

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 27, 2014
PROJECT ANALYST: Celia C. Inman
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10273-14 / Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis / Add one dialysis station for a total of 20 dialysis stations upon completion of this project and Project ID #F-10109-13 / Rowan County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

Total Renal Care of North Carolina, LLC (TRCNC) d/b/a Dialysis Care of Kannapolis (DC of Kannapolis) proposes to add one certified dialysis station to the existing facility for a total of 20 certified stations upon the completion of this project and Project ID# F-10109-13. This project seeks to relocate one station from Dialysis Care of Rowan County (DC of Rowan County), located in Salisbury to DC of Kannapolis. Both facilities are located in Rowan County. Project ID# F-10109-13 conditionally approved the relocation of six certified stations from DC of Kannapolis to Copperfield Dialysis Center in Concord in Cabarrus County. DC of Kannapolis is certified for 25, pending the relocation of six stations to Copperfield, which will leave 19 certified stations at DC of Kannapolis.

The January 2014 Semiannual Dialysis Report (SDR) reports two ESRD facilities in Rowan County, DC of Kannapolis and DC of Rowan County. DC of Rowan County has 29 certified dialysis stations.

This application proposes to relocate dialysis stations within Rowan County. Therefore, neither the county need nor the facility need methodologies in the 2014 SMFP are applicable to this review. Additionally, Policy GEN-3: BASIC PRINCIPLES is not applicable because neither need methodology is applicable to the review. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable because the applicant is not proposing a capital expenditure greater than \$2 million.

However, Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS is applicable to this review. Policy ESRD-2 states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations shall:

- (A) Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent Dialysis Report, and*
- (B) Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent Dialysis Report.”*

The project is scheduled for completion in January 2015. In this application, the applicant proposes to relocate dialysis stations between facilities within the county. Consequently, there is no change in dialysis station inventory in Rowan County. The application is consistent with Policy ESRD-2 in the 2014 SMFP. Therefore the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, TRCNC d/b/a DC of Kannapolis, proposes to relocate one dialysis station from DC of Rowan County to DC of Kannapolis for a total of 20 stations upon the completion of this project and Project ID# F-10109-13. As of June 30, 2013, DC of

Rowan County has 29 certified dialysis stations. In Section III.3, page 19, the applicant states:

“DC of Rowan County has 29 certified dialysis stations. The facility has never used more than 28 stations. DC of Kannapolis has 25 certified stations at present. However, six of those stations are pending transfer to the Copperfield Dialysis Center in Concord in Cabarrus County. This will leave DC of Kannapolis with 19 stations. DC of Kannapolis will need 20 stations in order to keep their patients on the current schedule. If the six stations are transferred and there is not a 20th station, several patients will have to change shifts or even the days they receive their dialysis services.”

Population to be Served

In Section III.7, pages 21-23, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

Projected Dialysis Patient Origin

COUNTY	OPERATING YEAR 1 2015		OPERATING YEAR 2 2016		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Rowan	32	14	33	14	46.0%	46.5%
Cabarrus	32	17	32	17	49.0%	48.5%
Mecklenburg	0	2	0	2	2.0%	2.0%
Stanly	0	3	0	3	3.0%	3.0%
Total	64	36	65	36	100.0%	100.0%

In Section IV.1, page 25, the applicant provides the patient origin at DC of Kannapolis as of June 30, 2013 as shown in the table below.

**DC of Kannapolis
 Patient Origin, as of 6/30/13**

COUNTY	IN-CENTER	HOME
Rowan	29	14
Cabarrus	32	17
Mecklenburg	0	2
Stanly	0	3
Total	61	36

As the tables above illustrate, the projected patient origin is based upon the historical patient origin. The DC of Kannapolis facility is located in Kannapolis near the Rowan/Cabarrus County line. 48% of the DC of Kannapolis in-center patients are from Rowan County and 52% are from Cabarrus County. The applicant adequately identified the population it proposes to serve.

