

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 22, 2021

Findings Date: January 22, 2021

Project Analyst: Misty L. Piekaar-McWilliams

Assistant Chief: Lisa Pittman

Project ID #: F-11924-20

Facility: Dialysis Care of Rowan County

FID #: 944673

County: Rowan

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 34 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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, which is the parent company’s name) 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 34 stations upon project completion. Dialysis Care of Rowan County provides in-center (IC) dialysis as well as a peritoneal dialysis (PD) program.

Need Determination

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, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Rowan 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 dialysis center 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 Dialysis Care of Rowan County on page 162 of the 2020 SMFP is 90.52 percent or 3.6206 patients per station per week, based on 105 in-center dialysis patients and 29 certified dialysis stations (105 in-center patients / 29 dialysis stations = 3.6206; $3.6206 / 4 = 90.52\%$ (percentage is rounded up)).

As shown in Table 9E, page 173 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the proposed number of dialysis stations needed at Dialysis Care of Rowan County is up to one (1) additional dialysis station; thus, the applicant is eligible to apply to add up to one (1) dialysis station pursuant to the facility need methodology.

The applicant proposes to add no more than one (1) new dialysis station to Dialysis Care of Rowan County; 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 which is applicable to this review. *Policy GEN-3: Basic Principles*, on 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 will promote safety and quality in Section B, pages 13-14; Section N, page 49; Section O, pages 51-52; and referenced exhibits. The information provided by the applicant is reasonable and adequately 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, pages 14-15; Section C, pages 23-24; Section L, pages 44-47; Section N, page 49; and referenced exhibits. The information provided by the applicant is reasonable and adequately 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 15; Section F, pages 30-34; Section N, page 49; 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 safety and quality, equitable access, and maximum healthcare 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 reasons:

- The application is consistent with Condition 2 of the facility need methodology for dialysis stations.
- The application is consistent with Policy GEN-3.

- (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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

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 34 stations upon project completion.

The following table, summarized from page 7 of the application, shows the current and projected number of dialysis stations at Dialysis Care of Rowan County upon project completion.

Dialysis Care of Rowan County

# of Stations	Description	Project ID #
33	Total # of existing certified stations as reported in the SMFP in effect on the day the review will begin	
1	# of stations to be added as part of this project	F-11924-20
0	# of stations to be deleted as part of this project	
0	# of stations previously approved to be added but not yet certified	
0	# of stations previously approved to be deleted but not yet certified	
0	# of stations proposed to be added in an application still under review	
0	# of stations proposed to be deleted in an application still under review	
34	Total # of stations upon completion of all facility projects	

NOTE: Dialysis Care of Rowan County (Project ID # F-11604-18) added 4 dialysis stations for a total of 33 dialysis stations.

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 and Graham counties and Avery, Mitchell, and Yancey counties.*” Dialysis Care of Rowan County is in Rowan County. Thus, the service area for this facility consists of Rowan County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin.

In Section C.2, page 19, the applicant provides the patient origin for Dialysis Care of Rowan County IC, HH and PD patients as of December 31, 2019, as summarized in the table below.

**Dialysis Care of Rowan County
 1/1/2019 to 12/31/2019**

COUNTY	# OF IC PATIENTS	% IC Total	# of HH Patients	% HH Total	# of PD Patients	% PD Total
Rowan	107	96.4%	0.0	0.0%	29	76.32%
Cabarrus	2	1.8%	0.0	0.0%	0	0.00%
Davidson	0	0.0%	0.0	0.0%	2	5.26%
Davie	0	0.0%	0.0	0.0%	4	10.53%
Iredell	0	0.0%	0.0	0.0%	2	5.26%
Stanly	0	0.0%	0.0	0.0%	1	2.63%
Other States	2	1.8%	0.0	0.0%	0	0.00%
Total	111	100.0%	0	0%	38	100.00%

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

**Dialysis Care of Rowan County
 1/1/2023 to 12/31/2023**

COUNTY	# OF IC PATIENTS	% IC Total	# of HH Patients	% HH Total	# of PD Patients	% PD Total
Rowan	129	97.0%	0.0	0.0%	33	78.57%
Cabarrus	2	1.5%	0.0	0.0%	0	0.00%
Davidson	0	0.0%	0.0	0.0%	2	4.76%
Davie	0	0.0%	0.0	0.0%	4	9.52%
Iredell	0	0.0%	0.0	0.0%	2	4.76%
Stanly	0	0.0%	0.0	0.0%	1	2.38%
Other States	2	1.5%	0.0	0.0%	0	0.00%
Total	133	100.0%	0	0%	42	100.00%

