

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 23, 2020

Findings Date: July 23, 2020

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Lisa Pittman

Project ID #: F-11889-20

Facility: Spencer Dialysis

FID #: 160495

County: Rowan

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 4 dialysis stations pursuant to facility need for a total of no more than 14 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 either (“TRC”) or the (“applicant”), proposes to add no more than 4 dialysis stations to the Spencer Dialysis facility pursuant to facility need for a total of no more than 14 stations upon project completion. DaVita, Inc. is the ultimate parent company of TRC.

Spencer Dialysis provides in-center (IC) dialysis, however, currently the facility does not offer either a peritoneal dialysis (PD) program or a home hemodialysis (HH) 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 1 of the facility need methodology in the 2020 SMFP if the facility is a “new” facility or a “small” facility (or both) as defined in the 2020 SMFP, and if the facility’s current reported utilization is at least 75 percent, or 3.0 patients per station in a given week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. In Section B, page 11, the applicant states it was serving 33 in-center patients on 10 certified stations on its current reporting date of December 31, 2019. This is a utilization rate of 82.5%, or 3.3 patients per station per week. According to Table 9B on page 162 of the 2020 SMFP, Spencer Dialysis is defined as both a new and a small facility.

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of 6 additional stations are needed at this facility, as illustrated in the following table.

**Spencer Dialysis  
Facility Need Methodology**

<b>1</b>	# of In-center Patients as of the Current Reporting Date	33
<b>2</b>	# of In-Center Patients as of the Previous Reporting Date	28
<b>3</b>	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	5
<b>4</b>	Divide Line 3 by Line 2 (6-month Growth Rate)	0.18
<b>5</b>	Multiply Line 4 by 2 (Annual Growth Rate)	0.36
<b>6</b>	Multiply Line 5 by Line 1 (New Patients)	11.79
<b>7</b>	Add Line 6 to Line 1 (Total Patients)	44.79
<b>8</b>	Divide Line 7 by 2.8 (Total # of Stations Needed)	15.99
<b>9</b>	# of Stations as of the Current Reporting Date ^	10.00
<b>10</b>	Subtract Line 9 from Line 8 (Additional Stations Needed)	5.99

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Spencer Dialysis is 6, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “*The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.*” The applicant proposes to add 4 new stations; therefore, the application is consistent with Condition 1 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, pages 49-50, 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 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), pages 14-15; Section L, pages 44-47; Section N, pages 49-50 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; and Section N, pages 49-50. 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 does not propose to develop more dialysis stations than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 because the applicant adequately demonstrates how Spencer Dialysis’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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

TRC proposes to add no more than 4 dialysis stations to the Spencer Dialysis facility pursuant to facility need for a total of no more than 14 stations upon project completion.

**Patient Origin**

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.*” Spencer Dialysis 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.

The following table illustrates current and projected patient origin for Spencer Dialysis.

County	Current (CY2019)		Third Full FY of Operation following Project Completion (CY2023)	
	Patients	% of Total	Patients	% of Total
Rowan	22	66.7%	32	74.4%
Davidson	10	30.3%	10	23.3%
Stanly	1	3.0%	1	2.3%
Total	33	100.0%	43	100.0%

Source: Section C, pages 19-20.

In Section C.3(b), pages 20-21, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C, page 21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- The applicant references Section B, Question 3 of its application, and the facility need table, wherein it demonstrates that up to 6 additional dialysis stations are needed at Spencer Dialysis based on application of the facility need methodology and the proposed application is only for 4 additional dialysis stations.

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

- The applicant states it was serving 33 in-center patients on 10 certified stations on its current reporting date of December 31, 2019. This is a utilization rate of 82.5%, or 3.3 patients per station per week. [ $33/10 = 3.3$ ;  $3/3/4 = 0.825$  or 82.5%]
- The applicant demonstrates the need for additional stations at Spencer Dialysis based on its existing and future patient population.
- According to Table 9B on page 162 of the 2020 SMFP, Spencer Dialysis is defined as both a new and a small facility and thus Condition 1 of the facility need methodology applies.
- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 1 of the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

### **Projected Utilization**

In Section C, page 21 and in Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table.

