

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 10, 2021

Findings Date: March 10, 2021

Project Analyst: Kim Meymandi

Team Leader: Lisa Pittman

Project ID #: K-11976-20

Facility: Roxboro Dialysis Center

FID #: 120225

County: Person

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Add no more than one station pursuant to Condition 2 of the facility need methodology for a total of no more than 38 stations upon project completion

### REVIEW CRITERIA

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

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

C

Total Renal Care of North Carolina, LLC (hereinafter referred to as “the applicant” or DaVita) proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 38 stations upon project completion.

#### **Need Determination (Condition 2)**

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, the county need methodology shows there is not a county need determination for additional dialysis stations in Person 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 2020 SMFP, if the utilization rate for the facility as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 75.68 percent or 3.03 patients per station per week, based on 112 in-center dialysis patients and 37 certified dialysis stations (112 patients / 37 stations = 3.03;  $3.03 / 4 = 75.68\%$ ).

As shown in Table 9E, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to five additional stations; thus, the applicant is eligible to apply to add up to five stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than one new station to the facility, which is consistent with the 2020 SMFP calculated facility need determination for up to five stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, pages 30-31 of the 2020 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 would promote safety and quality in Section B.5, pages 13-14; Section N, page 50, Section O, pages 52-53; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

**Promote Equitable Access** – The applicant describes how it believes the proposed project would promote equitable access in Section B.5(b), page 15; Section L, pages 45-48; Section N, page 50, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.5(c), page 15; Sections F and K, and Section N, page 50. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. 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 reasons:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 because the applicant adequately demonstrates how Roxboro Dialysis Center’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.

(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 one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 38 stations upon project completion.

### **Patient Origin**

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-*

*Mitchell-Yancey counties.*” Thus, the service area for this facility consists of Person County. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 19, the applicant provides the patient origin for in-center (IC) and peritoneal dialysis (PD) patients at Roxboro Dialysis Center for the last full operating year (CY2019), as summarized in the table below.

**Roxboro Dialysis Center Patient Origin - CY2019**

COUNTY	# IC PATIENTS	% IC Total	# PD Patients	% PD Total
Person	83.0	76.1%	3.0	37.5%
Caswell	11.0	10.1%	1.0	12.5%
Granville	2.0	1.8%	0.0	0.0%
Durham	1.0	0.9%	1.0	12.5%
Orange	3.0	2.8%	0.0	0.0%
Virginia	9.0	8.3%	3.0	37.5%
<b>Total</b>	<b>109.0</b>	<b>100.0%</b>	<b>8.0</b>	<b>100.0%</b>

Totals may not sum due to rounding

The following table summarizes projected patient origin for the second full operating year (CY2023) following project completion, as provided in Section C.3, page 20.

**Roxboro Dialysis Center Projected Patient Origin - CY2023**

COUNTY	# IC PATIENTS	% IC Total	# PD Patients	% PD Total
Person	85.0	76.6%	6.0	60.0%
Caswell	10.0	9.0%	1.0	10.0%
Granville	4.0	3.6%	0.0	0.0%
Durham	0.0	0.0%	0.0	0.0%
Orange	3.0	2.7%	0.0	0.0%
Virginia	9.0	8.1%	3.0	30.0%
<b>Total</b>	<b>111.0</b>	<b>100.0%</b>	<b>10.0</b>	<b>100.0%</b>

Totals may not sum due to rounding

In Section C, pages 20-24, the applicant provides the assumptions and methodology it used to project IC and PD patient origin. The applicant’s assumptions are reasonable and adequately supported, because they are based on the historical patient origin of Roxboro Dialysis Center.

**Analysis of Need**

In Section C.3, pages 20-22, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it begins projections with the IC patient census at Roxboro Dialysis as of August 31, 2020. On page 20, the applicant states that, on August 31,

2020, its IC patient census was comprised of 85 Person County patients and 26 patients from other North Carolina counties and other states.

