

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: October 22, 2021

Findings Date: October 22, 2021

Project Analyst: Celia C. Inman

Co-Signer: Gloria C. Hale

Project ID #: G-12108-21

Facility: Davie Kidney Center

FID #: 080689

County: Davie

Applicant(s): Wake Forest University Health Sciences

Davie Kidney Center of Wake Forest University

Project: Add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon project completion

### REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

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Wake Forest University Health Sciences (WFUHS) and Davie Kidney Center of Wake Forest University (DKC), collectively referred to as “the applicant”, proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon project completion.

## **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 9B, page 134, the county need methodology shows there is not a county need determination for additional dialysis stations in Davie County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2021 SMFP, if the utilization rate for the facility as reported in the 2021 SMFP is at least 75.00% or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9A, page 122, the utilization rate reported for the facility is 81.94% or 3.28 patients per station per week, based on 59 in-center dialysis patients and 18 certified dialysis stations (59 patients / 18 stations = 3.28;  $3.28 / 4 = 81.94\%$ ).

As shown in Table 9D, page 138, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 10 additional stations; thus, the applicant is eligible to apply to add up to 10 stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than six new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to 10 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

## **Policies**

There is one policy in the 2021 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 29 of the 2021 SMFP, states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

## **Promote Safety and Quality**

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 17-21, referencing other sections and specific exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 21, referencing Section L and Exhibits L-4 and L-5. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 21, referencing Sections C, E, F and G. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

### Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates how the facility's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on how it describes the facility's policies and programs, which promote the concepts of quality, equitable access and maximum value for resources.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon project completion.

**Patient Origin**

On page 113, the 2021 SMFP defines the service area for the county need methodology for dialysis stations as *“The service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.”* DKC is located in Davie County. Thus, the service area for this application is Davie County. Facilities may serve residents of counties not included in their service area.

In Section C, page 23, the applicant provides the following historical in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patient origin for DKC, as summarized below.

County	Historical Patient Origin 06/01/2020-05/31/2021					
	IC Patients		HH Patients		PD Patients	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Catawba	0.00	0.00%	0.00	0.00%	1.00	10.00%
Davidson	1.00	1.54%	0.00	0.00%	0.00	0.00%
Davie	55.00	84.62%	0.00	0.00%	7.00	70.00%
Forsyth	3.00	4.62%	0.00	0.00%	1.00	10.00%
Iredell	2.00	3.08%	0.00	0.00%	0.00	0.00%
Rowan	4.00	6.15%	0.00	0.00%	1.00	10.00%
<b>Total</b>	<b>65.00</b>	<b>100.00%</b>	<b>0.00</b>	<b>0.00%</b>	<b>10.00</b>	<b>100.00%</b>

Source: Section C.2, page 23

The following tables summarize the projected patient origin at DKC in the first and second full operating years (OY) following project completion.

County	Projected Patient Origin OY1 06/01/2022-05/31/2023					
	IC Patients		HH Patients		PD Patients	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Catawba	0.00	0.00%	0.00	0.00%	1.13	10.54%
Davidson	1.11	1.61%	0.00	0.00%	0.00	0.00%
Davie	58.12	84.32%	0.00	0.00%	7.40	69.24%
Forsyth	3.28	4.75%	0.00	0.00%	1.09	10.22%
Iredell	2.15	3.12%	0.00	0.00%	0.00	0.00%
Rowan	4.28	6.20%	0.00	0.00%	1.07	10.01%
<b>Total</b>	<b>68.94</b>	<b>100.00%</b>	<b>0.00</b>	<b>0.00%</b>	<b>10.68</b>	<b>100.00%</b>

Source: Section C.2, page 24

<b>Projected Patient Origin OY2 06/01/2023-05/31/2024</b>						
<b>County</b>	<b>IC Patients</b>		<b>HH Patients</b>		<b>PD Patients</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
Catawba	0.00	0.00%	0.00	0.00%	1.19	10.81%
Davidson	1.17	1.64%	0.00	0.00%	0.00	0.00%
Davie	59.75	84.16%	0.00	0.00%	7.60	68.85%
Forsyth	3.42	4.82%	0.00	0.00%	1.14	10.33%
Iredell	2.23	3.14%	0.00	0.00%	0.00	0.00%
Rowan	4.42	6.23%	0.00	0.00%	1.11	10.01%
<b>Total</b>	<b>70.99</b>	<b>100.00%</b>	<b>0.00</b>	<b>0.00%</b>	<b>11.05</b>	<b>100.00%</b>