Totals may not sum due to rounding

In Section C, pages 20-22, and the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant states that the in-center and peritoneal patient origin is based upon the December 2019 Data Collection Form for ESRD Facilities submitted by Dialysis Care of Rowan County. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 22, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“Section B, Question 2 clearly outlines the need that the population to [be]served, the in-center patients of DC Rowan County, has for the 1-station expansion proposed in this application. This application does not call for any changes to home hemo or PD services at DC Rowan County (Dialysis Care of Rowan County).”

Section B, Question 2 summarizes the facility need for Dialysis Care of Rowan County, as stated in the 2020 SMFP, which permits Dialysis Care of Rowan County to add no more than one (1) dialysis station.

The information is reasonable and adequately supported for the following reasons:

- According to the 2020 SMFP, as of December 31, 2018, Dialysis Care of Rowan County was operating at a rate of 3.6206 patients per station per week, or 90.52 percent of capacity.
- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology. The discussion regarding the need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant projects a utilization rate of 3.765 ($128/34 = 3.765$) in-center patients per station per week dialyzing at Dialysis Care of Rowan County as of the end of the first 12 months of operation following certification of the additional stations which exceeds the performance standards 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 additional stations as set forth in the Performance Standards in Rule 10A NCAC 14C .2203.

Projected Utilization

In Center Patients

In Section C, pages 19-22, and in Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table.

DIALYSIS CARE OF ROWAN COUNTY IN-CENTER PATIENTS

	IC Stations	IC Patients
The applicant begins with the 111 patients dialyzing on 33 stations at the facility as of 1/1/2020.	33	111
The facility's Rowan County patient census is projected forward a year to 12/31/2020 and is increased by the Five Year Average Annual Change Rate (AACR) of 4.9% for Rowan County.		$107 \times 1.049 = 112.2430$
The 4 patients from outside Rowan County are added to the facility's census. This is the ending census as of 12/31/2020.		$112.2430 + 4 = 116.24$
The facility's Rowan County patient census is projected forward a year to 12/31/2021 and is increased by 4.9% (Five Year AACR for Rowan County).		$112.24 \times 1.049 = 117.7429$
The 4 patients from outside Rowan County are added to the facility's census. This is the ending census as of 12/31/2021.		$117.74 + 4 = 121.74$
The proposed project is projected to be certified on 1/1/2022. This is the station count at the beginning of operating year 1 (OY1).	$33 + 1 = 34$	
The facility's Rowan County patient census is projected forward a year to 12/31/2022 and is increased by 4.9% (Five Year AACR for Rowan County).		$117.4 \times 1.049 = 123.5123$
The 4 patients from outside Rowan County are added to the facility's census. This is the ending census as of OY1.		$123.51 + 4 = 127.51$
The facility's Rowan County patient census is projected forward a year to 12/31/2023 and is increased by 4.9%.		$123.51 \times 1.049 = 129.5644$
The 4 patients from outside Rowan County are added to the facility's census. This is the ending census as of operating year 2 (OY2).		$129.56 + 4 = 133.56$

In both Section C, pages 19-22, and Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).

- The applicant begins its utilization projections by using the Dialysis Care of Rowan County patient census as of January 1, 2020, which was 111 total IC patients: 107 Rowan County patients, two (2) Cabarrus County patient, and two (2) patients residing in other states than North Carolina.
- The Cabarrus County patients and patients who reside in other states than North Carolina will be carried forward into projections of future patient census; however, the applicant does not project any growth for the Cabarrus County patients or patients who reside in other states than North Carolina.
- The applicant projects the facility patients who reside in Rowan County will grow at the Five Year AACR for Rowan County, 4.9%, as stated in Table 9C: ESRD Dialysis Station Need Determinations by Planning Area, page 168, of the 2020 SMFP.

At the end of OY1 (CY2022) Dialysis Care of Rowan County is projected to serve 127.51 in-center patients on 34 stations; and at the end of OY2 (CY2023) the facility is projected to serve 133.56 in-center patients on 34 stations.