- The applicant states that the Person County Five Year Average Annual Change Rate (AACR) published in Table 9C of the 2020 SMFP is -3.8%. However, the applicant states Roxboro Dialysis Center has experienced an average growth rate of -0.8% over the same five-year time period and in the first eight months of 2020 the facility has experienced a growth rate of 1.8%. This data is illustrated in the following table:

	# of IC Patients	% Change
12/31/2015	113	
12/31/2016	109	-3.5%
12/31/2017	106	-2.8%
12/31/2018	112	5.7%
12/31/2019	109	-2.7%
8/31/2020	111	1.8%

- The applicant states that given the facility's AACR for the past 5 years and the census count for the first eight months of 2020 it is reasonable and conservative to use a growth rate of 0.0% to project future utilization for the IC Person County patients.
- The applicant assumes the August 31, 2020 patients from outside Person County will continue to dialyze at Roxboro Dialysis Center but does not assume any growth in patients from those counties and adds them to the calculations when appropriate.
- The applicant states services will be offered as of December 31, 2021. Therefore, Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022 and OY2 is CY2023, January 1-December 31, 2023.

Projected Utilization

In-Center Projected Utilization

In Section C.3, page 21, and in Form C Utilization subsection of Section Q, the applicant provides the methodology used to project the patient census for OY1 and OY2, as summarized in the table below.

<b>Roxboro Dialysis Center Projected Utilization</b>		
	<b>IC Stations</b>	<b>IC Patients</b>
The applicant begins with the 111 patients dialyzing on 37 stations at the facility as of 8/31/2020.	37	111
The applicant projects Person County patient census forward four months to December 31, 2020 with no projected growth.		$85 \times 1.00 = 85$
The applicant adds 26 patients from counties other than Person County for a year-end census as of December 31, 2020.		$85 + 26 = 111$
The applicant projects the Person County patient census forward one year to December 31, 2021 with no projected growth.		$85 \times 1.00 = 85$
The applicant adds 26 patients from counties other than Person County for a year-end census as of December 31, 2021.		$85 + 26 = 111$
The project is projected to be certified on 1/1/2022. This is the station count at the beginning of OY1.	$37 + 1 = 38$	
The applicant projects the Person County patient census forward a year to December 31, 2022 with no projected growth.		$85 \times 1.00 = 85$
The applicant adds 26 patients from counties other than Person County for a year-end census as of December 31, 2022. This is the projected ending census for <b>Operating Year 1 (OY1)</b> .		$85 + 26 = 111$
The applicant projects the Person County patient census forward one year to December 31, 2023 with no projected growth.		$85 \times 1.00 = 85$
The applicant adds 26 patients from counties other than Person County for a year-end census as of December 31, 2023. This is the projected ending census for <b>Operating Year 2 (OY2)</b> .		$85 + 26 = 111$

The applicant projects to serve 111 in-center patients in OY1 and OY2. Thus, the applicant projects that Roxboro Dialysis Center will have a utilization rate of 73.02% or 2.9 patients per station per week ( $111 \text{ patients} / 38 \text{ stations} = 2.921 / 4 = 0.7302$  or 73.02%) in OY1 and OY2. The projected utilization of 2.9 patients per station per week at the end of OY1 and 2.9 patients per station per week at the end of OY2 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins the projections with the existing Person County patient census at Roxboro Dialysis Center as of August 31, 2020.

- The applicant projects IC utilization using no growth rate, which is conservative given the facility’s slightly negative five-year historical growth rate and 1.8 percent growth rate for the first eight months of 2020.
- The applicant assumes the patients residing outside of Person County will continue to dialyze at Roxboro Dialysis Center and are added to the projections without any future growth through the first two operating years of the project.
- The projected utilization rate by the end of OY1 and OY2 is above the minimum standard of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Peritoneal Dialysis Projected Utilization

- The applicant begins its utilization projections with the patient facility census on January 1, 2020. On page 22, the applicant states that, on January 1, 2020, its PD patient census was comprised of eight PD patients with three originating from Person County and the other five originating from other North Carolina counties and other states.
- The applicant assumes that the PD patient population will vary between seven and eight patients during the interim period and will increase by one patient per year during the period of growth in OY1 and OY2.
- The project is scheduled to begin offering services on January 1, 2022. OY1 is CY 2022. OY2 is CY 2023.

In Section C, page 22, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the PD patient census for OY1 and OY2, as summarized in the table below.

