

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 25, 2021

Findings Date: May 25, 2021

Project Analyst: Celia C. Inman

Assistant Chief: Fatimah Wilson

Project ID #: G-12036-21

Facility: Thomasville Dialysis Center

FID #: 020758

County: Davidson

Applicant(s): Wake Forest University Health Sciences

Thomasville Dialysis Center of Wake Forest University

Project: Add no more than 20 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 36 stations upon completion of this project, Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7)

### REVIEW CRITERIA

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

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

C

Wake Forest University Health Sciences (WFUHS) and Thomasville Dialysis Center of Wake Forest University (TVDC), collectively referred to as “the applicant”, proposes to add no more than 20 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 36 stations upon completion of this project, Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7).

## **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 Davidson 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 121, the utilization rate reported for the facility is 85.94% or 3.44 patients per station per week, based on 110 in-center dialysis patients and 32 certified dialysis stations (110 patients / 32 stations = 3.44;  $3.44 / 4 = 85.94\%$ ).

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 20 additional stations; thus, the applicant is eligible to apply to add up to 20 stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 20 new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to 20 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; Section H, pages 57-59; Section N, page 80; Section O, page 82; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 21; Section C, pages 34-35; Section L, pages 71-75; Section N, page 81; and referenced exhibits. 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; Section N, page 80; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

### Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with 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 20 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 36 stations upon completion of this project, Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7).

**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 area: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” TVDC is located in Davidson County. Thus, the service area for this application is Davidson County. Facilities may serve residents of counties not included in their service area.

The applicant provides the following historical in-center (IC) patient origin for TVDC, as summarized below.

County	Historical (1/1/2020-12/31/2020)	
	Patients	% of Total
Davidson	99.00	90.83%
Guilford	2.00	1.83%
Randolph	8.00	7.34%
<b>Total</b>	<b>109.00</b>	<b>100.00%</b>

Source: Section C.2, page 23.

The following table illustrates the projected in-center patient origin at TVDC in the first and second full fiscal year (FY) of operations, CY2023 and CY2024. The facility does not presently serve home training patients and does not propose to in the future.

County	Projected Patient Origin In-Center Patients			
	01/01/2023-12/31/2023		01/01/2024-12/31/2024	
	Patients	% of Total	Patients	% of Total
Davidson	94.53	90.01%	99.54	90.33%
Guilford	2.25	2.14%	2.34	2.12%
Randolph	8.24	7.85%	8.32	7.55%
<b>Total</b>	<b>105.02</b>	<b>100.00%</b>	<b>110.20</b>	<b>100.00%</b>

Source: Section C.3, page 24

In Section C, pages 25-31, the applicant provides the assumptions and methodology used to project its patient origin and its projected utilization. On page 25, the applicant states that Davidson County will experience a shortage of dialysis stations, stating:

*“Based on the data provided in the 2021 SMFP, there will be at least a 4-station deficit as soon as 12/31/2020. However, that information is outdated upon the effective date of the SMFP – 1/1/2021.”*

On page 28, the applicant states that the proposed project is necessary in order to serve the patients remaining at TVDC after the transfer of 19 stations from TVDC to North Davidson Dialysis Center (NDDC). On page 30, the applicant states that it assumes the patients served at TVDC will remain constant less those proposed to transfer their care to NDDC upon its certification; thus, beginning patients census consists of existing TVDC patients.

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

- The applicant begins its projection for patient origin using the existing patient origin
- The applicant reduces the Davidson County patients by the number projected to transfer their care to NDDC
- The applicant uses the Average Annual Change Rate (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: Davidson County – 5.3%, Guilford County – 4.0%, Randolph County – 1.0%

### **Analysis of Need**

In Section C, page 31, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant refers to Section C.3, where it states:

- The 2021 SMFP shows a Davidson County four-station deficit
- By the end of 2024, Davidson County is likely to have a 23-station deficit
- The applicant states that the proposed relocation of 19 stations from TVDC to NDDC in Project ID #sG-11844-20 and G-12011-21 and the proposed additional 20 stations in this application will allow for a county-wide redistribution of patients among the WFUHS dialysis facilities in Davidson and Guilford counties and is necessary to prevent over-utilization at TVDC after the relocation of stations to NDDC
- The applicant states that existing WFUHS IC patients residing in Davidson and Guilford counties will be given the option of transferring their care to the facility within the closest proximity to their homes for reasons of convenience (at least 20 TVDC Davidson County patients are expected to transfer their care to NDDC)
- The applicant states that without the additional stations, upon the relocation of 19 stations to NDDC as of December 31, 2022, TVDC would experience utilization of greater than 150%

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

- The 2021 SMFP shows a Davidson County four-station deficit and thus, no county need determination (page 134) and a facility need determination for 20 stations at TVDC (page 121)
- The applicant provides calculations showing that by the end of 2024, Davidson County could have a 23-station deficit (page 25)

- The applicant states it performed a mapping analysis to determine geographic accessibility to the proposed services as shown in Exhibit C-4 that shows patients do not attend the facility closest to their homes so they can be accommodated at their preferred treatment times (page 30)
- The applicant calculates a utilization rate at TVDC, after the proposed relocation of 19 stations to NDDC (Project ID #s G-11844-20 and G-12011-21) and the addition of 20 stations in this application, of 72.93% by the end of the first year of operations, December 31, 2023 (page 29)

Projected Utilization

In Section Q, the applicant provides the projected utilization, as illustrated in the following table.