Demonstration of Need

The applicant proposes to relocate one dialysis station from one existing TRCNC Rowan County dialysis facility to another existing TRCNC Rowan County dialysis facility. In Section III, page 19, the applicant states that the relocation of the dialysis station from DC of Rowan County (the only other existing dialysis facility in Rowan County) to DC of Kannapolis is needed because:

“DC of Rowan County has 29 certified dialysis stations. The facility has never used more than 28 stations. DC of Kannapolis has 25 certified stations at present. However, six of those stations are pending transfer to the Copperfield Dialysis Center in Concord in Cabarrus County. This will leave DC of Kannapolis with 19 stations. DC of Kannapolis will need 20 stations in order to keep their patients on the current schedule. If the six stations are transferred and there is not a 20th station, several patients will have to change shifts or even the days they receive their dialysis services.”

The applicant provides the assumptions and methodology it uses to project the proposed in-center patient utilization for DC of Rowan County and DC of Kannapolis following the proposed relocation of one dialysis station on pages 20-23.

In Section III, pages 20-21, the applicant discusses DC of Rowan County’s utilization. The January 2014 SDR shows there were 85 ESRD in-center dialysis patients receiving their treatments at DC of Rowan County, as of June 30, 2013. The facility utilization rate with 29 certified stations was 73.28% ($85 / 29 = 2.93$; $2.93 / 4 = 0.7325$). The applicant states:

“With one dialysis station transferring from DC of Rowan to DC of Kannapolis, this will leave 85 in-center patients and 28 dialysis stations at DC of Rowan County if we do not take into consideration any patient growth between June 30, 2013 and when DC of Kannapolis is projected to be certified (January 1, 2015).”

Assuming no growth and the reduction by one station for a total of 28 stations, DC of Rowan County would have a utilization rate of 75.8% ($85 \text{ patients} / 28 \text{ stations} = 3.03$ patients per station / $4 = 0.7589$).

With regard to the projected utilization of DC of Kannapolis, in Section III, page 22, the applicant projects 64 patients by the end of the first operating year and 65 patients by the end of the second operating year, for a utilization of 80% ($64 / 20 = 3.2 / 4 = 0.80$) and 81% ($65 / 20 = 3.25 / 4 = 0.81$), respectively.

In Section III, pages 22-23, the applicant provides the following data to support the above projected patient utilization for the two facilities:

- DC of Kannapolis had 61 in-center patients as of June 30, 2013, based on Table A of the January 2014 SDR. This is a station utilization rate of 61% based on DC of Kannapolis' 25 certified stations.
- Six of DC of Kannapolis' 25 stations are pending relocation to Copperfield Dialysis Center in Cabarrus County.
- With the 19 stations that will remain after the relocation of the six stations, DC of Kannapolis would have a utilization rate of 80%.
- After the relocation of the six stations, DC of Kannapolis will be in need of an additional dialysis station in order to adequately meet the needs of the growing in-center patient population.
- DC of Kannapolis' 2013 in-center patient origin show 48% of its patients are from Rowan County and 52% are from Cabarrus County.
- DC of Rowan County is certified for 29 in-center stations, but only uses 28 of the stations.
- This project is to relocate one station from DC of Rowan County to DC of Kannapolis. The project does not include the transfer of any patients.
- The number of patients and the fractions of patients were added to determine the number of patients that will be served.
- No growth is projected for the home-trained patient population.

The applicant summarizes the assumptions separately for DC of Kannapolis patients originating from Rowan and Cabarrus counties as shown below:

Rowan County Patients

- The period of growth begins January 1, 2014 forward to December 31, 2016.
- The January 2014 SDR shows the five-year average change rate (AAGR) in Rowan County is 5.1%.
- The calculations are based on 29 in-center patients living in Rowan County as of June 30, 2013.
- Projected January 1, 2014 - December 31, 2014 in-center dialysis patients = 29 in-center patients X 1.051 = 30.48.
- Projected January 1, 2015 - December 31, 2015 in-center dialysis patients = 30.48 in-center patients X 1.051 = 32.03.

- Projected January 1, 2016 - December 31, 2016 in-center dialysis patients = $32.03 \text{ in-center patients} \times 1.051 = 33.67$.
- Operating Year One is January 1, 2015 - December 31, 2015.
- Operating Year One is January 1, 2016 - December 31, 2016.