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

- OY1: 3.75 patients per station per week, or 93.75% utilization [$127.51 / 34 = 3.75$; $3.75 / 4 = 0.9375$ or 93.75%]. Note, the applicant rounded up to 128 patients and, thus, projected 3.765 patients per station per week or 94.1 percent utilization.
- OY 2: 3.92 patients per station per week, or 98% utilization [$133.56 \text{ patients} / 34 \text{ stations} = 3.92$; $3.92 / 4 = 0.98$ or 98%]. Note, the applicant rounded up to 134 patients and, thus, projected 3.941 patients per station per week or 98.5 percent utilization.

The projected utilization of 3.75 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 4.9 percent for Rowan County patients which reflects the Rowan County Five Year AACR as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its Cabarrus patients or for its patients residing in other states than North Carolina.
- The applicant demonstrated that the existing and approved stations are inadequate to serve the current and projected patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Peritoneal Patients

In both Section C, pages 21-22, and Section Q, Form C, the applicant provides the assumptions and methodology used to project PD utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).
- The applicant begins its utilization projections by using the Dialysis Care of Rowan County PD patient census as of December 31, 2019, which was:
 - 38 total PD patients: 29 Rowan County patients and nine (9) patients from outside the health service area (Davidson, Davie, Iredell and Stanly Counties)
- The non-Rowan County PD patients will be carried forward into projections of future patient census; however, the applicant does not project any growth of the non-Rowan County PD patients.
- The applicant projects the facility patients who reside in Rowan County will grow at the Five Year AACR for Rowan County, 4.9%, as stated in Table 9C: ESRD Dialysis Station Need Determinations by Planning Area, page 168, of the 2020 SMFP.

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 4.9 percent for Rowan County patients which reflects the Rowan County Five Year AACR as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its non-Rowan PD patients.

Access

In Section C.7, page 23, 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 handicap. 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. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need. DC of Rowan County 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.”

In Section C.7, page 23, the applicant further states,

“It is reasonable to assume that an estimated percentage of total patients for each group during OY2 would be similar to the percentage reported in Section L, Question 1 and Question 3 for the existing facility.”

In Section L.1, page 44, the applicant provides the following percentages for sex, age, and ethnicity for Dialysis Center of Rowan County.

	Percentage of Total Patients Served (All Modalities Combined)	Percentage of the Population of the Service Area
Female	44.4%	50.6%
Male	55.6%	49.4%
Unknown	0.0%	0.0%
64 and Younger	52.9%	82.1%
65 and Older	47.1%	17.9%
American Indian	0.7%	0.6%
Asian	0.7%	1.2%
Black or African-American	58.2%	16.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	34.6%	79.4%
Other Race	5.9%	1.8%
Declined / Unavailable		

In Section L, page 45, the applicant provides the historical payor mix for Dialysis Care of Rowan County patients during the last full operating year (CY2019) for the proposed services, as shown in the table below.

**Dialysis Care of Rowan County
 Historical Payor Mix CY 2019**

Payor Source	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.0	0.0%	1.0	2.6%
Insurance*	8.0	7.2%	0.0	0.0%	6.0	15.8%
Medicare*	85.0	76.6%	0.0	0.0%	27.0	71.1%
Medicaid*	6.0	5.4%	0.0	0.0%	1.0	2.6%
Miscellaneous (Incl. VA)	12.0	10.8%	0.0	0.0%	3.0	7.9%
Total	111	100.0%	0	0.0%	38	100.0%

*Including any managed care plans

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.

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 the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payer mix) and adequately supports its assumptions.

- (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, handicapped persons, 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 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 34 stations upon project completion.

In Section E, page 29, 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 maintaining the status quo would not be responsive to the growth of the patient census; therefore, this is not an effective alternative.

- Relocate Stations from Another DaVita Facility: the applicant states of the three (3) DaVita facilities in Rowan County, one is operating at less than 75% capacity. Relocating stations from Spencer Dialysis (the facility with less than 75% capacity) would negatively impact the patients served by this facility, given that this is a new facility with 10 stations.

On page 29, the applicant states its proposal is the most effective alternative because the growth of the patient census requires the facility to add stations.

