ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: June 29, 2018
Findings Date: June 29, 2018

Project Analyst: Gregory F. Yakaboski
Assistant Chief: Lisa Pittman

Project ID #: F-11489-18
Facility: Dialysis Care of Kannapolis
FID #: 980409
County: Rowan
Applicant(s): Total Renal Care of North Carolina, LLC
Project: Add two stations for a total of 22 stations upon completion of this project, Project I.D. #F-11264-16 (relocate two stations) and Project I.D. #F-11452-18 (relocate eight stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (TRC and/or the applicant), d/b/a Dialysis Care of Kannapolis (DC Kannapolis) proposes to add two stations to the DC Kannapolis facility for a total of 22 stations upon completion of this project, Project I.D. #F-11264-16 (relocate two stations) and Project I.D. #F-11452-18 (relocate eight stations). In addition to in-center (IC) dialysis, DC Kannapolis currently offers both a peritoneal dialysis (PD) program and a home hemodialysis (HH) program. The parent company of TRC is DaVita, Inc. (DaVita).

Need Determination

The 2018 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 the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Mecklenburg County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for BMA Nations Ford in the January 2018 SDR is 3.88 patients per station per week. This utilization rate was calculated based on 97 in-center dialysis patients and 25 certified dialysis stations as of June 30, 2017 (97 patients /25 stations = 3.88 patients per station per week). Application of the facility need methodology indicates that 3 additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		97.00%
Certified Stations		25
Pending Stations		5
Total Existing and Pending Stations		**30**
In-Center Patients as of 6/30/17 (SDR2)		97
In-Center Patients as of 12/31/16 (SDR1)		88
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.2045
(ii)	Divide the result of step (i) by 12	0.0170
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.1023
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	106.9205
(v)	Divide the result of step (iv) by 3.2 patients per station	33.4126
	and subtract the number of certified and pending stations to determine the number of stations needed	**3**

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 3 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 2018 SDR. Step (C) of the facility need methodology states, *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add 2 new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*. *Policy GEN-3*, on page 33, 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."*

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, Section O, page 53, and Exhibits O-2 and O-3. 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.4(b), page 10, Section L, pages 46-50, and Exhibit L-3. 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.4(c) and (d), page 11, Section C, pages 13-16, and Section N, page 52. 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

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

TRC proposes to add two stations to DC Kannapolis for a total of 22 stations upon completion of this project, Project I.D. #F-11264-16 (relocate two stations) and Project I.D. #F-11452-18 (relocate eight stations). In addition to in-center (IC) dialysis, DC Kannapolis currently offers both a peritoneal dialysis (PD) program and a home hemodialysis (HH) program.

Patient Origin

On page 365 the 2018 SMFP defines the service area for dialysis stations as *"a dialysis station's service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area."* 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.8, page 21, the applicant provides a table showing the historical patient origin for IC, HH and PD patients served by DC Kannapolis, as shown below:

Dialysis Patients as of 6/30/17

COUNTY	IC	HH	PD
Rowan	46	2	9
Anson	1	0	0
Cabarrus	44	7	11
Iredell	1	0	1
Mecklenburg	1	1	2
Stanly	1	1	1
Wake	1	0	0
Other States	2	0	0
Total	97	11	24

In Section C.1, page 13, the applicant provides the projected patient origin for DC Kannapolis for IC, HH and PD patients for the first two years of operation following completion of the project as follows:

COUNTY	OPERATING YEAR 1 CY2020			OPERATING YEAR 2 CY2021			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Rowan	55	6	13	59	7	14	66.1%	67.8%
Anson	1	0	0	1	0	0	0.9%	0.8%
Cabarrus	9	7	9	9	7	9	22.3%	21.2%
Iredell	1	0	1	1	0	1	1.8%	1.7%
Mecklenburg	1	1	2	1	1	2	3.6%	3.4%
Stanly	1	1	1	1	1	1	2.7%	2.5%
Wake	1	0	0	1	0	0	0.9%	0.8%
Other States	2	0	0	2	0	0	1.8%	1.7%
Total	71	15	26	75	16	27	100.0%	100.0%

The applicant provides the assumptions and methodology used to project patient origin on pages 13-16. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Sections C.1, page 13, the applicant states that the current utilization rate for Dialysis Care of Kannapolis is 97.0%, per the January 2018 SDR, which provides patient data as of June 30, 2017.