Source: Section C.2, page 24

In Section C, pages 24-27, 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:

- June 1, 2022 through May 31, 2023 will be the first operating year.
- The applicant begins its projection for patient origin using the existing patient utilization and origin.
- The applicant assumes the patient origin by county will remain constant, increased only by the county growth rate.
- The applicant uses the Average Annual Change Rate (AACR) published in the 2021 SMFP to grow its North Carolina patient census by county of origin: Catawba County – 6.1%, Davidson County – 5.3%, Davie County – 2.8%, Forsyth County – 4.5%, Iredell County – 3.7%, Rowan County – 3.4%.

**Analysis of Need**

In Sections C.3 and C.4, pages 24-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 25, the applicant states:

*“Based on WFUHS dialysis internal data, additional stations will be needed in Davie County to accommodate future patient populations, which include non-Davie County residents.”*

On pages 25-27, the applicant discusses the need relative to the following:

- The facility experienced tremendous growth between December 2019 and December 2020.
- DKC has a need for six additional stations.
- Without the additional stations, DKC will near 100% utilization by the end of OY2.
- The total of 24 stations at DKC will be utilized at a projected rate of 71.81% by the end of OY1, exceeding the required utilization threshold of 70% by the end of OY1.

- The additional stations at DKC will prevent a projected future county station deficit and improve geographic access of service to patients in the service area.

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

- The 2021 SMFP shows a facility need of up to 10 additional stations at DKC.
- The applicant uses the county growth rates published in Table 9B of the 2021 SMFP to project future need for services.
- The applicant provides calculations showing that by the end of OY1, DKC will have a utilization rate of 71.81%.

#### Projected Utilization

In Section Q Form C Utilization, the applicant provides the projected dialysis utilization, as illustrated in the following table.

<b>Form C Utilization</b>	<b>Prior OY</b>	<b>Interim OY</b>	<b>First Full OY 6/1/22-5/31/23</b>	<b>Second Full OY 6/1/23-5/31/24</b>
<b>In Center</b>				
# of Patients at the Beginning of the Year	59	65	67	69
# of Patients at the End of the Year	65	67	69	71
Average # of Patients during the Year	62	66	68	70
# of Treatments / Patient / Year	145	145	145	145
Total # of Treatments	8,990	9,570	9,860	10,150
<b>Home Hemodialysis</b>				
# of Patients at the Beginning of the Year	0	0	0	0
# of Patients at the End of the Year	0	0	0	0
Average # of Patients during the Year	0	0	0	0
# of Treatments / Patient / Year	145	145	145	145
Total # of HH Treatments	0	0	0	0
<b>Peritoneal Dialysis</b>				
# of Patients at the Beginning of the Year	5	10	10	11
# of Patients at the End of the Year	10	10	11	11
Average # of Patients during the Year	8	10	11	11
# of Treatments / Patient / Year	145	145	145	145
Total # of PD Treatments	1,160	1,450	1,595	1,595
<b>Total Dialysis Patients and Treatments</b>				
# of Patients at the Beginning of the Year	64	75	77	80
# of Patients at the End of the Year	75	77	80	82
Average # of Patients during the Year	70	76	79	81
# of Treatments / Patient / Year	145	145	145	145
Total # of Dialysis Treatments	10,150	11,020	11,455	11,745
Total HH Training Days	0	0	0	0
Total PD Training Days	30	39	51	66
Total Billable Treatments and Days	10,180	11,059	11,506	11,811

In Section Q, pages 82-83, the applicant provides the assumptions and methodology used to project its utilization.

The applicant's assumptions are reasonable and adequately supported based on the following:

- June 1, 2022 through May 31, 2023 will be the first operating year.
- The applicant begins its projection based on its current utilization.
- The applicant uses the AACR published in the 2021 SMFP to grow its patient census by county of origin, which is a reliable measure for predicting patient growth by county.
- Number of treatments per patient per year equals the maximum treatments (156) reduced by 7% missed treatments (11) for a total of 145 billable treatments per patient.

