

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 15, 2020

Findings Date: May 15, 2020

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: F-11886-20

Facility: Dialysis Care of Kannapolis

FID #: 980409

County: Rowan

Applicant: Central Carolina Dialysis Centers, LLC

Project: Add no more than three dialysis stations pursuant to the facility need determination for a total of no more than 25 stations upon completion of this project and Project I.D. # F-11452-18 (relocate 8 stations to Cannon Dialysis)

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

Central Carolina Dialysis Centers, LLC (hereinafter referred to as “the applicant” or DaVita, which is the parent company’s name) proposes to add no more than three dialysis stations to the existing Dialysis Care of Kannapolis pursuant to the facility need determination for a total of no more than 25 stations upon completion of this project and Project I.D. # F-11452-18 (relocate 8 stations to Cannon Dialysis).

Need Determination

The 2020 State Medical Facilities Plan (2020 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9C, page 168 of the 2020 SMFP, the county need methodology shows there is a surplus of one station in Rowan County; therefore, there is no county need determination for new dialysis stations for Rowan County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on Condition 2 of the Facility Need Methodology. The utilization rate reported for Dialysis Care of Kannapolis in the 2020 SFMP, page 162, is 83.33%, based on 100 in-center dialysis patients and 30 certified dialysis stations [$100 / 30 = 3.33$; $3.33 / 4 = 0.8333$], and the Facility Station Need Determination is for 14 dialysis stations for Dialysis Care of Kannapolis. The applicant proposes to add three new stations; therefore, the application is consistent with the Facility Station Need Determination for dialysis stations in the 2020 SMFP.

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, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 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.5 (a) and (d), pages 14-16, Section N.2(b), page 51; Section O, pages 53-54; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.5 (b) and (d), pages 15-16, Section C.7, pages 24-25; Section L, pages 46-49; Section N.2(c), page 51; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.5 (c) and (d), pages 15-16; Section N.2(a), page 51; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

- (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

The applicant proposes to add three dialysis stations to the existing Dialysis Care of Kannapolis for a total of 25 stations upon completion of this project and Project I.D. # F-11452-18 (relocate 8 stations to Cannon Dialysis).

The following table, summarized from page 7 of the application, shows the current and projected number of dialysis stations at Dialysis Care of Kannapolis.

Dialysis Care of Kannapolis

# of Stations	Description	Project ID #
30	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
3	# of stations to be added as part of this project	F-11878-20
	# of stations to be deleted as part of this project	
	# of stations previously approved to be added but not yet certified	
-8	# of stations previously approved to be deleted but not yet certified	F-11452-18
	# of stations proposed to be added in an application still under review	
	# of stations proposed to be deleted in an application still under review	
25	Total # of stations upon completion of all facility projects	

As outlined in the table above, in this application, the applicant proposes to add three dialysis stations for a total of 25 stations upon the project completion.

Patient Origin

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

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

Dialysis Care of Kannapolis Patient Origin - CY2019

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Rowan	56	57.1%	2	25.0%	6	24.0%
Cabarrus	36	36.7%	5	62.5%	16	64.0%
Mecklenburg	2	2.0%	0	0.0%	1	4.0%
Iredell	2	2.0%	0	0.0%	0	0.0%
Gaston	1	1.0%	0	0.0%	0	0.0%
Other States	1	1.0%	0	0.0%	0	0.0%
Lincoln	0	0.0%	1	12.5%	0	0.0%
Stanley	0	0.0%	0	0.0%	2	8.0%
Total	98	100.0%	8	100.0%	25	100.0%

Totals may not sum due to rounding

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

Dialysis Care of Kannapolis Projectd Patient Origin - CY2023

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Rowan	67	90.5%	6	50.0%	10	37.0%
Cabarrus	1	1.4%	5	41.7%	14	51.9%
Mecklenburg	2	2.7%	0	0.0%	1	3.7%
Iredell	2	2.7%	0	0.0%	0	0.0%
Gaston	1	1.4%	0	0.0%	0	0.0%
Other States	1	1.4%	0	0.0%	0	0.0%
Lincoln	0	0.0%	1	8.3%	0	0.0%
Stanley	0	0.0%	0	0.0%	2	7.4%
Total	74	100.0%	12	100.0%	27	100.0%

Totals may not sum due to rounding

In Section C, pages 20-21, the applicant provides the assumptions and methodology it used to project IC, HH, and PD patient origin. The applicant states that the in-center and home therapies patient origin is based upon the December 31, 2019 Data Collection Form for ESRD Facilities submitted by Dialysis Care of Kannapolis. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.3, pages 20-23, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it projects patients forward from the December 31, 2019 census data. The applicant states that it assumes the patients from Rowan County dialyzing at Dialysis Care of Kannapolis on December 31, 2019 will continue to dialyze there and will increase at a rate equal to the Rowan County Five Year Average Annual Change Rate (AACR) of 4.9% as published in the 2020 SMFP.
- The applicant assumes the December 31, 2019 patients from counties other than Rowan County counties will continue to dialyze at Dialysis Care of Kannapolis but does not assume any growth in patients from these counties.
- Services will be offered as of December 31, 2021. Therefore, Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022 and OY2 is CY2023, January 1-December 31, 2023.