Cabarrus County Patients

- The period of growth begins January 1, 2014 forward to December 31, 2016.
- The January 2014 SDR shows the AAGR in Cabarrus County is 0.7%.
- The calculations are based on 29 [32] in-center patients living in Cabarrus County as of June 30, 2013.
- Projected January 1, 2014 - December 31, 2014 in-center dialysis patients = $32 \text{ in-center patients} \times 1.007 = 32.22$.
- Projected January 1, 2015 - December 31, 2015 in-center dialysis patients = $32.22 \text{ in-center patients} \times 1.007 = 32.45$.
- Projected January 1, 2016 - December 31, 2016 in-center dialysis patients = $32.45 \text{ in-center patients} \times 1.007 = 32.68$.
- Operating Year One is January 1, 2015 - December 31, 2015.
- Operating Year One is January 1, 2016 - December 31, 2016.

Applying the methodology and assumptions outlined by the applicant, and listed above, results in the following table which projects in-center patients from January 1, 2014 through December 31, 2016 for DC of Kannapolis:

	Rowan County Patients	Cabarrus County Patients	Total Patients
TRCNC begins with the DC of Kannapolis in-center patients originating from Rowan and Cabarrus Counties as of June 30, 2013 and carries that number of patients forward to January 1, 2014.	29	32	61
TRCNC projects DC of Kannapolis in-center patients forward for 12 months to December 31, 2014, using each county's AAGR	$(29 \times .051) + 29 = 30$	$(32 \times .007) + 32 = 32$	62
TRCNC projects DC of Kannapolis in-center patients forward for 12 months to December 31, 2015, using each county's AAGR	$(30.48 \times .051) + 30.48 = 32$	$(32.22 \times .007) + 32.22 = 32$	64
TRCNC projects DC of Kannapolis in-center patients forward for 12 months to December 31, 2016, using each county's AAGR	$(32.03 \times .051) + 32.03 = 33$	$(32.45 \times .007) + 32.45 = 32$	65

Note: "The number of patients and the fractions of patients were added to determine the number of patients that will be served." Numbers may not sum due to rounding.

As the table above illustrates and the applicant states on page 22 of the application:

"Based on the patients and stations above, DC of Kannapolis is projected to have at least 64 in-center patients by the end of operating year 1 for a utilization rate of 80% or 3.2 patients per stations and at least 65 in-center patients by the end of operating year 2 for a utilization rate of 81% or 3.3 patients per station."

The applicant adequately demonstrates the need the population proposed to be served has for the relocation of one dialysis station from DC of Rowan County to DC of Kannapolis.

Access to Services

In Section III, page 21, the applicant states:

"The relocation of one station from DC of Rowan County to DC of Kannapolis will not affect the ability of either facility to continue to serve low income persons, racial and ethnic minorities, women, handicapped persons and other underserved group [sic] and the elderly who need to obtain health care."

In Section VI, page 31, the applicant states,

"DC of Kannapolis, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve patients without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay."

...

DC of Kannapolis makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. DC of Kannapolis provides dialysis six days per week with two patient shifts per day to accommodate patient need.

...

DC of Kannapolis does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. DC of Kannapolis works with patients who need transportation, when necessary.”

The applicant projects that 67.9% of its patients will be covered by Medicare, Medicaid or VA and another 26.4% will be covered by Medicare/Commercial. The applicant adequately demonstrates 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.

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and the extent to which all residents of the area are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (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.

C

The applicant, TRCNC d/b/a DC of Kannapolis proposes to relocate one dialysis station from DC of Rowan County to DC of Kannapolis. Both facilities are located in Rowan County. The applicant does not propose to transfer any patients from DC of Rowan County.

The January 2014 SDR shows DC of Rowan County with a utilization rate of 73.28% on 29 certified dialysis stations. The applicant discusses the number of patients and stations at DC of Rowan County after the relocation of one station on page 20, stating:

“With one dialysis station transferring from DC of Rowan to DC of Kannapolis, this will leave 85 in-center patients and 28 dialysis stations at DC of Rowan County if we do not take into consideration any patient growth between June

30, 2013 and when DC of Kannapolis is projected to be certified (January 1, 2015)."

