forward to 8/31/2022, using the Forsyth County Five-Year AACR of 4.7% and projects the future patient population for the interim year, OY1 and OY 2 prior to the relocation of stations.

$$5\text{-Year AACR} = 4.7\%$$

$$168 + (168 \times 0.047 \times 0.6603) = 173.24 \text{ patients Ending Current Year (8/31/2022)}$$

$$173.24 \times 1.047 = 181.38 \text{ patients End of Interim (8/31/2023)}$$

$$181.38 \times 1.047 = 189.90 \text{ patients end of OY1 (8/31/2024)}$$

$$189.90 \times 1.047 = 198.83 \text{ patients End of OY2 (8/31/2025)}$$

- The applicant projects the Forsyth County patient population growth of patients who are projected transfer their care to KVDC after the relocation of 24 stations from SKC to KVDC (Project ID# G-12137-21), using the Forsyth County Five-Year AACR of 4.7%, and project the future patient population for the 9-month period ending 8/31/2022, the interim year, OY1 and OY 2.

$$5\text{-Year AACR} = 4.7\%$$

$$0 + (0 \times 0.047 \times 0.6603) = 0.00 \text{ patients Ending Current Year (8/31/2022)}$$

$$0.00 \times 1.047 = 0.00 \text{ End of Interim (8/31/2023)}$$

$$44.51 \text{ (projections from Project ID \# G-12137-21) End of OY1 (8/31/2024)}$$

$$(44.51) \times 1.047 = (46.60) \text{ patients End of OY2 (8/31/2025)}$$

- The applicant projects the Forsyth County patient population growth of patients who are projected to transfer their care to SKC after the relocation of 19 in-center stations from MSDC and 11 in-center stations from NDC, using the Forsyth County Five-Year AACR of 4.7%, and projects growth for this population for the 9-month period ending 8/31/2022, the interim year, OY1 and OY 2.

$$5\text{-Year AACR} = 0.047 \text{ or } 4.7\%$$

$$0 + (0 \times 0.047 \times 0.6603) = 0.00 \text{ patients Ending Current Year (8/31/2022)}$$

$$27 \text{ from MSDC} + 20 \text{ patients from NDC} = 47.00 \text{ Pts. End of Interim (8/31/2023)}$$

$$47.00 \times 1.047 = 49.21 \text{ patients End of OY1 (8/31/2024)}$$

$$49.21 \times 1.047 = 51.52 \text{ patients End of OY2 (8/31/2025)}$$

- The applicant projects the patient population growth of patients residing outside of Forsyth County using the counties' respective Five-Year AACR, and projects growth for this population for the 9-month period ending 8/31/2022, the interim year, OY1 and OY 2, as illustrated in Section C, pages 29-30 of the application.

At the end of OY1, SKC is projected to serve 205.66 in-center patients and at the end of OY2 the facility is projected to serve 215.23 in-center patients on 65 stations.

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

- OY1: 3.16 patients per station per week or 79.10% (205.66 patients / 65 stations = 3.164/4 = 0.7910 or 79.10%)

- OY2: 3.311 patients per station per week or 82.78% (215.23 patients / 65 stations =  $3.311/4 = 0.8278$  or 82.78%)

The projected utilization of 3.16 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant projects growth using the Five-Year AACR for Forsyth, Davidson, Guilford, Iredell, Rockingham and Stokes counties, as published in the 2022 SMFP.
- The applicant projects utilization based on the number of SKC patients residing in Forsyth County and other counties that will transfer their services after the proposed and approved relocation of stations to and from SKC.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 IC patients per station per week required by 10A NCAC 14C .2203(b).

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

In Section C, page 34, the applicant states:

*“Admission of a patient is based solely upon medical necessity and not the patient’s ability to pay. Patients may only access the facility’s services via physician referral due to a diagnosis of ESRD. The majority of patients are covered by Medicare, Medicaid, or some other form or combination of healthcare coverage.*

...

*The facility accepts patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin nor disability.”*

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

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	8.12%
Racial and ethnic minorities	80.12%
Women	45.03%
Persons with disabilities	
Persons 65 and older	49.12%
Medicare beneficiaries	59.79%
Medicaid recipients	31.43%

Source: Section C, page 35

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. The applicant

owns and operates four dialysis stations in Forsyth County currently providing services to underserved groups.

**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 relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC to SKC for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to KVDC).