In-Center Projected Utilization

In Section C.3, page 21, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

The applicant begins with the Rowan County in-center patients as of December 31, 2019.	56
The applicant projects the Rowan County in-center patients forward one year to December 31, 2020 using the Rowan County AACR.	$56 \times 1.049 = 58.744$
The applicant adds 42 patients from counties other than Rowan County for a year-end census as of December 31, 2020.	$58.744 + 42 = 100.744$
The applicant projects 35 Cabarrus County patients will transfer to Cannon Dialysis from Dialysis Care of Kannapolis upon the completion of Project I.D. # F-11542-18, leaving 7 patients from counties other than Rowan County.	$42 - 35 = 7$
The applicant projects the Rowan County in-center patients forward one year to December 31, 2021 using the Rowan County AACR.	$58.744 \times 1.049 = 61.622$
The applicant adds 7 patients from counties other than Rowan County for a year-end census as of December 31, 2021.	$61.622 + 7 = 68.622$
The applicant projects the Rowan County in-center patients forward one year to December 31, 2022 using the Rowan County AACR.	$61.622 \times 1.049 = 64.642$
The applicant adds 7 patients from counties other than Rowan County for a year-end census as of December 31, 2022. This is the projected ending census for Operating Year 1 .	$64.642 + 7 = 71.642$
The applicant projects the Rowan County in-center patients forward one year to December 31, 2023 using the Rowan County AACR.	$64.642 \times 1.049 = 67.809$
The applicant adds 7 patients from counties other than Rowan County for a year-end census as of December 31, 2023. This is the projected ending census for Operating Year 2 .	$67.809 + 7 = 74.809$

The applicant projects to serve 72 in-center patients in OY1 and 75 in-center patients in OY2. Thus, the applicant projects that Dialysis Care of Kannapolis will have a utilization rate of 72.0% or 2.88 patients per station per week ($72 \text{ patients} / 25 \text{ stations} = 2.88 / 4 = 0.72$ or 72.0%) in OY1. The projected utilization of 2.88 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 begins the projections with the existing Rowan County Dialysis Care of Kannapolis patient census as of December 31, 2019.
- The applicant projects the Rowan County patient census at Dialysis Care of Kannapolis will increase by the Rowan County Five Year AACR of 4.9 percent, as reported in the 2020 SMFP.
- The applicant subtracts 35 Cabarrus County patients from the in-center census who are projected to transfer to Cannon Dialysis and adds 7 patients from other counties but does not project any growth in the number of out-of-county patients in the first two operating years of the project.

- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Home Hemodialysis (HHD) Projected Utilization

On page 22, the applicant provides the following table showing its projections of home hemodialysis (HHD) patients through the first two operating years of the project.

HHD Patient Projections	Start Date	# of Patients Start of Year	# of Patients End of Year	Average # of Patients in Year
Interim Period	1/1/2020	8	9	8.5
Interim Period	1/1/2021	9	10	9.5
Operating Year 1	1/1/2022	10	11	10.5
Operating Year 2	1/1/2023	11	12	11.5

Source: Table on page 22 of the application.

On page 22, the applicant describes its assumptions as follows:

“In the December 2019 Data Collection Form for ESRD Facilities submitted by Dialysis Care of Kannapolis, the facility reported 8 HHD patients as of December 31, 2019. Of these 8 patients, 2 lived in the service area, Rowan County and 6 lived outside of the service area (Cabarrus County and Lincoln County). ... The period of the growth begins January 1, 2020 and is calculated forward to December 31, 2023. It is reasonable to assume that the Dialysis Care of Kannapolis home-training program will grow at a rate of at least one patient per year during the period of growth.”

Projected utilization for HHD training and support is based on reasonable and adequately supported assumptions regarding continued growth.

Peritoneal Dialysis (PD) Projected Utilization

On page 23, the applicant provides the following table showing its projections of peritoneal dialysis (PD) patients through the first two operating years of the project.

