

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 25, 2021

Findings Date: May 25, 2021

Project Analyst: Misty L. Piekaar-McWilliams

Team Leader: Fatimah Wilson

Project ID #: F-12048-21

Facility: Dialysis Care of Kannapolis

FID #: 980409

County: Rowan

Applicant(s): Central Carolina Dialysis Centers, LLC

Project: Add no more than six (6) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion

### REVIEW CRITERIA

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

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

C

Central Carolina Dialysis Centers, LLC or DaVita, the parent company (hereinafter referred to as “the applicant”) proposes to add no more than six (6) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 in-center dialysis stations upon project completion.

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

Chapter 9 of the 2021 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9C, the county need methodology shows there is not a county need determination for additional dialysis stations in Rowan County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2021 SMFP, if the utilization rate for the facility as reported in the 2021 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 81.67 percent or 3.27 patients per station per week, based on 98 in-center dialysis patients and 30 certified dialysis stations (98 patients / 30 stations = 3.27;  $3.27 / 4 = 81.67\%$ ).

As shown in Table 9D, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to nine (9) additional stations; thus, the applicant is eligible to apply to add up to nine (9) dialysis stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than six (6) new dialysis stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to nine (9) stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2021 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, page 29 of the 2021 SMFP, states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

In Section B, pages 17-20, the applicant explains why it believes its application is consistent with Policy GEN-3. On pages 19-20, the applicant states:

*“For all its patients – current patients as well as those included in the projected utilization – DaVita is committed to:*

- *promoting a culture of safety;*
- *ensuring industry-leading quality of care;*
- *promoting equitable access; and*

- *maximizing healthcare value.*

*As discussed in Sections B-3(a), (b), & (c), established policy and procedure will continue to guide this commitment.”*

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 17-18; Section N, pages 64-65; Section O, pages 66-68; 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, page 19; Section L, pages 57-61; Section N, pages 64-65; 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, page 19; Section F, pages 37-38 (including applicable forms in Section Q); Section K, pages 53-54; and Section N, pages 64-65. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:

- The applicant adequately documents how the project will promote safety and quality in the delivery of end stage renal disease (ESRD) services in Rowan County.
  - The applicant adequately documents how the project will promote equitable access to ESRD services in Rowan County.
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended in Rowan County.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than six (6) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

The table below, summarized from page 14 of the application and the 2021 SMFP, shows the projected number of stations at Dialysis Care of Kannapolis upon completion of this project, Project ID #F-12048-21.

# of Stations	Description	Project ID #(s)
30	Total # of existing certified dialysis stations at the dialysis facility identified in Section A, Question 4, as reported in Table 9A in the SMFP	
6	# of dialysis stations to be added as part of this proposal	
0	# of dialysis stations to be deleted as part of this proposal	
3	# of dialysis stations previously approved to be added and are reported in Table 9A in the SMFP but not yet certified	F-11886-20*
0	# of dialysis stations previously approved to be added but are not reported in Table 9A in the SMFP	
8	# of dialysis stations previously approved to be deleted and are reported in Table 9A in the SMFP but have not yet been relocated or deleted	F-11452-18^
0	# of dialysis stations previously approved to be deleted but are not reported in Table 9A in the SMFP and have not yet been relocated or deleted	
0	# of dialysis stations proposed to be added in applications still under review as of the application deadline	
0	# of dialysis stations proposed to be deleted in applications still under review as of the application deadline	
31	Total # of dialysis stations upon completing of all proposals involving the dialysis facility identified in Section A, Question 4	

\*Development complete letter issued 4/12/2021.

^Development complete letter issued 2/9/2021.

### **Patient Origin**

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Dialysis Care of Kannapolis is located in Rowan County. Thus, the service area for this facility consists of Rowan County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 21, 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 (CY2020), as summarized in the table below.