<b>Form C Utilization</b>	<b>Current OY</b>	<b>Interim OY</b>	<b>First Full OY 1/1/23-12/31/23</b>	<b>Second Full OY 1/1/24-12/31/24</b>
# of Patients at the Beginning of the Year	109	114	101	105
# of Patients at the End of the Year	114	100	105	110
Average # of Patients during the Year	112	107	103	108
# of Treatments / Patient / Year	150	150	150	150
Total # of Treatments	16,800	16,050	15,450	16,200

In Section C.3, pages 24-31, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- Beginning census of the current operating year, CY2021, is 99 Davidson County residents, two Guilford County residents and eight Randolph County residents (page 29)
- The applicant grows the Davidson, Guilford and Randolph county patient census by 5.3%, 4.0%, and 1.0%, respectively, the 5-year AACR for each county as found in the 2021 SMFP, pages 134-135
- The applicant adjusts the Davidson County patient census for the transfer of 20 patients to NDDC (Project ID #s G-11844-20 and G-12011-21)

The applicant provides a table in Section C, page 29, and in Section Q illustrating the application of its assumptions and methodology. The following table summarizes the applicant’s assumptions and methodology, corrected for the assumption that the 20 patients that transfer out on December 31, 2022 will not be included in the utilization after 2022. The ending Davidson County patient utilization on December 31, 2022 is simply reduced by the 20 patients who transfer to NDDC.

County	AACR	Current OY 1/1/21-12/31/21	Interim OY 1/1/22-12/31/22	First Full OY 1/1/23-12/31/23	Second Full OY 1/1/24-12/31/24
Davidson	5.3%	104.25	109.77		
Davidson Transfer Out 12/31/22			-20.00		
Davidson After Transfer 12/31/22			89.78	94.53	99.54
Guilford	4.0%	2.08	2.16	2.25	2.34
Randolph	1.0%	8.08	8.16	8.24	8.32
<b>Totals</b>		<b>114.41</b>	<b>100.10</b>	<b>105.02</b>	<b>110.20</b>

Totals may not sum due to rounding.

As the table above shows, using conventional rounding, the applicant’s methodology achieves a projection of 105 in-center patients by the end of the first operating year, OY1 (December 31, 2023), for a utilization rate of 2.9 patients per station per week or 73% (105 patients / 36 stations = 2.9 patients per station per week / 4 = 0.73). By the end of OY2 (December 31, 2024), following the applicant’s methodology and assumptions, TVDC will have 110 in-center patients dialyzing at the center for a utilization rate of 76% (110 / 36 = 3.05 / 4 = .76). 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 adjusts for the proposed transfer of care of existing Davidson County patients to NDDC (Project ID #G-12011-21)
- The applicant projects the growth of the Davidson, Guilford and Randolph county patient census using the Davidson, Guilford and Randolph county Five-Year AACR of 5.3%, 4.0% and 1.0%, respectively, as reported in the 2021 SMFP
- 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 34-35, the applicant discusses access to services at TVDC, stating on page 34:

*“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.”*

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	5.00%
Racial and ethnic minorities	52.29%
Women	46.79%
Persons with Disabilities	Not Tracked
The elderly	44.95%
Medicare beneficiaries	87.00%
Medicaid recipients	5.00%

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 20 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 36 stations upon completion of this project, Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7).

In Section E, pages 44-46, 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:

- Policy ESRD-2 Transfer of Stations from a Contiguous County - the applicant states that of the contiguous counties, Davie and Forsyth have deficits of stations, WFUHS has no surplus stations in Guilford County, and the WFUHS facility in Randolph County is a 10-station facility with no available stations to transfer; thus, this alternative is not an effective alternative.
- Transfer Stations from Lexington Dialysis Center (LXDC) to TVDC to Add Back Stations at TVDC – the applicant states that the surplus at LXDC is short-term because of impending patient growth, which will fill those stations and LXDC will not be eligible to add back any stations during 2021 via facility need. The ability to re-balance the WFUHS dialysis patient population would be impaired. Thus this would not be an effective alternative to provide adequate WFUHS dialysis capacity in Davidson County.
- Add Stations via Facility Need Methodology (chosen alternative) – the applicant states that the facility need determination for TVDC (20 stations) would add the needed capacity and after the relocation of stations from TVDC to NDDC, which will free up plant capacity at TVCD, the stations could be added to the existing physical space; thus, this alternative is the most effective alternative.