In Section C.2, page 17, the applicant states:

> *"Section B-2 clearly outlines the need that the population to* [be] *served, the in-center patients of DC Kannapolis, has for the two-station expansion proposed in the application.*
>
> *This application does not call for any changes to home hemo or PD services at DC Kannapolis."*

Section B.2, page 7, includes the ESRD facility need methodology table which shows a need for up to three additional dialysis stations at Dialysis Care of Kannapolis.

In Section N.1, page 52, the applicant discusses the need for the additional stations at Dialysis Care of Kannapolis. The applicant states:

> *"..., 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 information is reasonable and adequately supported for the following reasons:

- the facility is currently operating at 97.0% capacity,
- the applicant bases the future need for services upon the facility's historical patient utilization, and
- the applicant utilizes the 5-year county average annual change rate (AACR) of 6.5% for Rowan County patients only and does not grow the patient population from outside Rowan County.

Projected Utilization

Projected Utilization – In-center

On pages 13-15, the applicant illustrates how in-center patient utilization was projected, which is summarized as follows:

- Operating Year One (OY1) is January 1, 2020 – December 31, 2020.
- Operating Year Two (OY2) is January 1, 2021 – December 31, 2021
- As of June 30, 2017, DC Kannapolis had 97 in-center patients, 46 of whom were residents of Rowan County and 51 of whom were non-Rowan county residents.
- On January 1, 2018 one patient from Rowan county is projected to transfer from DC Kannapolis to Spencer Dialysis (Project ID# F-11264-15).
- On January 1, 2020, thirty five non-Rowan county patients are projected to transfer from DC Kannapolis to Cannon Dialysis (Project ID #F-11452-18).
- In-center patient population of Rowan County residents is projected to grow at 6.5% (the Five-Year Average Annual Growth Rate (AAGR) for Rowan County) pursuant to Table D in the January 2018 Semi-Annual Dialysis Report (SDR).

The following table illustrates application of these assumptions and the methodology used.

Dialysis Care of Kannapolis	In-Center Patients
Begin with Dialysis Care of Kannapolis's in-center ESRD patient population from Rowan County, as of June 30, 2017.	46
Project the Rowan County population forward six months to December 31, 2017, using the Five Year AACR for Rowan County.	46 x 1.0325= 47.495
Project the Rowan County population forward one year to December 31, 2018, using the Five Year AACR for Rowan County.	47.495 x 1.065 = 50.582
Subtract 1 Rowan County patient projected to transfer to Spencer Dialysis in Rowan County (Project ID #F-11264-16)	50.582 – 1 = 49.582
Project the Rowan County population forward one year to December 31, 2019, using the Five Year AACR for Rowan County.	49 x 1.065= 52.185
Add the 51 non-Rowan County patients. This is the beginning census for the proposed project.	52.185 + 51 = 103.805
Project the Rowan County population forward one year to December 31, 2020, using the Five Year AACR for Rowan County.	52.185 x 1.065 = 55.577
Add the 51 non-Rowan County patients minus the 35 Cabarrus County patients projected to transfer to Cannon Dialysis. (51-35 =16). **This is the patient census at the end of OY1.**	55.577 + 16 = **71.577**
Project the Rowan County population forward one year to December 31, 2021, using the Five Year AACR for Rowan County.	55.577x 1.065 = 59.189
Add the 16 non-Rowan County patients. **This is the patient census at the end of OY2.**	59.189 + 16 = **75.189**

The applicant states on page 15 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2020) and OY2 (CY2021) the facility is projected to serve 71 and 75 in-center patients, respectively.