	<b>In-Center Patients</b>
The applicant begins with the 22 Rowan County patients dialyzing on 10 stations at the facility as of 12/31/2019.	22
The facility's Rowan County patient census is projected forward a year to 12/31/2020 and is increased by 10.0%.	$22 \times 1.10 = 24.2$
The facility's Rowan County patient census is projected forward a year to 12/31/2021 and is increased by 10.0%.	$24.20 \times 1.10 = 26.62$
The facility's Rowan County patient census is projected forward a year to 12/31/2022 and is increased by 10.0%.	$26.2 \times 1.10 = 29.282$
The 11 patients from outside Rowan County are added to the facility's census. <b>This is the ending census as of the end of OY1.</b>	$29.282 + 11 = \mathbf{40.282}$
The facility's Rowan County patient census is projected forward a year to 12/31/2023 and is increased by 10.0%.	$29.282 \times 1.10 = 32.2102$
The 11 patients from outside Rowan County are added to the facility's census. <b>This is the ending census as of the end of OY2.</b>	$32.2102 + 11 = \mathbf{43.2102}$

In both Section C, pages 19-21, 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).
- As of December 31, 2019, the patient censuses at Spencer Dialysis was 33 patients: 22 patients from Rowan County and 11 patients from outside Rowan County.
- The applicant begins its projections with the 22 patients residing in Rowan County.
- The dialysis patients who do not reside in Rowan County will be carried forward into projections of future patient census however, the applicant does not project any growth of the non-Rowan County patients.
- The Five-Year Average Annual Change Rate (AACR) for Rowan County is 4.9%, as published in the 2020 SMFP. However, on page 20, the applicant states that it experienced a 73.7% growth rate of patients in its first full year of operation (2019). Thus, the applicant uses a conservative growth rate of 10.0% which is less than the historical growth rate of 73.7% for IC patients during the first year of operation at the facility but higher than the 4.9% AACR for Rowan county.

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2022) the facility is projected to serve 40 in-center patients and at the end of OY2 (CY2022) the facility is projected to serve 43 in-center patients.

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

- OY1: 2.857 patients per station per week or 71.43% (40 patients / 14 stations = 2.857/4 = 0.7143 or 71.43%)
- OY2: 3.0714 patients per station per week or 76.78% (43 patients / 14 stations = 3.0714/4 = 0.7678 or 76.78%)

The projected utilization of 2.857 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 for the following reasons:

- The applicant projects future utilization based on historical utilization at Spencer Dialysis.
- The applicant applies a conservative growth rate of 10 percent based on the significant growth in its IC patients experienced during the first year of operation at Spencer Dialysis (73.7%), which is higher than the Five-Year AACR for Rowan County 4.9%, as published in the 2020 SMFP.
- The applicant conservatively does not project growth for its patients who do not reside in Rowan County.
- Projected utilization for IC patients at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

### Access

In Section C, 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 the handicapped, 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.*

*Spencer Dialysis 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, handicapped persons, elderly and other under-served persons.”*

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

**Spencer Dialysis  
Projected Payor Mix CY2023**

<b>Payment Source</b>	<b>% of IC Patients</b>	<b>% of HH Patients</b>	<b>% of PD Patients</b>
Self-pay	3.0%	0.0%	0.0%
Insurance*	9.1%	0.0%	0.0%
Medicare*	42.4%	0.0%	0.0%
Medicaid*	12.1%	0.0%	0.0%
Other (VA)	33.3%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>0.0%</b>	<b>0.0%</b>

Totals may not sum due to rounding

\*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

**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 (payor 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 a reduction, elimination or relocation of 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

TRC proposes to add no more than 4 dialysis stations to the Spencer Dialysis facility pursuant to facility need for a total of no more than 14 stations upon project completion.

In Section E, page 28, the applicant states that it considered the following alternatives related to serving the needs of the patients in the area:

1. Maintain the status quo – the applicant states that given the growth rate at Spencer Dialysis this alternative was dismissed. Therefore, this is not the most effective alternative.
2. Relocate stations from another DaVita facility – the applicant states that DaVita has three facilities in Rowan County and the other two, Dialysis Care of Kannapolis and Dialysis Care of Rowan County are both operating at over 75% capacity, thus relocating dialysis stations from either of those facilities would have a negative impact on patients currently being served by those facilities. Therefore, this is not the most effective alternative.

On page 28, the applicant states that the proposed project is a more effective alternative as it will provide additional capacity to meet the growing demand at Spencer Dialysis.

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

- The application is conforming 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

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 shall materially comply with all representations made in the certificate of need application.**

2. Pursuant to the facility need determination in the 2020 SMFP, Total Renal Care of North Carolina, LLC shall develop no more than 4 additional in-center dialysis stations at Spencer Dialysis for a total of no more than 14 in-center stations upon completion of this project.
  3. Total Renal Care of North Carolina, LLC 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

TRC proposes to add no more than 4 dialysis stations to the Spencer Dialysis facility pursuant to facility need for a total of no more than 14 stations upon project completion.