Assuming no growth, DC of Rowan County's utilization rate with 85 patients and 28 stations is 76% ($85 / 28 = 3.04 / 4 = 75.9\%$). The applicant did not discuss its rationale for assuming no growth; however, a review of the facility's historical utilization as provided in the applicable SDRs, provides support and credibility to that assumption. There has been a decrease in the patient population from 95 patients and 29 stations in December 2011 to 85 patients and 29 stations in June 2013. Therefore, there is no basis to project an increase in future patients.

In Section III, page 20, the applicant states that even though DC of Rowan County has 29 certified dialysis stations, it has never used more than 28 stations. In Section III, page 21, the applicant states:

"The relocation of one station from DC of Rowan County to DC of Kannapolis will not affect the ability of either facility to continue to serve low income persons, racial and ethnic minorities, women, handicapped persons and other underserved group [sic] and the elderly who need to obtain health care."

The applicant demonstrates that the needs of the population presently served at the DC of Rowan County facility will continue to be adequately met following the proposed relocation of one dialysis station to DC of Kannapolis. See discussion in Criterion (13) with regard to access by medically underserved groups which is incorporated hereby as if set forth fully herein. Therefore, the application is conforming to this criterion.

- (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

In Section III.9, page 24, the applicant discusses the alternatives considered prior to the submission of its application, which include:

- 1) Maintain the Status Quo – the applicant states that this alternative was dismissed since the facility is rapidly growing.
- 2) Chosen alternative – apply for the relocation of one station from DC of Rowan County to DC of Kannapolis.

On page 24, the applicant states:

"We chose the second alternative in order to help meet the growing demand for dialysis services at the DC of Kannapolis facility."

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the following:

- The DC of Rowan County facility does not fully utilize its 29 dialysis stations.
- The DC of Rowan County facility patient population has not seen an increase in the number of patients since December 2011; and in fact, the number of patients decreased 8.6 % from December 2012 to June 2013.
- Following the relocation of six stations from DC of Kannapolis to Copperfield, DC of Kannapolis will need one additional station to meet expected patients' needs.
- Minimal capital will be needed to achieve the relocation of the station. The applicant will utilize DaVita's centralized purchasing department with national contracts.
- The facility uses electronic patient charting and other documentation, reducing the need for paper.
- A DC of Kannapolis Bio-medical Technician will conduct preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule that reduces the need for repair maintenance and parts. This will extend the life of the dialysis machines.

Furthermore, the application is conforming or conditionally conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions and the conditions cited in Criterion (14) and 10A NCAC 14C .2202.

- 1. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall relocate and operate no more than one (1) additional certified dialysis station for a total of no more than twenty (20) certified stations, which shall include any home hemodialysis training stations or isolation stations, upon the completion of this project and Project ID # F-10109-13.**

- 3. After the certification of the additional one (1) dialysis station at Dialysis Care of Kannapolis, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Rowan County shall take steps to decertify one (1) dialysis station for a total of no more than twenty-eight (28) certified stations at Dialysis Care of Rowan County.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall install plumbing and electrical wiring through the walls for no more than twenty (20) dialysis stations which shall include any home training or isolation stations.**
 - 5. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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

In Section VIII, page 39, the applicant states, "*The capital cost for the project is estimated to be \$18,963.*" In the table in Section VIII, page 40, the applicant shows the cost consists of dialysis machines, dialysis chairs, a television system, patient computer system and other equipment and furniture.

In Section IX.3, page 44, the applicant states that there will be no start-up expenses or initial operating expenses associated with the proposed project.

Exhibit 17 contains a letter from the Chief Accounting Officer of DaVita Healthcare Partners Inc. (DaVita), who is also Chief Accounting Officer for Total Renal Care, Inc., confirming DaVita's commitment of cash reserves in the sum of \$18,963 for the capital needs of the project. DaVita's Form 10-K in Exhibit 18 confirms the availability of said cash reserves on the consolidated balance sheet, page F-6.