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

- OY1: 3.23 patients per station per week, or 80.75% (71 patients/22 stations = 3.23/4 = 0.8075 or 80.75%).

- OY2: 3.41 patients per station per week, or 85.22% (75 patients/22 stations = 3.409/4 = 0.8522 or 85.22%).

The projected utilization of 3.23 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization for in-center patients is reasonable and adequately supported for the following reasons:

- the applicant bases the future utilization of services upon the facility's historical patient utilization, and
- the applicant grows only the Rowan County patient population by the 5-year Rowan County average annual change rate (AACR) of 6.5%.

Projected Utilization-HH Patients

The applicant provides projected utilization for its HH patients in Section C.1, pages 15-16, as follows:

- Operating Year One (OY1) is January 1, 2020 – December 31, 2020.
- Operating Year Two (OY2) is January 1, 2021 – December 31, 2021
- The growth period starts July 1, 2017.
- As of June 30, 2017, DC Kannapolis had 11 HH patients. See Table C of the January 2018 SDR.
- The applicant states that it is reasonable to assume a growth rate for HH patients of 1 per year.

Operating Year	Start Date	Beginning Census of PD Patients	Ending Census of PD Patients
Interim Year	7/1/2017	11	12
Current Year	1/1/18	12	13
Interim Year	1/1/19	13	14
OY1	1/1/20	14	15
OY2	1/1/21	15	16

Projected Utilization-PD Patients

The applicant provides projected utilization for its PD patients in Section C.1, page 16, as follows:

- Operating Year One (OY1) is January 1, 2020 – December 31, 2020.
- Operating Year Two (OY2) is January 1, 2021 – December 31, 2021
- The growth period starts July 1, 2017.
- As of June 30, 2017, DC Kannapolis had 24 PD patients. See Table C of the January 2018 SDR.
- The applicant projects that, upon certification of the proposed Cannon Dialysis facility (Project ID# F-11452-18), two current PD patients of Dialysis Care of Kannapolis will transfer their care to Cannon Dialysis. Cannon Dialysis is projected to be certified as of January 1, 2020.
- The applicant states that it is reasonable to assume a growth rate for PD patients of 1 per year.

Operating Year	Start Date	Beginning Census of PD Patients	Ending Census of PD Patients
Interim Year	7/1/2017	24	25
Current Year	1/1/18	25	26
Interim Year	1/1/19	26	27
OY1	1/1/20	27-2 = 25	26
OY2	1/1/21	26	27

Projected utilization for the IC, HH and PD dialysis programs at DC Kannapolis is reasonable and adequately supported for the following reasons:

- The applicant projects the starting IC, HH and PD patient census for the proposed facility based on existing Dialysis Care of Kannapolis IC, HH and PD patients.

- The applicant's growth projections for Rowan County IC patients is based on an assumption that IC patient census will increase at an annual rate of 6.5%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Rowan County, as reported in Table D of the January 2018 SDR.

- The projected growth rates for HH and PD patients of 1 patient per year is reasonable.

- The applicant's projected utilization accounts for the existing DC Kannapolis IC and PD patients projected to transfer their care to Spenser Dialysis and Cannon Dialysis.

Access

In Section C.3, page 17, 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*."

In Section L.1, page 47, the applicant projects the following payor mix during the second full fiscal year of operation (CY2021) following completion of the project, as illustrated in the following table.

Payor Category	Percent of Total Patients
Medicaid	6.3%
Medicare	33.3%
Medicare/Medicaid	21.4%
Medicare/Commercial	22.2%
VA	6.3%
Commercial Insurance	10.5%
Total	**100.0%**

Source: Table, page 50 of the application.