**Capital and Working Capital Costs**

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

Site Costs	\$0.00
Construction Costs	\$0.00
Miscellaneous Costs	\$68,004
<b>Total</b>	<b>\$68,004</b>

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

In Section F.3, pages 30-31, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project because Spencer Dialysis is an operational facility.

**Availability of Funds**

In Section F, page 29, 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	\$	\$
Accumulated reserves or OE *	\$68,004	\$68,004
Bonds	\$	\$
Other (Specify)	\$	\$
<b>Total Financing</b>	<b>\$68,004</b>	<b>\$68,004</b>

\* OE = Owner's Equity

Exhibit F-1 contains a letter dated March 15, 2020 from Chief Accounting Officer of DaVita, the parent company of Spencer Dialysis, authorizing and committing cash reserves in the amount of \$68,004 for the capital costs of the project. Exhibit F-2 contains DaVita's Form 10-K for the Fiscal Year ended December 31, 2019 showing DaVita Inc. with a consolidated balance sheet total cash and cash equivalents of \$1,102,372,000, current assets exceeding \$17 billion, and equity of \$2.3 billion.

**Financial Feasibility**

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

	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year
Total Treatments	5,773	6,187
Total Gross Revenues (Charges)	\$1,968,610	\$2,109,877
Total Net Revenue	\$341	\$341
Average Net Revenue per Treatment	\$1,860,664	\$1,994,184
Total Operating Expenses (Costs)	\$1,688,801	\$1,764,031
Average Operating Expense per Treatment	\$293	\$285
Net Income	\$171,863	\$230,153

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.
  - 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

TRC proposes to add no more than 4 dialysis stations to the Spencer Dialysis facility pursuant to facility need for a total of no more than 14 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.”* Spencer Dialysis 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.

Currently, there are three existing dialysis facilities in Rowan County, all of which are owned by DaVita, as shown in the following table:

<b>Rowan County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
Dialysis Care of Kannapolis	DaVita	Kannapolis	30	83.33%
Dialysis Care of Rowan County	DaVita	Salisbury	29	90.52%
Spencer Dialysis <sup>^/^^</sup>	DaVita	Spencer	10	47.50%

Source: 2020 SMFP, Table 9B, page 162

<sup>^/^^</sup> Designated as both a new and a small facility per Condition 1.a. in the facility need determination methodology

In Section G, page 34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Rowan County. The applicant states:

*“While adding stations at the facility does increase the number of stations in Rowan County, it is based on the facility need methodology. It untimely serves to meet the need of the facility’s growing population of patients referred by the facility’s admitting nephrologists.”*

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

- The applicant's proposal to add dialysis stations is based on the facility need methodology.
- 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 which was publicly available during the review and used by the Agency

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

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

### C

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

Position	Current (As of 12/31/2019)	Projected	
		Operating Year 1 (CY2022)	Operating Year 2 (CY2023)
Administrator	1.00	1.00	1.00
Registered Nurse (RNs)	2.00	2.00	2.00
Technicians (PCT)	4.00	6.00	6.00
Dieticians	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Business Office	0.50	1.00	1.00
Other: Biomedical Tech	0.50	0.50	0.50
<b>TOTAL</b>	<b>9.00</b>	<b>11.50</b>	<b>11.50</b>

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.2 and H.3, pages 36- 37, the applicant describes the methods used 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 medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibit H-3, the applicant provides supporting documentation.

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 that the following ancillary and support services are necessary for the proposed services:

<b>Spencer Dialysis – Ancillary and Support Services</b>		
<b>Services</b>	<b>Provider</b>	<b>Explanation/Supporting Documentation</b>
Self-care training (performed in-center)	On site	
Home Hemodialysis training and follow-up program	Dialysis Care of Kannapolis	
Peritoneal dialysis training and follow-up program	Dialysis Care of Rowan County	
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.	Exhibit I-1
Acute dialysis in an acute care setting	Novant Rowan Regional Medical Center	Exhibit I-1
Emergency care	Novant Rowan Regional Medical Center	Exhibit I-1
Blood bank services	Novant Rowan Regional Medical Center	Exhibit I-1
Diagnostic and evaluation services	Novant Rowan Regional Medical Center	Exhibit I-1
X-ray services	Novant Rowan Regional Medical Center	Exhibit I-1
Pediatric nephrology	Novant Rowan Regional Medical Center	Exhibit I-1
Vascular surgery	Novant Rowan Regional Medical Center	Exhibit I-1
Transplantation services	Wake Forest Baptist Medical Center	Exhibit I-1
Vocational rehabilitation counseling and services	Rowan County DSS	Long Term, Established Relationship
Transportation	Rowan Transit System	Long Term, Established Relationship

On page 38, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.