The following tables show the projected number of stations at SKC upon project completion.

<b>Miller Street Dialysis Center</b>		
County where the facility is located		Forsyth
1	Total number of existing, approved, and proposed dialysis stations as of the application deadline	50
2	Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	-19
3	Total number of dialysis stations upon completion of this project and all other projects involving this facility (you should be able to subtract Line 2 from Line 1; if you cannot, explain why not)	50 (see Line 4)
4	March 2022 MSDC will file a CON to add back 19 stations in conjunction with the transfer of 19 stations to SKC	+19
5	The result upon completion of both projects will be 6 more stations at SKC than for which SKC is currently certified and no change in the number of stations at MSDC.	50 MSDC 65 SKC

Source: Section D, page 41



Northside Dialysis Center		
County where the facility is located		Forsyth
1	Total number of existing, approved, and proposed dialysis stations as of the application deadline	48
2	Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	-11
3	Total number of dialysis stations upon completion of this project and all other projects involving this facility (you should be able to subtract Line 2 from Line 1; if you cannot, explain why not)	48 (see line 4)
4	March 2022 NDC will file a CON to add back 11 stations in conjunction with the transfer of 11 stations to SKC	+11
5	The result upon completion of both projects will be 6 more stations at SKC than for which SKC is currently certified and no change in the number of stations at NDC.	48 NDC 65 SKC

Source: Section D, page 41

In Section D, pages 41-42, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On pages 41-42, the applicant states:

*“This proposed transfer of 19 stations from MSDC to SKC is part of a large multi-project effort to increase geographical availability of dialysis services in Forsyth County. In September 2021, WFUHS filed a CON to transfer 24 dialysis stations from SKC to KVDC. This CON will transfer 19 stations from MSDC and 11 stations from NDC to SKC for a total of 65 stations at SKC upon completion of all projects. All projects will be certified in conjunction with the certification of the KVDC facility. In March 2022 WFUHS will file two CON’s. One will add back 19 stations at MSDC and the other will add back 11 stations at NDC. Both will be certified in conjunction with the certification date of the KVDC project and this project, such that neither MSDC nor NDC will not experience any net reduction in dialysis stations.”*

The information is reasonable and adequately supported because the applicant’s proposals and the approved development of a new dialysis facility in Forsyth County will maintain the level of dialysis services in Forsyth County, enhance geographical access for dialysis patients, and avoid a possible station deficit in the service area.

In Section Q, pages 88-91, the applicant provides projected utilization, as illustrated in the following tables.

Miller Street Dialysis Center Projected Utilization						
		12/31/2021	8/31/2022	8/31/2023	8/31/2024	8/31/2025
County	AACR	Ending Prior Year	Ending Current year	Ending Interim	Ending OY1	Ending OY2
Davidson	4.50%	6.00	6.18	6.45	6.73	7.03
Davie	5.40%	3.00	3.11	3.28	3.45	3.64
Forsyth	4.70%	4.00	158.80	166.26	174.08	182.26
Guilford	3.30%	154.00	4.09	4.22	4.36	4.51
Randolph	0.01%	1.00	1.00	1.00	1.00	1.00
Yadkin	5.80%	1.00	1.04	1.10	1.16	1.23
MSDC Transfer to SKC	4.70%	1.00	0.00	-27.00	-28.27	-29.60
MSDC Transfer to KVDC	4.70%	0.00	0.00	0.00	-15.98	-16.73
<b>Total</b>		<b>169.00</b>	<b>174.21</b>	<b>155.31</b>	<b>146.53</b>	<b>153.33</b>
<b>50</b>		<b>84.50%</b>	<b>87.10%</b>	<b>77.65%</b>	<b>73.27%</b>	<b>76.67%</b>