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 to reduce or eliminate a service, nor does the applicant propose to 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

TRC proposes to add two stations to DC Kannapolis for a total of 22 stations upon completion of this project, Project I.D. #F-11264-16 (relocate two stations) and Project I.D. #F-11452-18 (relocate eight stations). In addition to in-center (IC) dialysis, DC Kannapolis currently offers both a peritoneal dialysis (PD) program and a home hemodialysis (HH) program.

In Section E, page 25, 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 Facility- DaVita has two other operational facilities in Rowan County, both of which are operating at over 80.0% capacity. Patients presently being served by these two other facilities would be negatively impacted if stations were relocated from these facilities.

On page 28, the applicant states that its proposal is the most effective alternative because the proposed project will address both the issues of growth and access to the facility. Developing a third shift is inconvenient for patients.

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 for the reasons stated above. Therefore, the application is approved subject to the following conditions:

1. **Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Pursuant to the facility need determination in the January 2018 SDR, Total Renal Care of North Carolina, LLC shall develop no more than 2 additional dialysis stations for a total of no more than 22 certified stations at Dialysis Care of Kannapolis upon completion of this project, Project I.D. #F-11264-16 (relocate two stations) and Project I.D. #F-11452-18 (relocate eight stations), which shall include any home hemodialysis training or isolation stations.**

3. **Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

TRC proposes to add two stations to DC Kannapolis for a total of 22 stations upon completion of this project, Project I.D. #F-11264-16 (relocate two stations) and Project I.D. #F-11452-18 (relocate eight stations). In addition to in-center (IC) dialysis, DC Kannapolis currently offers both a peritoneal dialysis (PD) program and a home hemodialysis (HH) program.

Capital and Working Capital Costs

In Section F, pages 26 and 28-29, the applicant states that the proposed project will not involve any capital expenditures or initial operating expenses.

Financial Feasibility

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

	1st Full Fiscal Year	2nd Full Fiscal Year
Total Treatments*	16,228	17,043
Total Gross Revenues (Charges)	$5,538,309	$5,817,685
Total Net Revenue	$5,295,570	$5,562,735
Average Net Revenue per treatment	$326.32	$326.39
Total Operating Expenses (Costs)	$3,959,256	$4,137,140
Average Operating Expense per treatment	$243.98	$242.75
Net Income	$1,336,313	$1,425,595

*Includes both IC, PD and HH treatments from Form C of Section R.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R 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
- 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 demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

TRC proposes to add two stations to DC Kannapolis for a total of 22 stations upon completion of this project, Project I.D. #F-11264-16 (relocate two stations) and Project I.D. #F-11452-18 (relocate eight stations). In addition to in-center (IC) dialysis, DC Kannapolis currently offers both a peritoneal dialysis (PD) program and a home hemodialysis (HH) program.

On page 365 the 2018 SMFP defines the service area for dialysis stations as *"a dialysis station's service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area."* Thus, the service area for this facility consists of Rowan County. Facilities may also serve residents of counties not included in their service area.

DaVita operates all three of the dialysis facilities in Rowan County. The three (2 existing and 1 approved) Rowan County dialysis facilities are shown below:

Rowan County Dialysis Facilities

Dialysis Facilities	Owner	Location	# of Certified Stations as of 6/30/17	Percent Utilization
Dialysis Care of Kannapolis*	DaVita	Kannapolis	25	97.00%
Dialysis Care of Rowan County**	DaVita	Salisbury	33	84.09%
Spencer Dialysis***	DaVita	Spencer	0	0.0%

Source: Table B, January 2018 SDR
*Note: Dialysis Care of Kannapolis has received a certificate of need to add 5 stations pursuant to Project I.D. #F-11245-16.
**Note: Dialysis Care of Rowan County has received a certificate of need for the following projects: Project I.D. #F-11154-16 (add six dialysis stations), Project I.D. #F-11264-16 (relocate eight stations), Project I.D. #F-11324-17(add one dialysis station) and Project I.D. #F-11408-17 (add three dialysis stations).
***Note: Total Renal Care of North Carolina, LLC, Project ID #F-11264-16, received a certificate of need dated April 7, 2017, to develop a new 10-station facility to be known as Spencer Dialysis by relocating 8 stations from DC Rowan County and 2 stations from Dialysis Care of Kannapolis.