**Dialysis Care of Kannapolis Patient Origin - CY2020**

COUNTY	# IC PATIENTS	% IC Total	#HH Patients	% HH Total	#PD Patients	%PD Patients
Rowan	47	54.00%	4	44.44%	9	39.13%
Cabarrus	36	41.40%	2	22.22%	10	43.48%
Anson	1	1.10%	0	0.00%	0	0.00%
Gaston	1	1.10%	0	0.00%	0	0.00%
Mecklenburg	1	1.10%	1	11.11%	2	8.70%
Other States	1	1.10%	0	0.00%	0	0.00%
Catawba	0	0.00%	1	11.11%	0	0.00%
Lincoln	0	0.00%	1	11.11%	0	0.00%
Stanley	0	0.00%	0	0.00%	1	4.35%
Iredell	0	0.00%	0	0.00%	1	4.35%
<b>Total</b>	<b>87</b>	<b>100.00%</b>	<b>9</b>	<b>100.00%</b>	<b>23</b>	<b>100.00%</b>

Totals may not sum due to rounding

The following table summarizes projected patient origin for the second full operating year (CY2024) following project completion, as provided in Section C, page 22.

**Dialysis Care of Kannapolis Patient Origin - CY2024\***

COUNTY	# IC PATIENTS	% IC Total	#HH Patients	% HH Total	#PD Patients	%PD Patients
Rowan	53.7254	57.30%	8	61.50%	13	48.15%
Cabarrus	36	38.40%	2	15.40%	10	37.04%
Anson	1	1.10%	0	0.00%	0	0.00%
Gaston	1	1.10%	0	0.00%	0	0.00%
Mecklenburg	1	1.10%	1	7.70%	2	7.41%
Other State(s)	1	1.10%	0	0.00%	0	0.00%
Catawba	0	0.00%	1	7.70%	0	0.00%
Lincoln	0	0.00%	1	7.70%	0	0.00%
Stanley	0	0.00%	0	0.00%	1	3.70%
Iredell	0	0.00%	0	0.00%	1	3.70%
<b>Total</b>	<b>93.7254</b>	<b>100.00%</b>	<b>13</b>	<b>100.00%</b>	<b>27</b>	<b>100.00%</b>

Totals may not sum due to rounding

\*The analyst notes the application reads 1/1/2024 to 1/1/2024 for the second full fiscal year; the analyst believes the application should read 1/1/2024 to 12/31/2024.

In Section C, pages 22-24, the applicant provides the assumptions and methodology it used to project IC, HH and PD patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the historical patient origin of Dialysis Care of Kannapolis.

## **Analysis of Need**

In Section C.4, page 25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 25, the applicant states:

*“The addition of stations serves to increase capacity and proactively address the issues of growth and access at the facility. Dialysis patients spend a significant amount of time in their facilities preparing for and receiving treatment -- three times a week for incenter patients. The additional stations provide opportunities to open appointment times on the more desirable first shift.”*

In Section C, pages 22-23, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states that it begins projections with the IC patient census at Dialysis Care of Kannapolis as of December 31, 2020. On page 22, the applicant states that on December 31, 2020, its IC patient census was comprised of 47 Rowan County patients and 40 patients from other North Carolina counties and other states.
- The applicant states that the Rowan County Five Year Average Annual Change Rate (AACR) published in Table 9B of the 2021 SMFP is 3.4%.
- The applicant states the period of growth begins January 1, 2021 and is calculated forward to December 31, 2024.
- The applicant assumes the December 31, 2020 patients from outside Rowan County will continue to dialyze at Dialysis Care of Kannapolis but does not assume any growth in patients from those counties and adds them to the calculations when appropriate.
- The applicant states services will be offered as of January 1, 2023. Therefore, operating year (OY) 1 is calendar year (CY) 2023, January 1, 2023 - December 31, 2023 and OY2 is CY2024, January 1, 2024 - December 31, 2024.

## **Projected Utilization**

### **In-Center Projected Utilization**

In Section C, page 23, and in Form C Utilization subsection of Section Q, the applicant provides the methodology used to project the patient census for OY1 and OY2, as summarized in the table below.