Based on information provided by the applicant in Section X.1, page 46, the dialysis facility's projected allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	ALLOWABLE CHARGE PER TREATMENT
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,175.00
VA	\$193.00
Medicare/Commercial	\$240.00

Based on the calculations presented in Section X.3, page 47, the facility reimbursement is as follows:

SOURCE OF PAYMENT	REIMBURSEMENT PER TREATMENT
Medicare	\$192.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,175.00
VA	\$193.00
Medicare/Commercial	\$240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.¹ In Sections X.2-X.4, pages 46-48, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$3,978,827	\$4,039,363
Total Operating Costs	\$3,590,376	\$3,654,906
Net Profit	\$388,451	\$384,457

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X of the application for the applicant's assumptions on number of treatments (3 days/week, 52 weeks/year with 5% missed treatments). On page 23, the applicant states,

“Note: The patient numbers for operating year 1 and 2 will be used to determine the number of treatments, operating revenue and operating expenses. The in-center and home-trained patient numbers cited on the chart above in Operating Year 1 and Operating Year 2 will be used to

¹ http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage_Renal_Disease_Pro prospective_Payment_System_ICN905143.pdf

determine the number of treatments in Section X of this application.”
 [Emphasis in original]

The applicant’s projections of treatments and revenues are reasonable based on the number of in-center and home patients projected for the first two operating years. In Section VII.1, page 35 and Section X.5, page 49, the applicant provides projected staffing and salaries. The applicant states compliance with all staffing requirements in 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 37. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

- (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 relocate one dialysis station from DC of Rowan County to DC of Kannapolis. The January 2014 SDR shows DC of Rowan County and DC of Kannapolis are the only two dialysis facilities in Rowan County.

ROWAN COUNTY DIALYSIS CENTERS				
FACILITY	LOCATION	UTILIZATION	CURRENT # OF STATIONS	# OF STATIONS AFTER RELOCATION
Dialysis Care of Rowan County	Salisbury	73.28%	29	28
Dialysis Care of Kannapolis	Kannapolis	61.00%	25-6 approved for relocation to Cabarrus County = 19	20

The applicant discusses projections for the in-center patient population on pages 22-24 of the application. At the end of Operating Year One, with 20 dialysis stations and 64 dialysis patients, the applicant projects DC of Kannapolis utilization will be 3.2 in-center patients per station (64 patients / 20 dialysis stations = 3.2). The applicant projects 36 patients in the home training program at DC of Kannapolis.

With the relocation of the one station, DC of Rowan County’s dialysis station inventory will be reduced to 28 stations. With 85 patients and 28 stations at January 1, 2015, DC of Rowan County’s utilization will be 75.8% or 3.03 patients per station.

The applicant adequately demonstrates the need to relocate one dialysis station from DC of Rowan County to DC of Kannapolis based upon historical and projected numbers of in-center patients to be served at both facilities. The total number of

dialysis stations in Rowan County will not change as a result of this project. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

- (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.

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The following table illustrates the projected staffing for DC of Kannapolis, as provided by the applicant in Section VII.1, page 35.

Position	Total FTEs
RN	4
HTRN	2
PCT	8
Bio-Med Tech	0.5
MD	
Admin	1
Dietician	1
Social Worker	1
Unit Secretary	1
Other-Reuse	1
Total	19.5

As shown in the above table, the applicant proposes to employ a total of 19.5 full-time equivalent (FTE) positions to staff the DC of Kannapolis facility upon completion of the proposed project. The Medical Director is a contract position. In Section VII.1, pages 35-36, the applicant states:

“The Regional Operations Director is responsible for the overall operation of the facility and serves as liaison to the governing body. She is also responsible for ensuring compliance with 42 C.F.R. and budgetary compliance.

...

The UA is responsible for the quality dialysis care for all patients in the facility on a daily basis through planning and teammate scheduling. ... The UA also ensures that direct patient care is provided. The UA also supervises orientation and training of new teammates and ensures that teammates adhere to facility policies and procedures”

The following table shows the projected number of direct care staff for each shift offered at DC of Kannapolis after the relocation.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11am	5	5	5	5	5	5
Afternoon	11am to 4pm	5	5	5	5	5	5
Evening	N/A	0	0	0	0	0	0

In Section V.4, page 29, the applicant states that William Halstenberg, M.D., of Metrolina Nephrology Associates, PA, will serve as Medical Director for the DC of Kannapolis facility. Exhibit 12 contains a letter signed by Dr. Halstenberg, expressing support for the relocation of the dialysis station and agreeing to be the Medical Director for the facility. In Section VII.2, page 36, the applicant states Dr. Halstenberg is board-certified in Nephrology with several years of experience in the care of ESRD patients.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion.