Northside Dialysis Center Projected Utilization											
		12/31/2021		8/31/2022		8/31/2023		8/31/2024		8/31/2025	
County	AACR	Ending Prior Year		Ending Current year		Ending Interim		Ending OY1		Ending OY2	
		IC	PD	IC	PD	IC	PD	IC	PD	IC	PD
Forsyth	4.70%	149.00	23.00	153.64	23.72	160.86	24.83	168.43	26.00	176.34	27.22
Guilford	3.30%	1.00	0.00	1.02	0.00	1.06	0.00	1.09	0.00	1.13	0.00
Stokes	3.90%	3.00	0.00	3.08	0.00	3.20	0.00	3.32	0.00	3.45	0.00
Yadkin	5.80%	1.00	0.00	1.04	0.00	1.10	0.00	1.16	0.00	1.23	0.00
NDC Transfer to SKC	4.70%	0.00	0.00	0.00	0.00	-20.00	0.00	-20.94	0.00	-21.92	0.00
<b>Total</b>		<b>154.00</b>	<b>23.00</b>	<b>158.78</b>	<b>23.72</b>	<b>146.22</b>	<b>24.83</b>	<b>153.06</b>	<b>26.00</b>	<b>160.22</b>	<b>27.22</b>
<b>Stations</b>											
<b>48</b>		<b>80.21%</b>		<b>82.70%</b>		<b>76.15%</b>		<b>79.72%</b>		<b>83.45%</b>	

In Section Q, pages 88-91, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins with Forsyth County MSDC and NDC facility census as of December 31, 2021 and projects forward using the Five-Year AACR of 4.7%, as published in the 2022 SMFP.
- 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 2022 SMFP.

- The applicant is proposing to relocate 19 stations from MSDC and 11 stations from NDC to SKC. This project is anticipated to be certified by August 31, 2023. The applicant subtracts the number of patients that are projected to transfer their services upon project completion.
- The applicant is proposing to file two CON applications on March 15, 2022, to add back the 30 stations to MSDC and NDC. This project is anticipated to be certified by August 31, 2023.

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

*Miller Street Dialysis (MSDC)*

- OY1: 2.93 patients per station per week or 73.27% (146.53 patients / 50 stations =  $2.9306/4 = 0.7327$  or 73.27%)
- OY2: 3.06 patients per station per week or 76.67% (153.33 patients / 50 stations =  $3.0666/4 = 0.7667$  or 76.67%)

*Northside Dialysis Center (NDC)*

- OY1: 3.19 patients per station per week or 79.72% (153.06 patients / 48 stations =  $3.1887/4 = 0.7972$  or 79.72%)
- OY2: 3.34 patients per station per week or 83.45% (160.22 patients / 48 stations =  $3.3379/4 = 0.8345$  or 83.45%)

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 maintain the availability of services, enhance geographical access and prevent a possible station deficit.

**Access to Medically Underserved Groups**

In Section D, page 42, the applicant states that services medically underserved groups will not be reduced.

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services will be adequately met because the applicant's proposal is part of a larger project that includes adding the 30 stations back to MSDC and NDC, which will not reduce the level of services for the 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.

### C

The applicant proposes to relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC to SKC for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to KVDC).

In Section E, pages 45-46, 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 states that Forsyth County is ineligible to receive stations from a contiguous county because the county does not have a deficit and transferring stations to Forsyth County would create a county station surplus.

*Add Stations to SKC via Facility Need Methodology*-The applicant states that there was not sufficient time to submit a CON application in response to the SKC 20-station facility need identified in the 2022 SMFP. Further, adding stations via facility need would not meet the need of the facility after the transfer of 24 stations to KVDC (Project ID# G-12137-21).

On page 45, the applicant states that its proposal is the most effective alternative because the host facilities (MSDC and NDC) demonstrate utilization rates above 80% and have a projected facility need identified in the 2022 SMFP. This would make the facilities eligible to replace any stations via facility need. Further, the proposed project would benefit patients currently dialyzing at the host facilities but reside closer to SKC.

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 proposal would benefit MSDC and NDC patients who reside closer to SKC.

- Based on the facility need of the host facilities identified in the 2022 SMFP, replacing stations would maintain the availability dialysis services in the service area.
- 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 Salem Kidney 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 relocate no more than 19 in-center stations from Miller Street Dialysis Center and 11 in-center stations from Northside Dialysis Center to Salem Kidney Center, for a total of 65 in-center stations at Salem Kidney Center upon completion of this project and Project ID# G-12137-21 (relocate 24 in-center stations from Salem Kidney Center to Kernersville Dialysis Center of Wake Forest University).**
- 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify 19 in-center stations from Miller Street Dialysis Center and 11 in-center stations from Northside Dialysis Center for a total of no more than 31 in-center stations at Miller Street Dialysis Center and 37 in-center stations at Northside Dialysis Center.**
- 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. **Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on November 1, 2022. The second progress report shall be due on March 1, 2023 and so forth.**
5. **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 relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC to SKC for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to KVDC).