<b>Dialysis Care of Kannapolis Projected Utilization</b>		
	<b>IC Stations</b>	<b>IC Patients</b>
The applicant begins with the 87 patients dialyzing on 25 stations at the facility as of 1/1/2021.	25	87
The applicant projects Rowan County patient census forward a year to December 31, 2021 and increased by the 5 year AACR of 3.4% for Rowan County.		$47 \times 1.034 = 48.598$
The applicant adds 40 patients residing in counties other than Rowan County for a year-end census as of December 31, 2021.		$48.598 + 40 = 88.598$
The applicant projects the Rowan County patient census forward one year to December 31, 2022 and increased by the 5 year AACR of 3.4% for Rowan County.		$48.598 \times 1.034 = 50.250$
The applicant adds 40 patients residing in counties other than Rowan County for a year-end census as of December 31, 2022.		$50.250 + 40 = 90.250$
The project is projected to be certified on 1/1/2023. This is the station count at the beginning of OY1.	$25 + 6 = 31$	
The applicant projects the Rowan County patient census forward a year to December 31, 2023 and increased by the 5 year AACR of 3.4% for Rowan County.		$50.250 \times 1.034 = 51.958$
The applicant adds 40 patients residing in counties other than Rowan County for a year-end census as of December 31, 2023. This is the projected ending census for <b>Operating Year 1 (OY1)</b> .		$51.958 + 40 = 91.958$
The applicant projects the Rowan County patient census forward one year to December 31, 2024 and increased by the 5 year AACR of 3.4% for Rowan County.		$51.958 \times 1.034 = 53.725$
The applicant adds 40 patients residing in counties other than Rowan County for a year-end census as of December 31, 2024. This is the projected ending census for <b>Operating Year 2 (OY2)</b> .		$53.725 + 40 = 93.725$

The applicant projects to serve 92 in-center patients in OY1 and 94 in-center patients in OY2. Thus, the applicant projects that Dialysis Care of Kannapolis will have a utilization rate of 74.2% or 2.968 patients per station per week ( $92 \text{ patients} / 31 \text{ stations} = 2.968 / 4 = 0.742$  or 74.2%) in OY1 and 75.8% or 3.032 patients per station per week ( $94 \text{ patients} / 31 \text{ stations} = 3.032 / 4 = 0.758$  or 75.80%) in OY2. The projected utilization of 2.9 patients per station per week at the end of OY1 and 3.0 patients per station per week at the end of OY2 exceeds the

minimum standard of 2.8 in-center patients per station per week as 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 patient census at Dialysis Care of Kannapolis as of December 31, 2020.
- The applicant projects IC utilization using Rowan County’s 5 Year AACR of 3.4 percent.
- The applicant assumes the patients residing outside of Rowan County will continue to dialyze at Dialysis Care of Kannapolis and are added to the projections without any future growth through the first two (2) operating years of the project.
- The projected utilization rate by the end of OY1 and OY2 is above the minimum standard of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Home Hemodialysis (HH) Projected Utilization

- The applicant begins its utilization projections with the patient facility census on December 31, 2020. On page 23, the applicant states that, on December 31, 2020, its HH patient census was comprised of nine (9) HH patients with four (4) living in Rowan County and the other five (5) originating from other North Carolina counties.
- The applicant assumes that the HH patient population will increase by one (1) patient per year during the period of growth in OY1 and OY2.
- The project is scheduled to begin offering services on January 1, 2023. OY1 is CY2023. OY2 is CY2024.

In Section C, pages 23-24, and Form C Utilization, the applicant provides the calculations used to project the HH patient census for OY1 and OY2, as summarized in the table below.