- (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 V.1, page 27, the applicant provides a list of providers of the necessary ancillary and support services. The applicant states that acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services, blood bank and vascular surgery will be provided by CMC-NorthEast Medical Center. The chart on page 27 states that transplantation services for DC of Kannapolis patients is provided by Carolinas Medical Center. Dr. William Halstenberg, Nephrologist with the Metrolina Transplant Clinic, is the Medical Director of DC of Kannapolis and expressed support for the project in Exhibit 12. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, 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

- (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

NA

- (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.

NA

- (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 VI.1(a), page 31, the applicant states DC of Kannapolis has a policy of making dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), page 31, the applicant reports that 89.7% of the patients who received treatments at DC of Kannapolis had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source for the existing facility:

CURRENT PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	30.0%
Medicaid	5.7%
Medicare/Medicaid	27.6%
Commercial Insurance	5.7%
VA	4.6%
Medicare/Commercial	26.4%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Rowan and Cabarrus Counties and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Rowan County	19%	7.6%	18.9%
Cabarrus County	14%	4.9%	18.5%
Statewide	17%	6.71%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by Dialysis Care of Kannapolis. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/31/2012*, page 74).

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The

population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*² (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)

The report states that the overall Medicare expenditures for chronic kidney disease for 2011 were \$49.2 billion, including Medicare Part D (p. 118). The 2013 USRDS Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
TOTAL	\$49.2	100.0%

*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 327.

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

² www.usrds.org/adr.aspx

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6.
 Table includes North Carolina statistics only.³

DC of Kannapolis demonstrates that it currently provides adequate access to medically underserved populations. 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

In Section VI.1(f), page 32, the applicant states,

“DC of 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.”

In Section VI.6(a), page 34, the applicant states, *“There have been no civil rights access complaints filed within the last five years.”*

³ www.esrdnetwork6.org/publications/reports.html

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 VI.1(c), page 32, the applicant provides the projected payor mix for the proposed services at the new facility as follows:

PROJECTED PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	30.0%
Medicaid	5.7%
Medicare/Medicaid	27.6%
Commercial Insurance	5.7%
VA	4.6%
Medicare/Commercial	26.4%
Total	100.0%

The applicant projects no change from the current DC of Kannapolis payor mix as stated in Criterion (13a) above.

In Section VI.1(a), page 31, the applicant states,

“DC of Kannapolis does not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. DC of Kannapolis works with patients who need transportation, when necessary.”

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, 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 VI.5, page 33, the applicant states that:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at DC of Kannapolis. These referrals most commonly come from primary care physicians or specialty physicians in Rowan, Cabarrus and Mecklenburg Counties. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact DC of Kannapolis directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the DC of Kannapolis catchment area requesting transfer to this facility will be processed in accordance with the DC of Kannapolis transfer and transient policies which comprise **Exhibit 13**. [Emphasis in original] The patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary.”*

The applicant adequately demonstrates that it provides a range of means by which a person can access the proposed services. Therefore, 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.

CA

In Section V.3, page 28, the applicant states,

*“DC of Kannapolis has offered the facility as a clinical learning site for nursing students from Rowan-Cabarrus Community College (See **Exhibit 11**).”*
[Emphasis in original]

Exhibit 11 contains no documentation of accommodating the clinical needs of health professional training programs. However, the information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion, subject to the following condition:

Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall provide the CON Section with a copy of the correspondence with Rowan-Cabarrus Community College indicating an interest in establishing a training program relationship at DC of Kannapolis.

- (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 relocate one dialysis station from DC of Rowan County to DC of Kannapolis. The January 2014 SDR shows DC of Rowan County and DC of Kannapolis are the only dialysis providers in Rowan County, as shown below.

ROWAN COUNTY DIALYSIS CENTERS				
FACILITY	LOCATION	UTILIZATION	CURRENT # OF STATIONS	# OF STATIONS AFTER RELOCATION
Dialysis Care of Rowan County	Salisbury	73.28%	29	28
Dialysis Care of Kannapolis	Kannapolis	61.00%	25-6 approved for relocation to Cabarrus County = 19	20

In Section V.7, page 30, the applicant discusses how any enhanced competition will have a positive impact on cost-effectiveness, quality and access, stating:

“The proposed expansion of the facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture. DC of Kannapolis is one of two dialysis facilities in Rowan County. The other facility, located in Salisbury in Rowan County, is owned and operated by Total Renal Care of North Carolina.