**Capital and Working Capital Costs**

In Section Q, page 93, the applicant projects the total capital cost of the project, as shown in the table below.

<b>Projected Capital Cost</b>	
Furniture	\$19,200
<b>Total</b>	<b>\$19,200</b>

In Section Q, page 93, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on the cost of chairs and TVs needed when adding stations.

In Section F, page 49, the applicant states that there are no start-up or initial operating costs associated with this project.

**Availability of Funds**

In Section F, page 47, 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 *	\$19,200	\$19,200
Bonds	\$0	\$0
Other	\$0	\$0
Total Financing	\$19,200	\$19,200

\* OE = Owner's Equity

Exhibit F-2(c)(2) contains a letter dated January 3, 2022, from the Chief Executive Officer of Atrium Health Wake Forest Baptist 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 needs of the project based on 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.

Salem Kidney Center	OY1 FY2024	OY2 FY 2025
Total Treatments	32,190	30,450
Total Gross Revenues (Charges)	\$74,348,921	\$70,330,061
Total Net Revenue	\$9,858,414	\$9,325,527
Average Net Revenue per Treatment	\$306	\$306
Total Operating Expenses (Costs)	\$8,199,935	\$7,758,662
Average Operating Expense per Treatment	\$255	\$255
Net Income	\$1,658,479	\$1,566,865

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 94. 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.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

### C

The applicant proposes to relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC to SKC for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to KVDC).

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

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



Facility Name	Certified Stations as of 12/31/2020	# IC Patients as of 12/31/2020	Utilization by Percent as of 12/31/2020	Patients Per Station Per Week
Miller Street Dialysis Center	48	170	88.54%	3.40
Northside Dialysis Center	45	159	88.33%	3.31
Piedmont Dialysis Center	64	180	70.31%	2.81
Salem Kidney Center	51	169	82.84%	2.86
Kernersville Dialysis Center	0	0		
<b>Total</b>	<b>208</b>	<b>678</b>		

Source: 2022 SMFP, Table 9A, page 124

In Section G, page 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 proposal is filed as one part of three CON filings proposed by WFUHS to meet the growing demand for dialysis services within Forsyth County.*

...

*...The 30 net new stations will prevent a shortfall of stations in Forsyth County that is projected to begin to occur as early as 8/31/2022.”*

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

- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.
- The applicant is proposing to submit two CON applications in March 2022 to add back the 30 stations relocated to SKC proposed in this application. The applicant’s proposal will maintain the level of dialysis services in Forsyth County, enhance geographical access for dialysis patients residing closer to SKC, and avoid a possible station deficit in the service area.

**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 relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC to SKC for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to KVDC).

In Section Q, page 110, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

	Current Staff	Projected FTE Staff	
	as of 12/31/2021	2 <sup>nd</sup> Full Fiscal Year FY 2024	3 <sup>rd</sup> Full Fiscal Year FY 2025
RN	7.00	8.50	8.50
LPN	0.25	1.00	1.00
Patient Care Tech	15.00	21.50	16.00
DON	1.00	1.00	1.00
Diet	2.00	2.00	2.00
Social Work	2.00	2.00	2.00
Dialysis Tech	3.25	3.25	3.25
Biomed	2.00	2.00	2.00
Clerical	4.00	4.00	4.00
<b>TOTAL</b>	<b>36.50</b>	<b>45.25</b>	<b>39.75</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 56-58, 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 “intensive” training for all new employees and the required annual participation in onsite continuing education.
- Employees are encouraged to obtain further education and participate in professional associations.

**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 relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC to SKC for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to KVDC).

#### **Ancillary and Support Services**

In Section I, page 60, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 61-64, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits A-4, H-3, I-1, and I-2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

#### **Coordination**

In Section I, pages 64-65, 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:

- As a subordinate of WFUHS, SKC has the same privileges and relationships as other WFUHS dialysis facilities.
- SKC has agreements with Wake Forest Baptist Medical Center who provides services such as acute dialysis and chronic dialysis care.
- WFUHS facilities provide access to local health professional programs and provide onsite experience and utilization by health science professional staff.

#### **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:
- would be available under a contract of at least 5 years duration;
  - would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - would cost no more than if the services were provided by the HMO; and
  - 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 relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC to SKC for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to KVDC).