As illustrated above, the three dialysis facilities (two existing and one approved) in Rowan County are operated by DaVita. Based on the most recent SDR, the two existing facilities in Rowan County operated at 84.0% utilization rate or above.

In Section G.2, page 32, 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:

> *"In Section B-2 and Section C of this application, we demonstrate the need that DC Kannapolis has for adding stations. While adding stations at this facility does increase the number of stations in Rowan County, it 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 would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- Based on the facility need methodology for dialysis stations, the potential number of stations needed at Dialysis Care of Kannapolis is 3 stations.

- The applicant adequately demonstrates that the two proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Rowan County.

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 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 H.1, page 33, the applicant provides the current staffing for the facility, and states that DC Kannapolis is not projected to add any full time equivalent (FTE) positions as a result of this proposal. The applicant states the facility currently staffs 22.0 FTE positions and will have a staff of 22.0 FTEs upon project completion. In addition, the applicant provides projected direct care staff in OY 2 in Section H.7, page 36.

The assumptions and methodology used to project staffing are provided in Section H.1, page 33 and Sections H.6 and H.7, page 36. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 34-35, the applicant describes the methods used to

recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-2, H-3 and H-4, the applicant provides supporting documentation. In Section I.3, page 41, the applicant identifies the proposed medical director. In Exhibit I-3, the applicant provides a letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services.

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

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 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.1, page 37, the applicant identifies the ancillary and support services necessary for the proposed services.

DIALYSIS CARE OF KANNAPOLIS DIALYSIS Ancillary and Support Services	
Services	**Provider**
In-center dialysis/maintenance	DC Kannapolis
Self-care training (in-center)	DC Kannapolis
Home training HH PD Accessible follow-up program	DC Kannapolis
Psychological counseling	DC Kannapolis
Isolation – hepatitis	DC Kannapolis
Nutritional counseling	DC Kannapolis
Social Work services	DC Kannapolis
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Carolinas Medical Center
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Carolinas Medical Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC DHHS Div of Vocational Rehab Services
Transportation	DSS, Rowan Transit System (RTS)

On page 37, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1.

In Section I, pages 38-39, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1 and I-3.

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
- 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.

(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 applicants are not a 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 to construct any new space nor renovate any existing space. 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.7, page 50, the applicant provides the historical payor mix during CY 2017 at DC Kannapolis, as shown in the table below.

Payor Category	Percent of Total Patients
Medicaid	6.3%
Medicare	33.3%
Medicare/Medicaid	21.4%
Medicare/Commercial	22.2%
VA	6.3%
Commercial Insurance	10.5%
Total	**100.0%**

Source: Table, page 50 of the application. Note: The dates on the table on page 50 contain a typo stating "From 1/1/2017 to 1/1/2017." From the heading on the table this should have read "From 1/1/2017 to 12/31/2017".

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	**% 65+**	**% Female**	**% Racial and Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
2016 Estimate	**2016 Estimate**	**2016 Estimate**	**2016 Estimate**	**2015 Estimate**	**2011-2015**	**2015 Estimate**
Rowan	17%	51%	27%	17%	12%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: http://www.census.gov/quickfacts/table Latest Data 7/1/16 as of 8/22/17
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."*

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc.*

2014 Annual Report[1] percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28[2]. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3, page 49, the applicant states

> *"DC Kannapolis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act."*

In Section L.6, page 49, 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.

[1] http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf
[2] http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

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.