PD Patient Projections	Start Date	# of Patients Start of Year	# of Patients End of Year	Average # of Patients in Year
Interim Period	1/1/2020	25	26	25.5
Two patients are projected to transfer to Cannon Dialysis by 1/1/2021				
Interim Period	1/1/2021	24	25	24.5
Operating Year 1	1/1/2022	25	26	25.5
Operating Year 2	1/1/2023	26	27	26.5

Source: Table on page 23 of the application.

On page 23, the applicant describes its assumptions as follows:

“In Project ID # F-011452-18 Total Renal Care of North Carolina, LLC, is approved to develop Cannon Dialysis in Cabarrus County via transfer of 11 stations from Dialysis Care of Kannapolis (8) and North Charlotte Dialysis Center (3). Total Renal Care of North Carolina, LLC indicated in the application that 2 peritoneal dialysis patients would transfer their care to Canon Dialysis from Dialysis Care of Kannapolis upon its projected certification date of January 1, 2021. Therefore, Dialysis Care of Kannapolis will have 24 peritoneal dialysis patients when Cannon Dialysis is certified...The period of the growth begins January 1, 2020 and is calculated forward to December 31, 2023. It is reasonable to assume that the Dialysis Care of Kannapolis home-training program will grow at a rate of at least one patient per year during the period of growth.”

Projected utilization for PD training and support is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section C.7, pages 24-25, 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...Dialysis Care of Kannapolis 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 person, elderly and other under-served persons.”

In Section L.3, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Dialysis Care of Kannapolis
 Projected Payor Mix CY2022**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	2.3	3.1%	0.0	0.0%	0.0	0.0%
Commercial Insurance*	5.3	7.1%	0.0	0.0%	6.5	24.0%
Medicare*	58.0	77.6%	12.0	100.0%	19.4	72.0%
Medicaid*	6.9	9.2%	0.0	0.0%	0.0	0.0%
Other (VA)	2.3	3.1%	0.0	0.0%	1.1	4.0%
Total	74.8	100.0%	12.0	100.0%	27.0	100.0%

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

The applicant proposes to add three dialysis stations to the existing Dialysis Care of Kannapolis for a total of 25 stations upon completion of this project and Project I.D. # F-11452-18 (relocate 8 stations to Cannon Dialysis).

In Section E, page 30, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because of the growth rate at the facility.
- *Relocate Stations from another DaVita* – The applicant states that both of the operational DaVita dialysis facilities in Rowan County are operating above 80.0% of capacity and, therefore, relocating stations from either of those two facilities is not the most effective alternative.

On page 30, the applicant states that its proposal is the most effective alternative because it will address the issues of growth and station/shift availability to the facility.

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. **Central Carolina Dialysis Centers, 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, Central Carolina Dialysis Centers, LLC shall develop no more than three additional in-center dialysis stations at Dialysis Care of Kannapolis for a total of no more than 25 in-center and home hemodialysis stations upon completion of this project and Project I.D. # F-11452-18 (relocate 8 stations to Cannon Dialysis).**
 3. **Central Carolina Dialysis Centers, 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

The applicant proposes to add three dialysis stations to the existing Dialysis Care of Kannapolis for a total of 25 stations upon completion of this project and Project I.D. # F-11452-18 (relocate 8 stations to Cannon Dialysis).

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, the applicant projects no capital costs associated with this project. In Section F.3, pages 32-33, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

Financial Feasibility

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

Dialysis Care of Kannapolis Projected Revenue and Operating Expenses

	OY 1 CY2022	OY 2 CY2023
Total Treatments (IC, HH, and PD)	15,729	16,484
Total Gross Revenue (charges)	\$5,560,960	\$5,817,464
Total Net Revenue	\$5,247,328	\$5,488,780
Average Net Revenue per Treatment	\$334	\$333
Total Operating Expenses (costs)	\$4,444,542	\$4,605,965
Average Operating Expense per Treatment	\$283	\$279
Net Income / Profit	\$802,786	\$882,815

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 for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add three dialysis stations to the existing Dialysis Care of Kannapolis for a total of 25 stations upon completion of this project and Project I.D. # F-11452-18 (relocate 8 stations to Cannon Dialysis).

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

The applicant operates three dialysis centers in Rowan County. The following table that shows the existing and approved dialysis facilities in Rowan County, from Table 9B of the 2020 SMFP:

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.

In Section G.2, page 36, 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:

“Two of three DaVita facilities in Rowan County were operating at 75% or greater utilization as reported in the 2020 SMFP. The third facility is a recently opened 10-station clinic certified in 2018. In Section B, Question 2 and Section C, Question 3 of this application, we demonstrate the need that Dialysis Care of Kannapolis has for adding stations. While adding stations at this facility does increase the number of stations in Rowan County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

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

- There is a facility need determination at Dialysis Care of Kannapolis, as calculated using the methodology in the 2020 SMFP, for the proposed three additional dialysis stations.
- The applicant adequately demonstrates that the three 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 Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Dialysis Care of Kannapolis, as summarized below.