<b>Roxboro Dialysis Center PD Projected Utilization</b>	
Starting point of calculations is Roxboro Dialysis Center PD patients as of January 1, 2020.	8
The PD patient population of Roxboro Dialysis Center is projected forward by one year to December 31, 2020, at a loss of one patient per year.	8 - 1 = 7
The PD patient population of Roxboro Dialysis Center is projected forward by one year to December 31, 2021, at a growth rate of one patient per year.	7 + 1 = 8
The PD patient population of Roxboro Dialysis Center is projected forward by one year to December 31, 2022, at a growth rate of one patient per year (end of OY1).	8 + 1 = 9
The PD patient population of Roxboro Dialysis Center is projected forward by one year to December 31, 2023, at a growth rate of one patient per year (end of OY2).	9 + 1 = 10

The applicant provides a table to summarize the end of year census and average number of patients each year for the PD home-training program at Roxboro Dialysis Center as shown below.

PD patient projections	Start Date	# of patients beginning of year	# of patients end of year	Average # of patients in year
Interim Period	1/1/2020	8	7	7.5
Interim Period	1/1/2021	7	8	7.5
Operating Year 1	1/1/2022	8	9	8.5
Operating Year 2	1/1/2023	9	10	9.5

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

- The applicant begins the projections with the existing PD patient census at Roxboro Dialysis Center as of January 1, 2020.
- The applicant projects the home-training program at Roxboro Dialysis Center will increase by at least one patient per year during the period of growth, which is reasonable.

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

In Section C, page 24, the applicant states:

*“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or [disability]. We will serve patients regardless of ethnic or socioeconomic situation.*

*We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. ...*

*Roxboro Dialysis Center will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, disabled persons, elderly and other under-served persons.”*

On page 24, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table. The applicant states it assumes the estimated percentage for the medically underserved groups listed in the following table will be the same as its patient population in CY 2019 and projected patient population in CY 2023.

Medically Underserved Groups	% of Total Patients
Women	39.8%
People age 65 and older	47.8%



Medicare beneficiaries	89.9%
Medicaid recipients	2.8%
American Indian	0.0%
Asian	0.0%
Black or African-American	66.4%
Native Hawaiian or Pacific Islander	0.0%
Other Race	0.0%

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 currently serves the needs of medically underserved groups that utilize ESRD services.
- The applicant has policies in place to prevent discrimination.

### **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 one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 38 stations upon project completion.

In Section E, page 30, 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:

- *Maintain the status quo* - The applicant states that maintaining the status quo is not an effective alternative due to the growth rate at the facility.
- *Relocate stations from another DaVita facility* – The applicant states that Roxboro Dialysis Center is the only dialysis facility operated by the applicant in Person County. While the applicant operates facilities in one of the contiguous counties, the applicant states they cannot relocate stations to Roxboro Dialysis Center because the 2020 SMFP indicates that there is a surplus of stations in Person County.

On page 30, the applicant states that its proposal is the most effective alternative because adding one station will help meet the need for services at Roxboro Dialysis Center.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC (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 2020 SMFP, the certificate holder shall develop no more than one additional in-center dialysis station for a total of no more than 38 in-center stations at Roxboro Dialysis Center upon completion of this project.**

**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 May 1, 2021. The second progress report shall be due on August 1, 2021 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 one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 38 stations upon project completion.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant provides a table to illustrate projected capital cost of the project, as shown in the table below:

ITEM	COST
Medical Equipment	\$14,850
Non-Medical Equipment	\$2,198
Furniture	\$1,400
<b>Total</b>	<b>\$18,448</b>

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 32, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

**Availability of Funds**

In Section F, page 31, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

Type	DaVita	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$18,448	\$18,448
Bonds	\$ 0	\$ 0
Other (Specify)	\$ 0	\$0
<b>Total Financing</b>	<b>\$18,448</b>	<b>\$18,448</b>

\* OE = Owner's Equity

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

- Exhibit F contains the Consolidated Financial Statements for the year ending December 31, 2019 that shows DaVita, Inc., parent company to Total Renal Care of North Carolina, LLC currently has \$1.1 billion in cash and cash equivalents and \$17 billion in total assets.