<b>Dialysis Care of Kannapolis HH Projected Utilization</b>	
Starting point of calculation at Dialysis Care of Kannapolis HH patients as of January 1, 2021.	9
The HH patient population of Dialysis Care of Kannapolis is projected forward by one year to January 1, 2022, at a growth rate of one patient per year.	9 + 1 = 10
The HH patient population of Dialysis Care of Kannapolis is projected forward by one year to January 1, 2023, at a growth rate of one patient per year.	10 + 1 = 11
The HH patient population of Dialysis Care of Kannapolis is projected forward by one year to January 1, 2024, at a growth rate of one patient per year (end of OY1).	11 + 1 = 12
The HH patient population of Dialysis Care of Kannapolis is projected forward by one year to January 1, 2025, at a growth rate of one patient per year (end of OY2).	12+1 = 13

The applicant provides a table on page 24 to summarize the end of year census and average number of patients each year for the HH patients at Dialysis Care of Kannapolis as shown below.

HH patient projections	Start Date	# of patients beginning of year	# of patients end of year	Average # of patients in year
Interim Period	1/1/2021	9	10	9.5
Interim Period	1/1/2022	10	11	10.5
Operating Year 1	1/1/2023	11	12	11.5
Operating Year 2	1/1/2024	12	13	12.5

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

- The applicant begins the projections with the existing HH patient census at Dialysis Care of Kannapolis as of December 31, 2020.
- The applicant projects the home-training program at Dialysis Care of Kannapolis will increase by at least one (1) patient per year during the period of growth. This is reasonable given that the applicant states on page 27 that physicians are referring more patients to home dialysis when appropriate.

Peritoneal Dialysis (PD) Projected Utilization

- The applicant begins its utilization projections with the patient facility census on December 31, 2020. On page 24, the applicant states that, on December 31, 2020, its PD patient census was comprised of 23 patients with nine (9) living in Rowan County and the other 14 originating from other North Carolina counties.
- The applicant assumes that the PD patient population will increase by one (1) patient per year during the period of growth in OY1 and OY2.
- The project is scheduled to begin offering services on January 1, 2023. OY1 is CY2023. OY2 is CY2024.

In Section C, page 24, and Form C Utilization, the applicant provides the calculations used to project the PD patient census for OY1 and OY2, as summarized in the table below.

<b>Dialysis Care of Kannapolis PD Projected Utilization</b>	
Starting point of calculation at Dialysis Care of Kannapolis PD patients as of January 1, 2021.	23
The PD patient population of Dialysis Care of Kannapolis is projected forward by one year to January 1, 2022, at a growth rate of one patient per year.	$23 + 1 = 24$
The PD patient population of Dialysis Care of Kannapolis is projected forward by one year to January 1, 2023, at a growth rate of one patient per year.	$24 + 1 = 25$
The PD patient population of Dialysis Care of Kannapolis is projected forward by one year to January 1, 2024, at a growth rate of one patient per year (end of OY1).	$25 + 1 = 26$
The PD patient population of Dialysis Care of Kannapolis is projected forward by one year to January 1, 2025, at a growth rate of one patient per year (end of OY2).	$26 + 1 = 27$

The applicant provides a table on page 24 to summarize the end of year census and average number of patients each year for the PD patients at Dialysis Care of Kannapolis as shown below.

PD patient projections	Start Date	# of patients beginning of year	# of patients end of year	Average # of patients in year
Interim Period	1/1/2021	23	24	23.5
Interim Period	1/1/2022	24	25	24.5
Operating Year 1	1/1/2023	25	26	25.5
Operating Year 2	1/1/2024	26	27	26.5

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

- The applicant begins the projections with the existing PD patient census at Dialysis Care of Kannapolis as of December 31, 2020.
- The applicant projects the home-training program at Dialysis Care of Kannapolis will increase by at least one (1) patient per year during the period of growth. This is reasonable given that the applicant states on page 27 that physicians are referring more patients to home dialysis when appropriate.

**Access to Medically Underserved Groups**

In Section C, page 28, the applicant states:

*“By policy, the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.*”

*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 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, disabled persons, elderly and other under-served persons.”*

On page 29, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table. The applicant states it assumes the estimated percentage for the medically underserved groups listed in the following table will be the same as its patient population in CY2020 and projected patient population in CY2024.