The applicant provides a table in Section Q, page 83, illustrating the application of its assumptions and methodology. The following table summarizes the applicant’s assumptions and methodology for in-center and home training projections.

**Projected Utilization**

County	AACR	Prior OY 6/1/20-5/31/21			Interim OY 6/1/21-5/31/22			First Full OY 6/1/22-5/31/23			Second Full OY 6/1/23-5/31/24		
		IC	PD	HH	IC	PD	HH	IC	PD	HH	IC	PD	HH
Catawba	6.1%	0.00	1.00	0.00	0.00	1.06	0.00	0.00	1.13	0.00	0.00	1.19	0.00
Davidson	5.3%	1.00	0.00	0.00	1.05	0.00	0.00	1.11	0.00	0.00	1.17	0.00	0.00
Davie	2.8%	55.00	7.00	0.00	56.54	7.20	0.00	58.12	7.40	0.00	59.75	7.60	0.00
Forsyth	4.5%	3.00	1.00	0.00	3.14	1.05	0.00	3.28	1.09	0.00	3.42	1.14	0.00
Iredell	3.7%	2.00	0.00	0.00	2.07	0.00	0.00	2.15	0.00	0.00	2.23	0.00	0.00
Rowan	3.4%	4.00	1.00	0.00	4.14	1.03	0.00	4.28	1.07	0.00	4.42	1.11	0.00
<b>Total</b>		<b>65.00</b>	<b>10.00</b>	<b>0.00</b>	<b>66.94</b>	<b>10.34</b>	<b>0.00</b>	<b>68.94</b>	<b>10.68</b>	<b>0.00</b>	<b>70.99</b>	<b>11.05</b>	<b>0.00</b>

Totals may not sum due to rounding.

As the table above shows, using conventional rounding, the applicant’s methodology achieves a projection of 68.94 in-center patients by the end of the first operating year, OY1, for a utilization rate of 2.9 patients per station per week or 71.8% (68.94 patients / 24 stations = 2.87 / 4 = 0.718). By the end of OY2, following the applicant’s methodology and assumptions, DKC will have 70.99 in-center patients dialyzing at the center for a utilization rate of 74% (70.99 / 24 = 2.958 / 4 = .739). The projected utilization of 2.9 patients per station per week for OY1 satisfies the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on the ending census of the previous year.
- The applicant uses the AACR published in the 2021 SMFP to grow its patient census by county of origin, which is a reliable measure for predicting patient growth by county.
- The projected utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

**Access to Medically Underserved Groups**

In Section C, pages 32-34, the applicant discusses access to services at DKC, stating on page 32:

*“Admission of a patient is based solely upon medical necessity and not the patient’s ability to pay. Patients may only access the facility’s services via physician referral due to a diagnosis of ESRD. The majority of patients are covered by Medicare, Medicaid, or some other form or combination of healthcare coverage. The facility’s social worker assists patients in seeking out and obtaining coverage for their care when necessary. However,*



*should a circumstance arise in which a patient is ineligible for healthcare coverage, that patient is not turned away due to a lack of ability to pay.”*

On page 34, 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	3.75% of IC and 1.19% of HH/PD
Racial and ethnic minorities	35.62%
Women	45.21%
Persons with Disabilities	Not Tracked
Persons 65 and Older	61.64%
Medicare beneficiaries	66.17%
Medicaid recipients	19.69%

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 states that its admission policy is based on medical necessity and not the patient’s ability to pay.
- The applicant has historically provided care and services to medically underserved populations.
- The applicant states that patients are not turned away due to a lack of ability to pay.

### **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.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon project completion.

In Section E, pages 41-42, 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:

- Policy ESRD-2 Transfer of Stations from a Contiguous County - the applicant states that of the contiguous counties, Forsyth, Iredell and Yadkin counties are shown to have surpluses in the 2021 SMFP. However, the applicant states that this data is out of date as of its release and that current facility data reveals no surpluses available for transfer. Thus, this alternative is not an effective alternative.
- Policy ESRD-2 In-County Transfer of Stations– the applicant states that DKC is the sole provider of dialysis services in Davie County; there is no facility in-county from which to transfer stations. Thus, this would not be an effective alternative.
- Add Stations via Facility Need Methodology (chosen alternative) – the applicant states that adding six stations pursuant to the facility need determination would add the needed capacity at DKC; thus, this alternative is the most effective alternative.