**Financial Feasibility**

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

**Roxboro Dialysis Center Projected Revenue and Operating Expenses**

	OY 1 CY 2022	OY 2 CY 2023
Total In-Center Treatments	17,710	17,858
Total Gross Revenue (charges)	\$4,966,767	\$5,005,688
Total Net Revenue	\$4,654,364	\$4,690,671
Average Net Revenue per Treatment	\$263	\$263
Total Operating Expenses (costs)	\$3,918,244	\$3,980,665
Average Operating Expense per Treatment	\$221.25	\$222.91
<b>Net Income / Profit</b>	<b>\$736,120</b>	<b>\$710,005</b>

\*Source: application Form F.2, Section Q  
 Numbers may not sum due to rounding

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 discussion regarding projected utilization found in Criterion (3) 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 based on the following:

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

### C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 38 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Person County. Facilities may serve residents of counties not included in their service area.

The applicant operates the only dialysis center in Person County. The following table shows the existing and approved dialysis facilities in Person County, from Table 9B, page 161 of the 2020 SMFP:

**Person County Dialysis Facilities**

<b>DIALYSIS FACILITY</b>	<b>CERTIFIED STATIONS 12/31/18</b>	<b># IN-CTR PATIENTS</b>	<b>PATIENTS / STATION</b>	<b>PERCENT UTILIZATION</b>
Roxboro Dialysis Center	37	112	3.03	75.68%
<b>Total</b>	<b>37</b>	<b>112</b>		

Source: 2020 SMFP, Table 9B, page 163.

In Section G.2, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Person County. The applicant states:

*“While adding stations at this facility does increase the number of stations in Person County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”*

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a facility need determination in the 2020 SMFP at Roxboro Dialysis Center for five dialysis stations. The applicant proposes to add one station.
- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing or approved dialysis stations.

**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 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 one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 38 stations upon project completion.

In Section Q Form H Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Roxboro Dialysis Center, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 8/2020	OY1 (1/1/2022 to 12/31/2022)	OY2 (1/1/2023 to 12/31/2023)
Administrator	1.00	1.00	1.00
RNs	4.75	4.75	4.75
Home Training Nurse	0.50	0.50	0.50
Technicians (PCT)	14.00	14.25	14.25
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Admin/Business Office	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
<b>TOTAL</b>	<b>23.75</b>	<b>24.00</b>	<b>24.00</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 37-38, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 38, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant projects an increase in the FTE staffing positions necessary to accommodate the proposed increase in healthcare services at Roxboro Dialysis Center.
- The increased costs are accounted for in the budgeted Operating Costs.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.
- A letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services is provided.

**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 described above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 38 stations upon project completion.

**Ancillary and Support Services**

In Section I, the applicant identifies the necessary ancillary and support services for the proposed services. On page 39, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.

<b>ANCILLARY AND SUPPORT SERVICES</b>	
<b>SERVICES</b>	<b>PROVIDER</b>
Self-care training	On site
Hemodialysis training & follow-up	Durham West Dialysis
Peritoneal dialysis training & follow-up	On site
Psychological counseling	On site by RN
Isolation – hepatitis	On site
Nutritional counseling	On site by RD
Social Work services	On site by MSW
Acute dialysis in an acute care setting	Person Memorial Hospital
Emergency care	Person Memorial Hospital
Blood bank services	Person Memorial Hospital
Diagnostic and evaluation services	Person Memorial Hospital
X-ray services	Person Memorial Hospital
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Person Memorial Hospital
Vascular surgery	Person Memorial Hospital
Transplantation services	Duke University Medical Center
Vocational rehabilitation & counseling	Roxboro Vocational Rehabilitation
Transportation	Person Area Transportation

The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

**Coordination**

In Section I, pages 39-40, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides



supporting documentation of established relationships with local health care providers and for referrals. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has numerous years of experience serving the needs of dialysis patients.
- The applicant has established relationships and agreements with the community health care and ancillary service providers and where dialysis patients can receive appropriate referrals for necessary services and care related to their condition.

### **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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 38 stations upon project completion.

In Section K, page 42, the applicant states that the project does not involve the construction of new space or significant up-fit of the current space. The applicant states the only necessary additions to the current space for the proposed project are furniture, fixtures and equipment. The facility floor plan is included in Exhibit K-2.

On page 42, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 43, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 43, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs

identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 46, the applicant provides the historical payor mix for Roxboro Dialysis Center during the last full operating year (CY2019) for its existing services, as shown in the table below.