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 application is 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 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. Dialysis Care of Rowan County (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 1 additional in-center dialysis station for a total of no more than 34 in-center stations at Dialysis Care of Rowan County 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 fourth month. The first progress report shall be due on June 1, 2021. The second progress report shall be due on October 1, 2021 and so forth.

4. Dialysis Care of Rowan County 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

Dialysis Care of Rowan County 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 34 stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant states the project will incur capital costs of \$12,598.

In Section F, pages 31-33, the applicant states there are no projected working capital costs because it is an existing facility that is already operational.

Availability of Funds

In Section F, page 30, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Dialysis Care of Rowan County	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$12,598	\$12,598
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$12,598	\$12,598

* OE = Owner's Equity

Exhibit F-2 contains a letter dated July 31, 2020, from the Chief Accounting Officer for DaVita Kidney Care, parent company to Total Renal Care of North Carolina, LLC, authorizing the use of accumulated reserves for the capital needs of the project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
Dialysis Care of Rowan County	Full Fiscal Year 1 CY 2022	Full Fiscal Year 2 CY 2023
Total Treatments	24,472	25,496
Total Gross Revenues (Charges)	\$8,549,035	\$8,898,313
Total Net Revenue	\$8,063,671	\$8,392,636
Average Net Revenue per Treatment	\$329.51	\$329.18
Total Operating Expenses (Costs)	\$4,177,797	\$4,322,128
Average Operating Expense per Treatment	\$170.72	\$169.53
Net Income/Profit	\$3,885,874	\$4,070,508

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 because 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

Dialysis Care of Rowan County 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 34 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 and Graham counties and Avery, Mitchell, and Yancey counties.” Dialysis Care of Rowan County is in Rowan county. Thus, the service area for this facility consists of Rowan County. Facilities may serve residents of counties not included in their service area.

According to Table 9B of the 2020 SMFP, the applicant operates three dialysis centers in Rowan County. Information from Table 9B of the 2020 SMFP, is provided below:

Rowan County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	CON Issued Not Certified	In-Center Patients	Percent Utilization
Dialysis Care of Kannapolis	30	-8	100	83.33%
Dialysis Care of Rowan County	29	0	105	90.52%
Spencer Dialysis	10	0	19	47.50%

Source: 2020 SMFP, Table 9B, page 162.

In Section G, page 35, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Rowan County. The applicant states the additional stations are needed to support the growing patient census at the facility. The applicant also states the stations are for patients being served by this facility, not for patients being served by another provider.

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, as calculated using the methodology in the 2020 SMFP, for the proposed dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

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 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

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

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 12/31/2019	1 st Full Operating Year (1/1/2022 to 12/31/2022)	2nd Full Operating Year (1/1/2023 to 12/31/2023)
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	4.25	4.25	4.25
Licensed Practical Nurses(LPNs)	0.00	0.00	0.00
Home Training Nurse	1.00	1.00	1.00
Technicians (PCT)	12.50	13.00	13.00
Medical Records	0.00	0.00	0.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Housekeeping	0.00	0.00	0.00
Maintenance	0.00	0.00	0.00
Admin./Business Office	1.00	1.00	1.00
Other: Biomedical Technician	0.50	0.50	0.50
TOTAL	22.25	22.75	22.75

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, page 36, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 37, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director indicating his support for the proposed project and his intent to continue serving as medical director for the facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

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

In Section I, page 38, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

DIALYSIS CARE OF ROWAN COUNTY ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	On Site
Home Hemodialysis training	Referral to DC Kannapolis
Peritoneal dialysis training	On Site
Isolation – Hepatitis B	On Site
Psychological counseling	On site by RN
Nutritional counseling	On site by RD
Social work services	On site by MSW
Laboratory services	DaVita Laboratory Services, Inc.
Acute dialysis in an acute care setting	Rowan Medical Center
Emergency care	Rowan Medical Center
Blood bank services	Rowan Medical Center
Diagnostic and evaluation services	Rowan Medical Center
X-ray services	Rowan Medical Center
Pediatric nephrology	Rowan Medical Center
Vascular surgery	Rowan Medical Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation counseling & services	NC DHHS Division of Vocational Rehab Services
Transportation	Rowan Transit System (RTS)

In Section I, pages 38-39, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

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.