<b>Medically Underserved Groups</b>	<b>% of Total Patients</b>
Low income persons	86.6%
Racial and ethnic minorities	49.1%
Women	42.7%
Persons with disabilities	100.0%
Persons 65 and older	63.6%
Medicare beneficiaries	72.3%
Medicaid recipients	12.6%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

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

**Conclusion**

The Agency reviewed the:

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of

the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to add no more than six (6) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

In Section E, page 36, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the status quo* - The applicant states that maintaining the status quo is not an effective alternative due to the growth rate at the facility.
- *Relocate stations from another DaVita facility* – The applicant states that of the three (3) DaVita facilities in Rowan County, all three (3) operate at greater than 75% capacity. By relocating a station to Dialysis Care of Kannapolis from another DaVita facility located in Rowan County, the applicant states the transfer of a dialysis station to Dialysis Care of Kannapolis would negatively impact the transferring facility's operations and the patients presently served by that facility.

On page 36, the applicant states that its proposal is the most effective alternative because adding six (6) stations will help meet the need for services at Dialysis Care of Kannapolis.

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

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

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Central Carolina Dialysis Centers, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to Condition 2 of the facility need determination in the 2021 SMFP, the certificate holder shall develop no more than six (6) additional in-center dialysis stations for a total of no more than 31 in-center (and home hemodialysis) stations at Dialysis Care of Kannapolis upon completion of this project.**
  - 3. Progress Reports:**
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. The certificate holder shall complete all sections of the Progress Report form.**
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on February 1, 2022 and so forth.**
  - 4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than six (6) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

**Capital and Working Capital Costs**

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

**Dialysis Care of Kannapolis Capital Cost**

ITEM	COST
Medical Equipment	\$45,000
Non-Medical Equipment	\$5,319
Furniture	\$8,400
<b>Total</b>	<b>\$58,719</b>

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states the costs are based on the input from the North Carolina project manager and the applicant’s finance department.

In Section F, page 38, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

**Availability of Funds**

In Section F, page 37, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

Type	DaVita	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$58,719	\$58,719
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$58,719</b>	<b>\$58,719</b>

\* OE = Owner’s Equity

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

- Exhibit F.2 contains the Consolidated Financial Statements for the year ending December 31, 2020, that shows DaVita, Inc., parent company to Central Carolina Dialysis Centers, LLC currently has \$3.2 million in cash and cash equivalents and \$16 billion in total assets.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two (2) 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 (2) operating years of the project, as summarized in the table below.

	<b>OY 1 CY 2023</b>	<b>OY 2 CY 2024</b>
Total In-Center Treatments	18,985	19,539
Total Gross Revenue (charges)	\$6,555,335.54	\$6,762,264.99
Total Net Revenue*	\$6,697,522.58	\$6,908,600.46
Average Net Revenue per Treatment	\$352.78	\$353.58
Total Operating Expenses (costs)	\$3,450,876.89	\$3,487,757.37
Average Operating Expense per Treatment	\$181.77	\$178.50
<b>Net Income / Profit</b>	<b>\$3,246,645.69</b>	<b>\$3,420,843.09</b>

Source: Section Q, Form F.2

\*Applicant included 2020 data including the consolidation of the components of "Adjustments to Revenue" in its total net revenue calculations.

Numbers may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant's accounting department projected the financial feasibility of the proposed project and adjusted the reporting of some of its 2020 data into a single line item and reported it as Total Adjustments to Revenue in its calculations for Total Net Revenue.
- Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

The applicant proposes to add no more than six (6) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.”* Dialysis Care of Kannapolis is located in Rowan County. Thus, the service area for this facility is Rowan County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 129 of the 2021 SMFP, the applicant operates three (3) dialysis centers in Rowan County. Information from Table 9A of the 2021 SMFP is provided below:

**Rowan County Dialysis Facilities**

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/19	# IN-CTR PATIENTS	PATIENTS / STATION	PERCENT UTILIZATION
Dialysis Care of Kannapolis	30	98	3.26	81.67%
Dialysis Care of Rowan County	33	111	3.36	84.09%
Spencer Dialysis	10	33	3.30	82.50%
<b>Total</b>	<b>73</b>	<b>242</b>		

Source: 2021 SMFP, Table 9A, page 129 and page 43 of the application.