(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.1, page 47, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Percent of Total Patients
Medicaid	6.3%
Medicare	33.3%
Medicare/Medicaid	21.4%
Medicare/Commercial	22.2%
VA	6.3%
Commercial Insurance	10.5%
Total	**100.0%**

Source: Table, page 50 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 83.2% of total services will be provided to Medicaid/Medicare patients.

On page 50, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for DC Kannapolis.

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.

(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.4, page 49, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

(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 51, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

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 demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

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

C

TRC proposes to add two stations to DC Kannapolis for a total of 22 stations upon completion of this project, Project I.D. #F-11264-16 (relocate two stations) and Project I.D. #F-11452-18 (relocate eight stations). In addition to in-center (IC) dialysis, DC Kannapolis currently offers both a peritoneal dialysis (PD) program and a home hemodialysis (HH) program.

On page 365 the 2018 SMFP defines the service area for dialysis stations as *"a dialysis station's service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area."* Thus, the service area for this facility consists of Rowan County. Facilities may also serve residents of counties not included in their service area.

DaVita operates the all three of the dialysis facilities in Rowan County. The three (2 existing and 1 approved) Rowan County dialysis facilities are shown below:

Rowan County Dialysis Facilities

Dialysis Facilities	Owner	Location	# of Certified Stations as of 6/30/17	Percent Utilization
Dialysis Care of Kannapolis*	DaVita	Kannapolis	25	97.00%
Dialysis Care of Rowan County**	DaVita	Salisbury	33	84.09%
Spencer Dialysis***	DaVita	Spencer	0	0.0%

Source: Table B, January 2018 SDR

*Note: Dialysis Care of Kannapolis has received a certificate of need to add 5 stations pursuant to Project I.D. #F-11245-16.

**Note: Dialysis Care of Rowan County has received a certificate of need for the following projects: Project I.D. #F-11154-16 (add six dialysis stations), Project I.D. #F-11264-16 (relocate eight stations), Project I.D. #F-11324-17(add one dialysis station) and Project I.D. #F-11408-17 (add three dialysis stations).

***Note: Total Renal Care of North Carolina, LLC, Project ID #F-11264-16, received a certificate of need dated April 7, 2017, to develop a new 10-station facility to be known as Spencer Dialysis by relocating 8 stations from DC Rowan County and 2 stations from Dialysis Care of Kannapolis.

As illustrated above, the three dialysis facilities (two existing and one approved) in Rowan County are operated by DaVita. Based on the most recent SDR, the two existing facilities in Rowan County operated at 84.0% utilization rate or above.

In Section N, page 52, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 52, the applicant states:

> *"The expansion of DC Kannapolis will have no effect on completion in Rowan County…this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita….The expansion of DC 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."*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

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.

(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 A.11, page 5, the applicant states DaVita operates more than 75 dialysis facilities in North Carolina. Exhibit A-11 contains a list of the DaVita dialysis facilities located in North Carolina.

In Section O, page 53, and Exhibit O-3 the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care

occurred in one of these facilities, Southeastern Dialysis Center-Wilmington. The applicant provided supplemental information to the Agency that demonstrates that Southeastern Dialysis Center-Wilmington is currently back in full compliance with all CMS requirements as of March 21, 2018. The applicant provides additional documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage for the facility in Exhibit O-3. Furthermore, in Project ID#F-11452-18, the applicant, in Section O, page 56, and Exhibit O-3 the applicant states that a survey conducted on October 26, 2017, led to the identification of an Immediate Jeopardy for Goldsboro South Dialysis, that all of the problems have been corrected and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided 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 application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(*a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- The applicant is not proposing to establish a new End Stage Renal Disease facility.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations

based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.1, page 13, the applicant projects to serve 71 in-center patients by the end of OY1 (CY2020) for a utilization rate of 80.75% or 3.23 patients per station per week (71 patients / 22 stations = 3.23/ 4 = 0.8075 or 80.75%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13-16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.