On pages 44-45, the applicant states that its proposal is the most effective alternative because WFUHS has no surplus stations in contiguous counties and an in-county transfer of any number of stations from LXDC to TVDC is both more costly and less effective than the alternative proposed.

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

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

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 Thomasville Dialysis 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 20 additional in-center dialysis stations for a total of no more than 36 in-center (and home hemodialysis) stations at Thomasville Dialysis Center upon completion of this project and Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7).**
- 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 December 1, 2021. The second progress report shall be due on March 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 20 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 36 stations upon completion of this project, Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7).

**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	\$290,000
<b>Total</b>	<b>\$290,000</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 20 dialysis stations at \$14,500 per station.

In Section F, page 49, 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 47, the applicant states that the capital cost will be funded as shown below in the table.

Type	WFUHS
Loans	\$0
Accumulated Reserves or OE *	\$290,000
Bonds	\$0
Other (Specify)	\$0
<b>Total Financing</b>	<b>\$290,000</b>

\* OE = Owner's Equity.

The applicant states that WFUHS is the whole owner of TVDC and is committed to funding the project. Exhibit F.2(c)(2) contains a copy of a letter dated March 1, 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 Full FY CY2022</b>	<b>1<sup>st</sup> Full FY CY2023</b>	<b>2<sup>nd</sup> Full FY CY2024</b>
Total Billable Treatments	16,050	15,450	16,200
Total Gross Revenues (Charges), including Drug Administration Charges	\$36,636,212	\$35,266,634	\$36,978,606
Total Net Revenue	\$5,331,942	\$5,132,617	\$5,381,773
Average Net Revenue per Procedure	\$332	\$332	\$332
Total Operating Expenses (Costs)	\$3,736,155	\$3,588,423	\$3,750,411
Average Operating Expense per Procedure	\$233	\$232	\$232
Net Income	\$1,595,787	\$1,544,194	\$1,631,362

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 20 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 36 stations upon completion of this project, Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7).

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 area: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.”* Thus, the service area for this facility consists of Davidson County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are three existing or approved dialysis facilities in Davidson County, all of which are owned and operated by WFUHS. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

<b>Davidson County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019</b>				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Lexington Dialysis Center of Wake Forest University	WFUHS	Lexington	42	72.62%
North Davidson Dialysis Center of Wake Forest University	WFUHS	Winston-Salem	0	0.00%
Thomasville Dialysis Center of Wake Forest University	WFUHS	Thomasville	32	85.94%

Source: 2021 SMFP, Table 9A.

In Section G, pages 54-55, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Davidson County. The applicant provides a table depicting the 2024 station deficit in Davidson County and states:

*“It is clear based upon the facility need determination for TVDC and the projected future station deficit for Davidson County illustrated, above, the requested additional*

*stations at TVDC will not duplicate services, but will go far to prevent a shortfall of services within Davidson County. TVDC 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.”*

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, Davidson County will likely experience a 23-station deficit by CY2024
- The applicant adequately demonstrates that the proposed addition of 20 stations at TVDC after the relocation of 19 stations from TVDC to NDDC is needed in addition to the existing and approved stations in Davidson 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 20 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 36 stations upon completion of this project, Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7).

In Section Q Form H Staffing, page 103, 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	CY2020 FTE POSITIONS	PROJECTED FTE POSITIONS CY2023	PROJECTED FTE POSITIONS CY2024
RN	5.75	4.75	4.75
Patient Care Tech	13.25	10.00	10.75
Clinical Nurse Manager (DON)	1.00	1.00	1.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Dialysis Tech	1.00	1.00	1.00
Bio-med Technician	1.00	1.00	1.00
Clerical	1.00	1.00	1.00
<b>Total</b>	<b>25.00</b>	<b>20.75</b>	<b>21.50</b>

Source: Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section Q, page 104. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, page 101. In Section H, pages 57-59, 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 it bases its staffing on its experience providing dialysis services at the existing dialysis facility and 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 20 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 36 stations upon completion of this project, Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7).

**Ancillary and Support Services**

In the table in Section I, page 61, 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 62-65, 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 65-66, 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 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 20 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 36 stations upon completion of this project, Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7). 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 one additional station) 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 71, the applicant provides the historical payor mix during CY2020 for TVDC, as shown in the table below.

Primary Payor Source at Admission	Thomasville Dialysis Center CY2020					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	1	1%	0	0%	0	0%
Insurance *	8	7%	0	0%	0	0%
Medicare *	80	73%	0	0%	0	0%
Medicaid *	21	19%	0	0%	0	0%
Other	0	0%	0	0%	0	0%
<b>Total</b>	<b>110</b>	<b>100%</b>	<b>0</b>	<b>100%</b>	<b>0</b>	<b>100%</b>

\*Including any managed care plans

In Section L, page 72, the applicant provides the following comparison for TVDC and the population of the service area.