In Section G, page 45, 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 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 in the 2021 SMFP for Dialysis Care of Kannapolis for nine (9) dialysis stations. The applicant proposes to add six (6) stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

### **Conclusion**

The Agency reviewed the:

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

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

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

### C

The applicant proposes to add no more than six (6) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

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

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 12/31/2020	OY1 (CY2023)	OY2 (CY2024)
Administrator	1.00	1.00	1.00
RNs	3.25	4.00	4.00
Home Training Nurse	1.00	1.00	0.50
Technicians (PCT)	9.50	11.75	11.75
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Admin./Business Office	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
<b>TOTAL</b>	<b>18.25</b>	<b>21.25</b>	<b>20.75</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 45-46, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant projects an increase in the FTE staffing positions necessary to accommodate the proposed increase in healthcare services at Dialysis Care of Kannapolis.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.
- The applicant provides supporting documentation of their annual in-service training as well as courses offered by DaVita’s School of Clinical Education continuing education program.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

### C

The applicant proposes to add no more than six (6) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

#### **Ancillary and Support Services**

In Section I, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 47-50, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the providers of the ancillary and support services.
- The applicant provides documentation identifying providers the dialysis facility has agreements in place with to offer ancillary and supporting services to its patients.

#### **Coordination**

In Section I, page 50, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has numerous years of experience serving the needs of dialysis patients.
- The applicant has established relationships and agreements with community health care providers and social service agencies and can provide appropriate referrals for necessary services and care related to their patients' conditions.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

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

NA

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

C

The applicant proposes to add no more than six (6) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

In Section K, page 53, the applicant states that the project does not involve the construction of new space or renovation of the current space. The facility floor plan is included in Exhibit K-2.

On pages 53-54, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states a project manager partners with the finance department to use a corporate model and regional database to ensure project costs are reasonable.
- The applicant's proposed project is using existing space to add additional dialysis stations and does not include the construction of new space or renovation of the current space.

On page 54, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states costs and charges to the public for the proposed services are not expected to be unduly increased by the proposed project given that the majority of the patients receiving services from the applicant are covered by Medicare/Medicaid in which a single case-mix-adjusted payment rate is paid to the applicant for services.

On pages 54-55, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

In Section L, page 57, the applicant provides the historical payor mix for Dialysis Care of Kannapolis during the last full operating year (CY2020) for its existing services, as shown in the table below.

**Dialysis Care of Kannapolis  
 Historical Payor Mix CY 2020\*\***

Payor Category	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1	1.1%			1	4.3%
Insurance*	5	5.7%	1	11.1%	6	26.1%
Medicare*	62	71.3%	8	88.9%	16	69.6%
Medicaid*	15	17.2%				
Other (Incl. VA)	4	4.6%				
<b>Total</b>	<b>87</b>	<b>100.0%</b>	<b>9</b>	<b>0.0%</b>	<b>23</b>	<b>100.0%</b>

\*Including any managed care plans

Totals may not sum due to rounding

\*\*The project analyst observes that the application lists the last fiscal year from 1/1/2020-12/31/2021; the project analyst believes it should read 1/1/2020-12/31/2020; however, this does not have an effect on the applicant's analysis.

In Section L, page 58, the applicant provides the following comparison.