**Roxboro Dialysis Center  
 Historical Payor Mix CY 2019**

Payor Category	In-Center		HOME HEMODIALYSIS		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.0	0.9%	0.0	0.0%	0.0	0.0%
Insurance*	3.0	2.8%	0.0	0.0%	0.0	0.0%
Medicare*	98.0	89.9%	0.0	0.0%	7.0	80.0%
Medicaid*	3.0	2.8%	0.0	0.0%	0.0	0.0%
Miscellaneous (Incl. VA)	4.0	3.7%	0.0	0.0%	1.0	12.5%
<b>Total</b>	<b>109.0</b>	<b>100.00%</b>	<b>0.0</b>	<b>0.0%</b>	<b>8.0</b>	<b>100.00%</b>

\*Including any managed care plans

In Section L, page 45, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full OY	Percentage of the Population in the Service Area*
Female	39.8%	51.7%
Male	60.2%	48.3%
Unknown	0.0%	0.0%
64 and Younger	52.2%	79.9%
65 and Older	47.8%	20.1%
American Indian	0.0%	0.9%
Asian	0.0%	0.4%
Black or African-American	66.4%	26.8%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	33.6%	70.0%
Other Race	0.0%	1.9%
Declined / Unavailable	-	-

\*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

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, the applicant states in Section L, page 46, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 46, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 46, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Roxboro Dialysis Center  
 Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.0	0.9%	0.0	0.0%	0.0	0.0%
Insurance*	3.1	2.8%	0.0	0.0%	0.0	0.0%
Medicare*	99.8	89.9%	0.0	0.0%	8.8	87.5%
Medicaid*	3.1	2.8%	0.0	0.0%	0.0	0.0%
Miscellaneous (incl. VA)	4.1	3.7%	0.0	0.0%	1.3	12.5%
<b>Total</b>	<b>111</b>	<b>100.0%</b>	<b>0.0</b>	<b>0.0%</b>	<b>10.0</b>	<b>100.0%</b>

Totals may not sum due to rounding

\*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 0.9% of in-center dialysis services will be provided to self-pay patients, 89.9% to Medicare patients, and 2.8% to Medicaid patients. In addition, 87.5% and 0.0% of PD services will be provided to Medicare and Medicaid patients, respectively.

On page 46, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix and treatment volumes of Roxboro Dialysis Center.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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.5., pages 47-48, 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 49, 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-2.

### **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 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 38 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee-Clay-Graham counties and Avery-*

*Mitchell-Yancey counties.*” Thus, the service area for this facility is Person County. Facilities may serve residents of counties not included in their service area.

According to Table 9B of the 2020 SMFP, there is one existing or approved dialysis facility in Person County, and it is owned and operated by DaVita. Information on the dialysis facility, from Table 9B of the 2020 SMFP, is provided in the table below:

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CTR PATIENTS	PATIENTS / STATION	PERCENT UTILIZATION
Roxboro Dialysis Center	37	112	2.54	75.68%
<b>Total</b>	<b>37</b>	<b>112</b>		

Source: 2020 SMFP, Table 9B, page 161.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 50, the applicant states:

*“The expansion of Roxboro Dialysis Center will have no effect on competition in Person County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita. ”*

Regarding the impact of the proposal on cost effectiveness, quality, and access to medically underserved groups in Section N, page 50, the applicant states:

*“As discussed in Section B, DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients. The expansion of Roxboro Dialysis Center will enhance accessibility to dialysis for current and projected patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”*

See also Sections B, C, F, L, N, O and Q 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 projected revenues and operating costs are reasonable, which collectively results in a cost-effective proposal.

- The quality of care to be provided is 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.
- 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 A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O.2, pages 51-52, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident related to quality of care that resulted in a finding of "*Immediate Jeopardy*" occurred in one DaVita facility; Waynesville Dialysis Center. The applicant states that a plan of correction was prepared and accepted, and that Waynesville Dialysis Center is currently back in compliance. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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



center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services. The specific criteria are discussed below.

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following *certification* of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.
- NA- Roxboro Dialysis Center is an existing facility. Therefore, this Rule 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 21, and Form C in Section Q, the applicant projects that Roxboro Dialysis Center will serve 111 in-center patients on 38 stations, or a rate of 2.9 patients per station per week or 73.0% ( $111 / 38 = 2.921/4 = 0.7302$  or 73.0%), as of the end of the first operating year (CY2022) following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- C- In Section C, pages 20-21, in Section Q, Form C, the applicant provides the assumptions and methodology it used to project utilization of the facility.