POSITION	FTE Positions as of 3/1/20	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.0	1.0	1.0
Registered Nurse	4.0	4.0	4.0
Home Training Nurse	1.0	1.0	1.0
Technicians	12.0	10.0	10.0
Dietitian	1.0	1.0	1.0
Social Worker	1.0	1.0	1.0
Administrative	1.0	1.0	1.0
Biomedical Technician	0.5	0.5	0.5
Total	21.5	19.5	19.5

Source: Section Q, Form H

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 Operating Costs. In Section H, pages 38-39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 39, the applicant identifies the current medical director for the facility. In Exhibit H-4, the applicant provides a letter from medical director indicating his intent to continue to serve as medical director for the proposed services.

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

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 40, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	On site
Home training HH PD Accessible follow-up program	On site
Psychological counseling	On site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Atrium Health Cabarrus
Emergency care	Atrium Health Cabarrus
Blood bank services	Atrium Health Cabarrus
Diagnostic and evaluation services	Atrium Health Cabarrus
X-ray services	Atrium Health Cabarrus
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Atrium Health Cabarrus
Vascular surgery	Atrium Health Cabarrus
Transplantation services	Atrium Health-CMC
Vocational rehabilitation & counseling	Cabarrus County Vocational Rehabilitation
Transportation	Rowan County Transportation

Source: Table in Section I, page 40

In Section I, pages 40-41, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

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

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 47, the applicant provides the historical payor mix for Dialysis Care of Kannapolis patients during CY2019 for its existing services, as shown in the table below.

**Dialysis Care of Kannapolis
 Historical Payor Mix (CY2019)**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	3	3.1%	0	0.0%	0	0.0%
Commercial Insurance*	7	7.1%	0	0.0%	6	24.0%
Medicare*	76	77.6%	8	100.0%	18	72.0%
Medicaid*	9	9.2%	0	0.0%	0	0.0%
Other (VA)	3	3.1%	0	0.0%	1	4.0%
Total	98	100.0%	8	100.0%	25	100.0%

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 46, the applicant provides comparison of the demographical information on Dialysis Care of Kannapolis patients and the service area patients during CY2019, as summarized below.

	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population of the Service Area*
Female	45.7%	50.6%
Male	54.3%	49.4%
Unknown		
64 and Younger	62.0%	82.4%
65 and Older	38.0%	17.6%
American Indian	0.0%	0.6%
Asian	1.6%	1.3%
Black or African-American	36.4%	16.8%
Native Hawaiian or Pacific Islander	0.8%	0.1%
White or Caucasian	49.6%	71.7%
Other Race	11.6%	1.7%
Declined / Unavailable	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>. Just enter in the name of the county.

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 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 47, 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, page 47, 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.3, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Dialysis Care of Kannapolis
 Projected Payor Mix CY2022**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	2.3	3.1%	0.0	0.0%	0.0	0.0%
Commercial Insurance*	5.3	7.1%	0.0	0.0%	6.5	24.0%
Medicare*	58.0	77.6%	12.0	100.0%	19.4	72.0%
Medicaid*	6.9	9.2%	0.0	0.0%	0.0	0.0%
Other (VA)	2.3	3.1%	0.0	0.0%	1.1	4.0%
Total	74.8	100.0%	12.0	100.0%	27.0	100.0%

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

As shown in the table above, in the second full year of operation, the applicant projects that 3.1% of in-center dialysis services will be provided to self-pay patients, 77.6% to Medicare patients, and 9.2% to Medicaid patients.

On page 48, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes.

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

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.

- (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 48-49, 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 50, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.

- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

The applicant proposes to add three dialysis stations to the existing Dialysis Care of Kannapolis for a total of 25 stations upon completion of this project and Project I.D. # F-11452-18 (relocate 8 stations to Cannon Dialysis).

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

The applicant operates three dialysis centers in Rowan County. The following table that shows the existing and approved dialysis facilities in Rowan County, from Table 9B of the 2020 SMFP:

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.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 51, the applicant states:

“The expansion of Dialysis Care of Kannapolis 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 Dialysis Care of Kannapolis 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 51, 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 Dialysis Care of Kannapolis 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.

In Section Q Form A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O.2, pages 53-54, 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 .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 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- The applicant is not proposing to establish a new kidney disease treatment center or dialysis facility.

(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.3, page 21, the applicant projects that Dialysis Care of Kannapolis will serve 72 in-center patients on 25 stations, or a rate of 2.88 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section C.3, pages 20-23, the applicant provides the assumptions and methodology it used to project utilization of the facility.