	Percentage of Total Patients Served during the Last Full OY <sup>^</sup>	Percentage of the Population in the Service Area <sup>*</sup>
Female	42.7%	50.6%
Male	57.3%	49.4%
Unknown	0.0%	0.0%
64 and Younger	36.4%	82.1%
65 and Older	63.6%	17.9%
American Indian	0.0%	0.6%
Asian	0.9%	1.2%
Black or African-American	32.7%	16.9%
Native Hawaiian or Pacific Islander	0.9%	0.1%
White or Caucasian	50.9%	79.4%
Other Race	14.5%	1.8%
Declined / Unavailable	0.0%	0.0%

<sup>^</sup>Includes IC, HH and PD dialysis patients.

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

The Agency reviewed the:

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 59, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 59, the applicant states that during the last 18 months immediately preceding the application deadline that no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 60, 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 CY2024**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	1.08	1.1%			1.17	4.3%
Insurance*	5.39	5.7%	1.44	11.1%	7.04	26.1%
Medicare*	66.79	71.3%	11.56	88.9%	18.78	69.6%
Medicaid*	16.16	17.2%				
Other (incl. VA)	4.31	4.6%				
<b>Total</b>	<b>93.73</b>	<b>100.0%</b>	<b>13</b>	<b>100.0%</b>	<b>27</b>	<b>100.0%</b>

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

As shown in the table above, in the second full year of operation, the applicant projects that 1.1% of in-center dialysis services will be provided to self-pay patients, 71.3% to Medicare patients, and 17.2% to Medicaid patients. In addition, 88.9% of home hemodialysis services will be provided to Medicare patients and 69.6% of peritoneal dialysis services will be provided to Medicare patients.

On page 60, 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 patient payment that has been received by the existing facility in the last fiscal year. 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.

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 61, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L.5.

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 63, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant states the facility will continue to serve as a clinical training site for students.
- The applicant submits supporting documentation showing the facility has a training agreement with Keiser University.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than six (6) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 31 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Dialysis Care of Kannapolis is located in Rowan County. Thus, the service area for this facility is Rowan County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 129 of the 2021 SMFP, the applicant operates three (3) dialysis centers in Rowan County. Information from Table 9A of the 2021 SMFP is provided below:

**Rowan County Dialysis Facilities**

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/19	# IN-CTR PATIENTS	PATIENTS / STATION	PERCENT UTILIZATION
Dialysis Care of Kannapolis	30	98	3.26	81.67%
Dialysis Care of Rowan County	33	111	3.36	84.09%
Spencer Dialysis	10	33	3.30	82.50%
<b>Total</b>	<b>73</b>	<b>242</b>		

Source: 2021 SMFP, Table 9A, page 129 and page 43 of the application.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 64, 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.”*

Regarding the impact of the proposal on cost effectiveness, quality, and access to medically underserved groups in Section N, page 64, the applicant states:

*“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... As discussed in Section B and Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients.”*

See also Sections B, C, F, L, N, O and Q of the application and any exhibits.

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because it adequately demonstrates the following:

- The need the population to be served has for the proposal, the proposal would not result in an unnecessary duplication of existing and approved health services, and the projected revenues and operating costs are reasonable, which collectively results in a cost-effective proposal.
- The quality of care to be provided is based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

In Section Q, Form O Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 108 of this type of facility located in North Carolina.

In Section O, page 68, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care resulting in a finding of "*Immediate Jeopardy*" occurred in any of its facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality

of care provided at all DaVita facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

### C

The application is conforming or conditionally conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

#### **10A NCAC 14C .2203 Performance Standards**

(a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following *certification* of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- Dialysis Care of Kannapolis is an existing facility. Therefore, this Rule is not applicable to this review.

(b) An applicant proposing to increase the number of dialysis stations in:

(1) an existing dialysis facility; or

(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C, page 23, and Form C in Section Q, the applicant projects that Dialysis Care of Kannapolis will serve 92 in-center patients on 31 stations, or a rate of 2.9 patients per station per week or 74.2% ( $92 / 31 = 2.968 / 4 = 0.742$  or 74.2%), as of the end of the first operating year (CY2023) following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
  
- C- In Section C, pages 22-23, in Section Q, Form C, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.