...

The bottom line is that patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. DC of Kannapolis provides access to all qualified Nephrologists to admit his or her patients. None of the Nephrologists associated with Fresenius Medical Care have sought admitting privileges at DC of Kannapolis.”

See also Sections II, III, V, VI and CII where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed dialysis services. This determination is based on the information in the application referenced above and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

- (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

TRCNC currently provides dialysis services in Rowan County at Dialysis Care of Rowan County in Salisbury and Dialysis Care of Kannapolis. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, both facilities operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. 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.

CA

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming or conditionally conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

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

.2202 INFORMATION REQUIRED OF APPLICANT

(a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*

(1) *Utilization rates;*

-C- In Section II.1, page 10, the applicant states the utilization rate is addressed in the January 2014 SDR provided in Exhibit 7. The January 2014 SDR utilization rate of 61% was calculated based on 61 in-center dialysis patients and 25 certified dialysis stations as of June 30, 2013 (61 patients / 25 stations = 2.44 patients per station; 2.44 patients per station / 4.00 patients per station = 0.61. However, upon the pending relocation of six stations, the facility will have 61 patients dialyzing on 19 machines for a utilization rate of 80% (61 / 19 = 3.2 / 4 = 0.80).

(2) *Mortality rates;*

-CA- In Section II.1(2), page 10, the applicant responds, “*Addressed in Section IV, Question 2.*” However, Section IV.2, page 25, contains no response. The application is found conforming with this rule, subject to the following condition:

Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall provide the Certificate of Need Section with the facility’s mortality rates for 2011, 2012 and 2013.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section II.1(3), page 10, the applicant responds, “*Addressed in Section IV, Question 3.*” In Section IV.3, page 25, the applicant states that DC of Kannapolis had 36 home-trained patients as of December 31, 2013.

(4) *The number of transplants performed or referred;*

- CA- In Section II.1(4), page 10, the applicant responds, “*Addressed in Section IV, Question 4.*” However, Section IV.4, page 26, does not provide the number of transplants performed or referred. The application is found conforming with this rule, subject to the following condition:

Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall provide the Certificate of Need Section with the number of transplants performed or referred.

- (5) *The number of patients currently on the transplant waiting list;*

- CA- In Section II.1(5), page 10, the applicant responds, “*Addressed in Section IV, Question 5.*” However, Section IV.5, page 26, does not provide the number of DC of Kannapolis patients currently on the transplant list. The application is found conforming with this rule, subject to the following condition:

Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall provide the Certificate of Need Section with the number of patients currently on the transplant list.

- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

- CA- In Section II.1(6), page 10, the applicant responds, “*Addressed in Section IV, Question 6.*” However, Section IV.6, page 26, does not provide the facility’s hospital admission rates. The application is found conforming with this rule, subject to the following condition:

Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall provide the Certificate of Need Section with the facility’s hospital admission rates, by admission diagnosis.

- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

- CA- In Section II.1(7), page 10, the applicant responds, “*Addressed in Section IV, Question 7 of the application.*” However, Section IV.7, page 26, does not provide the requested information. The application is found conforming with this rule, subject to the following condition:

Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis shall

provide the Certificate of Need Section with the number of patients with infectious disease.

(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*

-NA- This application does not involve a new facility.

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

(A) *timeframe for initial assessment and evaluation of patients for transplantation,*

(B) *composition of the assessment/evaluation team at the transplant center,*

(C) *method for periodic re-evaluation,*

(D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*

(E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- The application does not involve a new facility.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- The application does not involve a new or replacement facility.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Exhibit 8, in which the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- The application does not involve a new facility.

(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section XI.6(g), page 54, the applicant states, “DC of Kannapolis has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health safety requirements.”

The applicant states that DC of Kannapolis maintains Medicare Certification. See Exhibit 22 for excerpts from the Health and Safety Policy and Procedure Manual and Exhibit 23 for the In-Service Calendar with mandatory training classes.

(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- The applicant provides the following projected patient origin on page 21 of the application, as shown below.