On page 42, the applicant states that the 2021 SMFP shows that DKC is eligible to add up to 10 stations and it has shown a need for six additional stations. Thus, the project as proposed is the most effective alternative because WFUHS has no surplus stations in contiguous counties and an in-county transfer is not an option.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The application is conforming or conditionally conforming to all statutory and regulatory review criteria.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.

## **Conclusion**

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 for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Wake Forest University Health Sciences and Davie Kidney Center of Wake Forest University (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to Condition 2 of the facility need determination in the 2021 SMFP, the certificate holder shall develop no more than six additional in-center dialysis stations for a total of no more than 24 stations at Davie Kidney Center upon project completion.**
  - 3. Progress Reports:**
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. The certificate 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 third month. The first progress report shall be due on April 1, 2022. The second progress report shall be due on July 1, 2022 and so forth.**
  - 4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon project completion.

**Capital and Working Capital Costs**

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

Medical Equipment Costs	\$87,000
Furniture	\$19,200
<b>Total</b>	<b>\$106,200</b>

In Section Q, 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 cost of six dialysis stations and related furniture.

In Section F, page 46, the applicant states that there will be no start-up or initial operating costs associated with this project.

**Availability of Funds**

In Section F, page 44, the applicant states that the capital cost will be funded as shown below in the table.

Type	WFUHS
Loans	\$0
Accumulated Reserves or OE *	\$106,200
Bonds	\$0
Other (Specify)	\$0
<b>Total Financing</b>	<b>\$106,200</b>

\* OE = Owner's Equity

The applicant states that WFUHS is the whole owner of DKC and is committed to funding the project. Exhibit F.2(c)(2) contains a copy of a letter dated May 18, 2021 from a Wake Forest Baptist Health official expressing WFUHS' intention to fund the capital cost of the project with accumulated reserves. Exhibit F.2(c)(3) contains a copy of the audited financial statements for Wake Forest University which indicate WFUHS had cash and cash equivalents of \$106,870,000 as of June 30, 2020.

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

- documentation of its intent to fund the project in Exhibit F.2
- availability of funds documented in the audited financials provided in Exhibit F.2

**Financial Feasibility**

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

	<b>Interim OY 6/1/21-5/31/22</b>	<b>First Full OY 6/1/22-5/31/23</b>	<b>Second Full OY 6/1/23-5/31/24</b>
Total Billable Treatments, including HH and PD Treatments and Training Days	11,059	11,506	11,811
Total Gross Revenues (Charges), including Drug Administration Charges	\$25,649,692	\$26,685,745	\$27,393,634
Total Net Revenue	\$4,048,988	\$4,216,548	\$4,327,218
Average Net Revenue per Procedure	\$366	\$366	\$366
Total Operating Expenses (Costs)	\$3,235,277	\$3,375,646	\$3,468,120
Average Operating Expense per Procedure	\$293	\$293	\$294
Net Income	\$813,712	\$840,902	\$859,098

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Charges and expenses are based on historical facility operations projected forward.
- FTEs and salaries are based on current staffing and projected to average annual salary increases of 3%.
- 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.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
  - 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 costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for the county need methodology for dialysis stations as *“The service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.”* DKC is located in Davie County. Thus, the service area for this application is Davie County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, DKC is the only provider of dialysis services in Davie County. Information on DKC, from Table 9A of the 2021 SMFP, is provided below:

<b>Davie County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
Davie Kidney Center of Wake Forest University	WFUHS	Mocksville	18	81.94%

Source: 2021 SMFP, Table 9A.