C

In Section K, page 41, the applicant states that the project does not involve renovating existing space. Line drawings are provided in Exhibit K-2.

On page 41, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 42, 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.

In Section K, pages 42, 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
- 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.

- (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 handicapped persons, 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 45, the applicant provides the historical payor mix for Dialysis Care of Rowan County patients during the last full operating year (CY2019) for the proposed services, as shown in the table below.

**Dialysis Care of Rowan County
 Historical Payor Mix CY 2019**

Payor Source	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.0	0.0%	1.0	2.6%
Insurance*	8.0	7.2%	0.0	0.0%	6.0	15.8%
Medicare*	85.0	76.6%	0.0	0.0%	27.0	71.1%
Medicaid*	6.0	5.4%	0.0	0.0%	1.0	2.6%
Miscellaneous (Incl. VA)	12.0	10.8%	0.0	0.0%	3.0	7.9%
Total	111	100.0%	0	0.0%	38	100.0%

*Including any managed care plans

In Section L, page 44, the applicant provides the following comparison.

	Percentage of Total Patients Served (All Modalities Combined)	Percentage of the Population of the Service Area
Female	44.4%	50.6%
Male	55.6%	49.4%
Unknown	0.0%	0.0%
64 and Younger	52.9%	82.1%
65 and Older	47.1%	17.9%
American Indian	0.7%	0.6%
Asian	0.7%	1.2%
Black or African-American	58.2%	16.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	34.6%	79.4%
Other Race	5.9%	1.8%
Declined / Unavailable	0.0%	0.0%

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 handicapped persons 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.2(a), page 45, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L.2(c), page 45, 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.

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.

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

C

In Section L, page 46, 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.

**Dialysis Care of Rowan County
 Projected Payor Mix CY 2023**

Payor Source	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.0	0.0%	1.1	2.6%
Insurance*	9.7	7.2%	0.0	0.0%	6.6	15.8%
Medicare*	102.6	76.6%	0.0	0.0%	29.8	71.1%
Medicaid*	7.2	5.4%	0.0	0.0%	1.1	2.6%
Other (Incl. VA)	14.5	10.8%	0.0	0.0%	3.3	7.9%
Total	134	100.0%	0	0.0%	42	100.0%

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 0.0% of IC services will be provided to self-pay patients, 76.6% to Medicare patients, and 5.4% to Medicaid patients.

On page 46, 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 because the projected payor mix is based on the historical payor mix and treatment volumes of Dialysis Care of Rowan County.

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 46-47, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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.

- (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 48, 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

Dialysis Care of Rowan County 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 34 stations upon project completion.

On page 113, the 2020 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-Graham counties and Avery-Mitchell-Yancey counties.*” Dialysis Care of Rowan County is in Rowan County. Thus, the service area for this application is Rowan County. Facilities may serve residents of counties not included in their service area.

According to Table 9B of the 2020 SMFP, the applicant operates three dialysis centers in Rowan County. Information from Table 9B of the 2020 SMFP, is provided below:

Rowan County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	CON Issued Not Certified	In-Center Patients	Percent Utilization
Dialysis Care of Kannapolis	30	-8	100	83.33%
Dialysis Care of Rowan County	29	0	105	90.52%
Spencer Dialysis	10	0	19	47.50%

Source: 2020 SMFP, Table 9B, page 162.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 49, the applicant states:

“The expansion of DC Rowan County will have no effect on competition in Rowan 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. The expansion of DC of Rowan County will enhance accessibility to dialysis for our 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.”

Regarding the impact of the proposal on cost effectiveness, quality, and access to medically underserved groups, in Section N.2, page 49, 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 DC Rowan County 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.”

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 (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections L and N of the application and any exhibits)

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. The applicant identifies over 100 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

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.
- (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 .2203 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 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- Dialysis Care of Rowan County 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, pages 19-22, and in Section Q, Form C, the applicant projects that Dialysis Care of Rowan County will serve 127.51 in-center patients on 34 stations, or a rate of 3.09 patients per station per week or 77.25% utilization rate ($127.51 / 34 = 3.75 / 4 = 0.9375$ or 93.75%), 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. See the discussion regarding projected utilization in Criterion (3) which 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 19-22, and in Section Q, Form C, the applicant provides the assumptions and methodology it used to project utilization of the facility.