Projected Dialysis Patient Origin

COUNTY	OPERATING YEAR 1 2015		OPERATING YEAR 2 2016		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Rowan	32	14	33	14	46.0%	46.5%
Cabarrus	32	17	32	17	49.0%	48.5%
Mecklenburg	0	2	0	2	2.0%	2.0%
Stanly	0	3	0	3	3.0%	3.0%
Total	64	36	65	36	100.0%	100.0%

See Section III.7, pages 22–24 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- This application does not involve a new facility.

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II. 1, page 12, the applicant states,

“Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Kannapolis will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

.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- This application does not involve a new 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- On page 13, the applicant states:

“Based on the patients and stations above, DC of Kannapolis is projected to have at least 64 in-center patients by the end of operating year 1 for a utilization rate of 80% or 3.2 patients per stations and at least 65 in-center patients by the end of operating year 2 for a utilization rate of 81% or 3.3 patients per station.”

See further discussion on utilization and methodology in Criterion (3) which is hereby incorporated as if set forth fully herein.

.2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

- (1) *diagnostic and evaluation services;*
 - C- The table in Section V.1, page 27, states patients will be referred to CMC-NorthEast Medical Center for diagnostic and evaluation services.
- (2) *maintenance dialysis;*
 - C- The table in Section V.1, page 27, states the applicant will provide in-center maintenance dialysis.
- (3) *accessible self-care training;*
 - C- The table in Section V.1, page 27, states the applicant will provide in-center hemodialysis self-care training and intermittent peritoneal dialysis.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
 - C- The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 28, stating,

“DC of Kannapolis provides protocols and routines for patient follow-up. The social workers and dieticians contact the home-trained patients monthly. The patients are supported by monthly visits to their Board Certified Nephrologist for examination. The Home Training nursing teammates perform monthly medication reviews, nursing assessments and laboratory review of blood work in order to continuously monitor the well being of home patients. Patient’s blood chemistries are sent to a Medicare certified laboratory where they are analyzed. The results are reviewed by the teammates for adequacy and then reviewed by the dietitian and Nephrologist. Home trained patients are monitored by our Quality Management team.”
- (5) *x-ray services;*
 - C- The table in Section V.1, page 27, states patients will be referred to CMC-NorthEast Medical Center for x-ray services.
- (6) *laboratory services;*

- C- The table in Section V.1, page 27, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.
 - (7) *blood bank services;*
- C- The table in Section V.1, page 27, states patients will be referred to CMC-NorthEast Medical Center for blood bank services.
 - (8) *emergency care;*
- C- The table in Section V.1, page 27, states patients will be referred to CMC-NorthEast Medical Center for emergency care.
 - (9) *acute dialysis in an acute care setting;*
- C- The table in Section V.1, page 27, states patients will be referred to CMC-NorthEast Medical Center for acute dialysis in an acute care setting.
 - (10) *vascular surgery for dialysis treatment patients;*
- C- The table in Section V.1, page 27, states dialysis patients will be referred to CMC-NorthEast Medical Center for vascular surgery.
 - (11) *transplantation services;*
- C- The table in Section V.1, page 27, states patients will be referred to Carolinas Medical Center for transplantation services.
 - (12) *vocational rehabilitation counseling and services; and*
- C- The table in Section V.1, page 27, states patients will be referred to the North Carolina Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.
 - (13) *transportation.*
- C- The table in Section V.1, page 27, states patients will be referred to Cabarrus and Rowan county transportation services.

.2205 STAFFING AND STAFF TRAINING

- (a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*
- C- In Section VII.1, page 35, the applicant provides the proposed staffing for DC of Kannapolis. The applicant states, *“The facility complies with all*

staffing requirements as stated in 42 C.F.R. Section 405.2100 [now 42 C.F.R. Section 494], as evidenced below.” DC of Kannapolis plans for two dialysis shifts; direct care staffing of 5.0 FTE per shift on Monday through Saturday as noted in response to VII.10.

(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

-C- In Section VII.5, page 36, the applicant refers to Exhibit 16 for a copy of the training program outlines. Exhibit 16 contains a copy of DaVita’s Training Programs for New Patient Care Provider. Exhibit 23 contains the DC of Kannapolis Annual In-Service Calendar.