In Section G, pages 50-51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Davie County. The applicant provides a table depicting the 2024 station deficit in Davie County and states:

*“It is clear based upon the facility need determination for DKC and the projected future station deficit for Davie County illustrated, above, the requested additional stations at DKC will not duplicate services, but will go far to prevent a shortfall of services within Davie County. DKC proves the need the proposed patient population has for the*

*proposed service in compliance with ESRD Performance Standards. Thus, approval of this project will not result in duplication of services in Davie County nor at DKC.”*

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 without the addition of stations, Davie County will likely experience a nine-station deficit by OY2024.
- The applicant adequately demonstrates that the proposed addition of six stations at DKC is needed in addition to the existing and approved stations in Davie County.

### **Conclusion**

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.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

### C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon project completion.

In Section Q Form H Staffing, page 99, the applicant provides the current and projected staffing in full-time equivalent (FTE) positions for the proposed services, as summarized in the following table.

POSITION	CURRENT FTE POSITIONS AS OF 5/31/21	PROJECTED FTE POSITIONS 6/1/22-5/31/23	PROJECTED FTE POSITIONS 6/1/23-5/31/24
RN	3.88	4.00	4.00
Patient Care Tech	7.00	7.75	7.75
DON	1.00	1.00	1.00
Dietician	0.75	0.75	0.75
Social Worker	1.00	1.00	1.00
HT Nurse	0.50	0.75	0.75
Dialysis Tech	0.50	0.50	0.50
Bio-med Technician	0.25	0.25	0.25
Clerical	1.00	1.00	1.00
<b>Total</b>	<b>15.88</b>	<b>17.00</b>	<b>17.00</b>

Source: Section Q of the application

The assumptions and methodology used to project staffing are provided in Section Q, page 100. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, page 96. In Section H, pages 53-55, 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 states that current salary amounts were projected to increase by 3% annually and FTE positions are based on projected patient volumes and adjusted with facility census.
- The applicant states that it staffs to meet or exceed a ratio of 3:1 (3 patients to 1 direct care staff member).
- The applicant provides documentation of its policies in regard to recruitment, training and continuing education.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support



services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon project completion.

### **Ancillary and Support Services**

In the table in Section I, page 57, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. In the applicant's table on pages 58-61, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits A-4, H-3, and I-1.

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

- The applicant provides evidence of its policies and provision of services in Exhibit H-3.
- The applicant provides evidence of its contracts for services in Exhibit I-1.

### **Coordination**

In Section I, pages 61-62, the applicant describes its efforts to develop 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 discusses DKC's and its parent company's relationships with the local health care and social service providers.
- The applicant provides evidence of its agreements with local health care and social service providers in Exhibits I-1 and I-2.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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.

NA

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon project completion. The applicant does not propose to make more than minor renovations (uncover existing plumbing and wiring in the wall and tapping into those resources to connect the additional stations) to existing space.

- (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 67, the applicant provides the historical payor mix during its last full operating year, as shown in the table below.

Primary Payor Source at Admission	Davie Kidney Center June 1, 2020- May 31, 2021					
	Total Facility		In-center Dialysis		HH and PD	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.62	0.88%	0.32	0.51%	0.30	3.75%
Insurance	9.20	13.15%	7.77	12.54%	1.43	17.86%
Medicare *	46.32	66.17%	40.40	65.16%	5.92	74.04%
Medicaid *	13.78	19.69%	13.44	21.67%	0.35	4.35%
VA	0.07	0.11%	0.07	0.12%	0.00	0.00%
<b>Total</b>	<b>70.00</b>	<b>100.00%</b>	<b>62.00</b>	<b>100.00%</b>	<b>8.00</b>	<b>100.00%</b>

\*Including any managed care plans  
 Totals and percentages may not foot due to rounding

In Section L, page 68, the applicant provides the following comparison for DKC and the population of the service area.

<b>Davie Kidney Center</b>	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY</b>	<b>Percentage of the Population of the Service Area</b>
Female	45.21%	51.20%
Male	54.79%	48.80%
Unknown	NA	NA
64 and Younger	38.36%	48.80%
65 and Older	61.64%	51.20%
American Indian	1.37%	0.70%
Asian	1.37%	0.90%
Black or African-American	21.92%	6.50%
Native Hawaiian or Pacific Islander	NA	NA
White or Caucasian	64.38%	83.90%
Other Race	10.96%	9.30%
Declined / Unavailable	NA	NA

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 68, the applicant states that while the facility is not required nor obligated to provide uncompensated care nor community service; as a Medicare Participating Provider, it is at a minimum subject to Federal laws and regulations regarding equal access and non-discrimination.