In Section K, page 67, the applicant states that the project involves renovating 720 square feet of existing space. Line drawings are provided in Exhibit K-2.

On page 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 existing space will be upfitted and plumbed to accommodate the relocated stations.
- The proposed project will not duplicate existing and approved healthcare services because the project involves relocating stations not adding stations to any facility.

On page 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 applicant's proposal to file two additional applications to add stations back to the host facilities in Forsyth County which will maintain utilization on two shifts per day at SKC while enhancing geographical access to services in Forsyth County.

On page 68, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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 70, the applicant provides the historical payor mix during CY 2021 for the proposed services, as shown in the table below.

Salem Kidney Center Historical Payor Mix 01/01/2021 to 12/30/2021		
Payor Category	Average In-Center Patients	% of In-Center Patients
Self-Pay	2	1.33%
Commercial Insurance Only	11	6.30%
Medicare*	103	59.79%
Medicaid*	54	31.43%
VA	2	1.15%
<b>Total</b>	<b>172</b>	<b>100.0%</b>

\*Including any managed care plans.

In Section L, pages 71-72, 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	45.03%	52.7%
Male	54.97%	47.3%
Unknown	N/A	N/A
64 and Younger	50.88%	83.6%
65 and Older	49.12%	16.4%
American Indian	0.00%	0.9%
Asian	0.58%	2.6%
Black or African-American	71.35%	27.5%
Native Hawaiian or Pacific Islander	0.00%	0.1%
White or Caucasian	19.88%	56.3%
Other Race	7.60%	15.6%
Declined / Unavailable	0.58%	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 [sic] The facility, as a Medicare Participating Provider, is at a 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 74, 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

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.

<b>Salem Kidney Center Projected Payor Mix Ending OY2</b>		
<b>Payor Category</b>	<b>Average In-Center Patients</b>	<b>% of In-Center Patients</b>
Self-Pay	3	1.33%
Commercial Insurance Only	13	6.30%
Medicare*	126	59.79%
Medicaid*	66	31.43%
VA	2	1.15%
<b>Total</b>	<b>210</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.33% of total services will be provided to self-pay patients, 59.79% to Medicare patients and 31.43% to Medicaid patients.

The applicant does not include charity care in the projected payor mix. However, on page 75, the applicant states that charity care is calculated as a percentage of gross revenue. Historically, SKC experienced charity care as 0.20% of gross revenue. In Section L, pages 75-76, the applicant states that with the assumption of 145 treatments per year per patient, the following formula was used to project number of charity care patients:

*Projected Gross (Billable) Annual SKC Revenue x 0.20% = Annual SKC Dollars of Charity Care*

*Annual SKC Dollars of Charity Care / Annual Gross Revenue Per Patient = Annual Charity Care Patients*

On pages 74-75, 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 projects payor mix as of the last day of each month based on the daily fluctuation of patients.
- The applicant projects the payor mix based on the facility's last operating year's payor mix.

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 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 relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC to SKC for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to 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(a). The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- SKC has an existing agreement with Forsyth Technical Community College Nursing Program.
- WFUHS facilities provide onsite educational experiences to local training programs in the area.

**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 relocate 19 in-center dialysis stations from MSDC and 11 in-center dialysis stations from NDC to SKC for a total of no more than 65 in-center dialysis stations upon completion of this project and Project ID# G-12137-21 (relocate 24 stations from SKC to KVDC).

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

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

Facility Name	Certified Stations as of 12/31/2020	# IC Patients as of 12/31/2020	Utilization by Percent as of 12/31/2020	Patients Per Station Per Week
Miller Street Dialysis Center	48	170	88.54%	3.40
Northside Dialysis Center	45	159	88.33%	3.31
Piedmont Dialysis Center	64	180	70.31%	2.81
Salem Kidney Center	51	169	82.84%	2.86
Kernersville Dialysis Center	0	0		
<b>Total</b>	<b>208</b>	<b>678</b>		

Source: 2022 SMFP, Table 9A, page 124

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

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

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

See also Sections 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 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
- 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 112, 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, four facilities were cited for deficiencies, however, all four facilities are 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.*

-NA- The applicant is not proposing to establish a new dialysis facility.

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

-C- In Section C, page 27 and Section Q, page 86, the applicant projects that Salem Kidney Center will serve 205.66 in-center patients on 65 stations, or a rate of 3.16 patients per station per week, as of 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 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 27-30, 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.