In Section I, pages 38-39, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1.

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. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

NA

The applicant does not propose any construction or renovation with this project. Therefore, Criterion (12) is not applicable to this review.

- (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 during the last full operating year, for the proposed services, as shown in the table below.

**Spencer Dialysis  
 Projected Payor Mix CY2019**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Self-pay	3.0%	0.0%	0.0%
Insurance*	9.1%	0.0%	0.0%
Medicare*	42.4%	0.0%	0.0%
Medicaid*	12.1%	0.0%	0.0%
Other (VA)	33.3%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>0.0%</b>	<b>0.0%</b>

Totals may not sum due to rounding  
 \*Including any managed care plans

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

Spencer Dialysis	Percentage of Total Patients Served (all modalities combined)	Percentage of the Population of the Service Area where the Stations will be Located or Services Offered*
Female	48.2%	50.6%
Male	51.8%	49.4%
Unknown	0.0%	0.0%
64 and Younger	55.3%	82.4%
65 and Older	44.7%	17.6%
American Indian	0.0%	0.6%
Asian	2.6%	1.3%
Black or African-American	57.9%	16.8%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	36.0%	71.7%
Other Race	3.5%	1.7%
Declined / Unavailable	0.0%	0.0%

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

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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, page 45, that it has no obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L.2, page 45, the applicant states no patient civil rights access complaints have been filed against Spencer Dialysis within the last five years.

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.3, page 46, the applicant projects the following payor mix for the proposed services during the second full operating year following completion of the project, as summarized in the table below.

**Spencer Dialysis  
Projected Payor Mix CY2022**

<b>Payment Source</b>	<b>% of IC Patients</b>	<b>% of HH Patients</b>	<b>% of PD Patients</b>
Self-pay	3.0%	0.0%	0.0%
Insurance*	9.1%	0.0%	0.0%
Medicare*	42.4%	0.0%	0.0%
Medicaid*	12.1%	0.0%	0.0%
Other (VA)	33.3%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>0.0%</b>	<b>0.0%</b>

Totals may not sum due to rounding  
\*Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 3.0% of in-center dialysis services will be provided to self-pay patients, 42.4% to Medicare patients, and 12.1% to Medicaid patients.

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. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Spencer Dialysis.

### **Conclusion**

The Agency reviewed the:

- application, and
- 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 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

TRC proposes to add no more than 4 dialysis stations to the Spencer Dialysis facility pursuant to facility need for a total of no more than 14 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.*” Spencer Dialysis 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.

Currently, there are three existing dialysis facilities in Rowan County, all of which are owned by DaVita, as shown in the following table:

<b>Rowan County Dialysis Facilities            Certified Stations and Utilization as of December 31, 2018</b>				
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b>Utilization</b>
Dialysis Care of Kannapolis	DaVita	Kannapolis	30	83.33%
Dialysis Care of Rowan County	DaVita	Salisbury	29	90.52%
Spencer Dialysis <sup>^/^^</sup>	DaVita	Spencer	10	47.50%

Source: 2020 SMFP, Table 9B, page 162

<sup>^/^^</sup> Designated as both a new and a small facility per Condition 1.a. in the facility need determination methodology

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

*“The expansion of Spencer Dialysis 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.*”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 49, the applicant states:

*“The expansion of Spencer Dialysis 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.”*

Regarding the impact of the proposal on quality, in Section N, page 49, the applicant states:

*“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.”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 49, the applicant states:

*“...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.”*

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 C, L and N of the application and any exhibits)

### **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 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, 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 a DaVita 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, one facility, Waynesville Dialysis Center, had an incident related to quality of care that resulted in a finding of *“Immediate Jeopardy”*. The applicant further states that Waynesville Dialysis Center is currently 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 .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

**10A NCAC 14C .2203 PERFORMANCE STANDARDS**

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.
- (b) *An applicant proposing to increase the number of dialysis stations in:*  
(1) *an existing dialysis facility; or*  
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*
- C- In Section C, page 21, and Section Q, Form C, the applicant projects Spencer Dialysis will serve 40 patients on 14 stations, or a rate of 2.857 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section C, pages 19-21, and Section Q, Form C, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.