In Section L, page 70, the applicant states that during the preceding 18 months no patient civil rights access complaints have been filed against the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.3(a), page 71, the applicant projects the following payor mix for the proposed services during the second full year of operation following completion of the project, as shown in the table below.

Primary Payor Source at Admission	Davie Kidney Center June 1 2023- May 31, 2024					
	Total Facility		In-Center		HH/PD	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.77	0.95%	0.36	0.51%	0.41	3.75%
Insurance	10.74	13.26%	8.78	12.54%	1.96	17.86%
Medicare *	53.76	66.37%	45.61	65.16%	8.14	74.04%
Medicaid *	15.65	19.32%	15.17	21.67%	0.48	4.35%
VA	0.00	0.10%	0.08	0.12%	0.00	0.00%
<b>Total</b>	<b>81.00</b>	<b>100.00%</b>	<b>70.00</b>	<b>100.00%</b>	<b>11.00</b>	<b>100.00%</b>

Totals may not sum due to rounding

\*Including any managed care plans

As shown in the table above, during the second full year of operation, the applicant projects that 1% of IC dialysis services will be provided to self-pay patients, 65% to Medicare recipients and 22% to Medicaid recipients.

On page 71, 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 calculates payor mix based on monthly snapshots as of the last day of each month for the 12-month interval and averages it for the annual payor mix percentage.

- The applicant states that the most recent last year of payor mix is the most applicable data for the anticipated payor mix; thus, the applicant bases DKC's projected payor mix on its last operating year's payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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, page 73, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 75, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant projects access at the proposed facility based on its experience.
- The applicant provides documentation of its association with health professional training programs in the area.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
  - (16) Repealed effective July 1, 1987.
  - (17) Repealed effective July 1, 1987.
  - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

## C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 24 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for the county need methodology for dialysis stations as *“The service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.”* DKC is located in Davie County. Thus, the service area for this application is Davie County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, DKC is the only provider of dialysis services in Davie County. Information on DKC, from Table 9A of the 2021 SMFP, is provided below:

<b>Davie County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
Davie Kidney Center of Wake Forest University	WFUHS	Mocksville	18	81.94%

Source: 2021 SMFP, Table 9A

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 76, the applicant states:

*“WFUHS is the whole owner of the sole provider of dialysis services within Davie County. This application requests to add new stations via facility need methodology, which is specific to DKC. The project will have no effect on competition in the proposed service area of Davie County because no other provider exists and because the need determination for DKC is not applicable to any other dialysis provider.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 76, the applicant states:

*“The proposal will add 6 new stations at a well-utilized facility that has seen unprecedented growth in the last year. The additional stations will mean Davie 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 [sic] ensure the existing and projected patient volumes will have access to care on two daily shifts.”*

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

Regarding the impact of the proposal on quality, in Section N, page 76, the applicant states:

*“Service quality will remain of the highest standard.”*

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 76, the applicant states:

*“The new 6 stations requested in this proposal will represent additional 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. . . . Patient access to service is not based upon a patient’s ability nor inability to pay. All patients with ESRD will continue to have access to the facility’s services.”*

See also Sections B, 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 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.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q Form O Facilities, page 101, the applicant identifies the dialysis facilities 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; 18 of the facilities are operational.

In Section O, page 78, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care, not involving immediate jeopardy, occurred at one facility. The table on page 78 shows that the facility was back in compliance at the time of application submittal. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 18 operational facilities, the applicant provides sufficient evidence that quality care has been provided in the past.

(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 kidney disease treatment center or dialysis facility shall document the need for at least 10 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.
- (b) *An applicant proposing to increase the number of dialysis stations in:*  
(1) *an existing dialysis facility; or*  
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*
- C- In Section Q, page 83, the applicant projects that DKC will serve 68.94 in-center patients for a utilization rate of 2.9 patients per station per week or 71.8% ( $68.94 \text{ patients} / 24 \text{ stations} = 2.87 \text{ patients per station per week} / 4 = 0.718$ ) during the first full operating year following project completion, exceeding the required performance standard of 2.8 patients per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section Q, pages 82-83, 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.