<b>Thomasville Dialysis 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	46.79%	51.10%
Male	53.21%	48.90%
Unknown	Not Available	0.00%
64 and Younger	55.05%	81.50%
65 and Older	44.95%	18.50%
American Indian	0.92%	0.80%
Asian	3.67%	1.60%
Black or African-American	39.45%	10.10%
Native Hawaiian or Pacific Islander	Not Available	0.10%
White or Caucasian	47.71%	79.40%
Other Race	7.34%	9.20%
Declined / Unavailable	0.92%	0.00%

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 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 74, the applicant states that during the last five years 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 75, 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.

Primary Payor Source at Admission	Thomasville Dialysis Center CY2024					
	In-center Dialysis		Home Hemodialysis		HH/PD Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	1	1%	0	0%	0	0%
Insurance *	8	7%	0	0%	0	0%
Medicare *	79	73%	0	0%	0	0%
Medicaid *	21	19%	0	0%	0	0%
Other	0	0%	0	0%	0	0%
Total	108	100%	0	100%	0	100%

Totals may not sum due to rounding

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1% of IC dialysis services will be provided to self-pay patients, 73% to Medicare recipients and 19% to Medicaid recipients.

On page 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 calculates a five-year average annual payor mix over TVDC's last five operating years

- The applicant states that the five-year average is strikingly similar to the payor mix for the last operating at TVDC; thus, the applicant bases TVDC'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, pages 77-78, 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 79, 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(b). 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 20 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 36 stations upon completion of this project, Project ID# G-11844-20 (relocate 12) and Project ID# G-12011-21 (relocate 7).

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 area: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.”* Thus, the service area for this facility consists of Davidson County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are three existing or approved dialysis facilities in Davidson County, all of which are owned and operated by WFUHS. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

<b>Davidson 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>
Lexington Dialysis Center of Wake Forest University	WFUHS	Lexington	42	72.62%
North Davidson Dialysis Center of Wake Forest University	WFUHS	Winston-Salem	0	0.00%
Thomasville Dialysis Center of Wake Forest University	WFUHS	Thomasville	32	85.94%

Source: 2021 SMFP, Table 9A.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 80, the applicant states:

*“WFUHS is the whole owner of the two existing dialysis facilities within Davidson County. This application requests to add back stations transferred to NDDC to serve patients who will remain at TVDC and/or those who will transfer in to TVDC after a county-wide facility rebalance. Because all facilities have common ownership, there will be no impact on competition in the service area.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 80, the applicant states:

*“The proposal will replace stations being transferred to NDDC at a well-utilized facility in an area of Davidson County with a large population of ESRD patients. The additional stations will mean Davidson County will not suffer a persistent station shortfall that will strain existing healthcare services. By adding back the 20 stations at TVDC, where they are needed and planning certification in conjunction with the transfer of 19 stations to NDDC health service resources will be maximized. The projected rise in treatment volumes due to convenience of care will result in a lower overall cost per treatment over time, making the proposed project more cost effective than the status quo.”*

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 80, the applicant states:

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

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 81, the applicant states:

*“The transfer out [relocation] of stations from TVDC to an underserved area of Davidson county 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. This project replaces the transferred [relocated] stations and adds a station to TVDC to serve patients who will remain and/or*

*transfer their care to TVDC due to a county-wide patient rebalance. Reductions in travel time, increased convenience of care, and enhanced access to care will reduce a financial burden on the patient and community resources, overall.”*

See also Section L and C of the application and any exhibits.

Considering all the information in the application, 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 it adequately demonstrates the following:

- the need the population to be served has for the proposal, the proposal would not result in an unnecessary duplication of existing and approved health services, and the reasonableness of projected revenues and operating costs which collectively results in a cost-effective proposal
- the quality of the care to be provided based on the applicant’s representations about how it will ensure the quality of continued services at TVDC and WFUHS’s record of providing quality care in the past
- medically underserved groups will have access to the proposed services based on the facility’s history and 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 105, 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 and two are approved but not certified.

In Section O, page 83, the applicant states that, during the 18 months immediately preceding the submittal of the application, standard level incidents related to quality of care (not resulting in immediate jeopardy) occurred at five facilities. The table on page 83 shows that the facilities were 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 C, page 28, and Section Q Form C, page 85, the applicant projects that TVDC will serve 105 in-center patients on 36 stations, or a rate of 2.9 ( $105 / 36 = 2.9$ )

in-center patients per station per week, as of the end of the first 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 C, pages 25-31, and Section Q, pages 85-86, 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.